Nos. 21-1055 and 21-1323

In the United States Court of Appeals for the First Circuit

No. 21-1055

DR. LYLE E. CRAKER,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, D. CHRISTOPHER EVANS, in his official capacity as Acting Administrator of Drug Enforcement Administration,

Respondents.

No. 21-1323

SCOTTSDALE RESEARCH INSTITUTE,

Petitioner,

v.

US DRUG ENFORCEMENT ADMINISTRATION; D. CHRISTOPHER EVANS, Administrator of Drug Enforcement Administration; MERRICK B. GARLAND, Attorney General,

Respondents.

PETITIONERS' OPENING BRIEF

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DISCLOSURE STATEMENT

In compliance with Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioner Scottsdale Research Institute certifies that it has no parent corporations, nor is there any publicly held corporation that own 10% or more of the company.

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INTRODUCTION

Whatever one thinks about the longstanding "presumption of regularity," little about the promulgation of the Final Rule under review entitled *Controls to Enhance the Cultivation of Marihuana for Research in the United States*, 85 Fed. Reg. 82,333 (Dec. 18, 2020) (Add. 1), was regular.

Put in a difficult position by its parent agency, the Drug Enforcement Agency ("DEA") birthed this Final Rule through lawsuits and into the Federal Register by cutting corners. More than four years earlier, in August 2016, DEA announced a new policy intending to increase the number of entities registered under the Controlled Substances Act ("CSA") to grow marijuana to supply US researchers. Nearly three years after that, however, the program was at a standstill. The agency had neither approved nor denied a single applicant, even though more than 30 had applied.

The explanation for the delay rested behind the scenes. In secret, the Attorney General had instructed DOJ's Office of Legal Counsel ("OLC") to evaluate the lawfulness of the August 2016 plan put forward by his predecessor. In a June 2018 opinion entitled "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs" (Add. 39), OLC concluded that DEA had to change both its current practices

and the policy it announced in 2016 to comply with the Single Convention before it could approve any additional marijuana growers.

This opinion formed the entire basis for the delay and the Proposed Rule, 85 Fed. Reg. 16,292 (Mar. 23, 2020) (Add. 64). But neither DOJ nor DEA disclosed it to the public until midway through the notice and comment period on the Proposed Rule—after Petitioner Scottsdale Research Institute ("SRI") sued DOJ for violating the Freedom of Information Act ("FOIA").

The consequence of this irregularity is simple: the Final Rule must be set aside in its entirety and the process must start over. Notice and comment are critical safeguards of the modern administrative state, and absent good cause, the public deserves regular rulemaking. And that means regular order: a proper notice and a full comment period, not a process weighed down by patching over illegal conduct with an abbreviated comment period. Here, neither DEA nor DOJ provided the OLC Opinion in the Proposed Rule, thus depriving the public of notice and a meaningful opportunity to comment. Then, after DOJ disclosed the OLC Opinion midway through the comment period, DEA did not offer a reasoned explanation for the new policy announced in the Final Rule, as it must under the Administrative Procedure Act ("APA"). Instead, it simply characterized itself as bound to follow the directives of DOJ and the OLC Opinion.

Underscoring the need to start anew, were this Court to move past these irregularities and confront the Final Rule on substance, it would fail for three additional reasons.

First, several components to the Final Rule run contrary to the text. The Final Rule purports to implement the considerations for approving manufacturer applications that Congress laid out in § 823(a) (Add. 106). On examination, however, it rewrites several statutory provisions in important respects. For example, § 823(a)(4) instructs DEA to consider the "prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances." 21 U.S.C. § 823(a)(4). In the Final Rule, however, DEA rewrites subsection (a)(4) to evaluate *compliance* with Federal and State laws as opposed to convictions, as the statute instructs. *See* Final Rule at 82,335.

Second, the Final Rule improperly redefines "medicinal cannabis" to mean "a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act." DEA says little to support its "understanding" that "medicinal cannabis" means "a form that the United States has approved for medical use" or why "medicinal cannabis" excludes developmental products, other than to say that such developmental products have not been approved for

"full medical use." Final Rule at 82,340. None of what DEA says follows from the plain meaning of "medicinal," and its definition is directly contrary to this Court's precedent and the CSA's text. DEA's attempt to use rulemaking to improperly conflate the CSA with the FDCA by equating "medicinal" with medical products *approved* by the FDA should again be rejected by this Court.

Third, the Final Rule flunks other bedrock administrative-law principles. It impermissibly applies retroactively, fails to consider relevant alternatives, and parts of it rest on irrational reasoning. For these reasons also, the Court should grant the petitions, set aside the Final Rule, and remand to DEA for reasoned decision-making.

JURISDICTIONAL STATEMENT

The Final Rule of the Drug Enforcement Administration was issued on December 20, 2020. The petitions were filed on January 19, 2021 (No. 21-1055) and (No. 21-1323). This Court has jurisdiction under 21 U.S.C. § 877. DEA had jurisdiction to promulgate the Final Rule under 21 U.S.C. § 871.

PERTINENT STATUTES AND CONSTITUTIONAL PROVISIONS

Pertinent statutes and constitutional provisions appear in the addendum.

STATEMENT OF THE ISSUES

1. Whether DEA provided a meaningful opportunity for comment before promulgating the Final Rule?

2. Whether the Final Rule rests on an impermissible interpretation of federal law or the Single Convention?

3. Whether the Final Rule is arbitrary and capricious?

STATEMENT OF THE CASE

I. Registration to Manufacture Marijuana Under the Controlled Substances Act

The CSA requires all persons who seek to manufacture a controlled substance to register with DEA.[1] 21 U.S.C. § 822(a)(1). The Act defines "manufacture" to include the "production" of a controlled substance, which in turn includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. *Id.* §§ 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marijuana—a schedule I substance—must obtain a registration to manufacture from DEA.

Under § 823(a) of the CSA, DEA "shall register an applicant to manufacture controlled substances in schedule I or II" if doing so "is

[1] Sections 822(a) and 823(a) vest authority over registration for such licenses in the Attorney General. Pursuant to 21 U.S.C. § 871(a), the Attorney General delegated this function to DEA. 28 C.F.R. § 0.100(b).

consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a). In determining "the public interest," Congress instructed DEA to "consider" six enumerated "factors":

> (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
>
> (2) compliance with applicable State and local law;
>
> (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> (6) such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a)(1)-(6). The "United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971" referenced in

§ 823(a) include those under the Single Convention on Narcotic Drugs ("Single Convention"), Mar. 30, 1961, 18 U.S.T. 1407 (Add. 90).[2]

The Single Convention entered into force for the United States on June 24, 1967 when the Senate gave its advice and consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. It requires parties to impose stringent controls on the cultivation, manufacture, and distribution of narcotic drugs, including "cannabis," which it defines as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated." Single Convention art. 1(1)(b) (Add 91). Parties must, among other things, establish quotas on the import and manufacture of cannabis, generally prohibit the possession of cannabis, and adopt penal provisions making violations of those controls punishable offenses. *Id*. arts. 21, 33, 36.

Under Article 28 of the Single Convention, parties must subject any lawful cultivation of the cannabis plant to the same system of strict controls

[2] The Single Convention was amended by a 1972 protocol, but immaterial to the issues presented here. *See* Protocol Amending the Single Convention on Narcotic Drugs, Mar. 25, 1972, 26 U.S.T. 1439.

"as provided in article 23 respecting the control of the opium poppy." *Id.* art.

28. The requirements of that "system of strict controls" are as follows:

> 1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
>
> 2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
>
> > a. The Agency shall designate the area in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
> >
> > b. Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
> >
> > c. Each license shall specify the extent of the land on which the cultivation is permitted.
> >
> > d. All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
> >
> > e. The agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium, or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.
>
> 3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

The agency's "exclusive right[s]" over the harvested marijuana need not extend to "medicinal" marijuana or marijuana "preparations." *Id.* art. 23(2)(d)(e).

II. Regulatory and Procedural Background

A. DEA, NIDA, and the National Center

In 1970, three years after the United States acceded to the Single Convention, Congress enacted the CSA, 21 U.S.C. § 801 *et seq.*, "a comprehensive statute designed to rationalize federal control of dangerous drugs." *Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977).

For over fifty years, DEA licensed only one such grower to supply researchers with marijuana—the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi. *See Lyle E. Craker*, 74 Fed. Reg. 2101, 2104 (2009). The National Center cultivates marijuana under a contract administered by NIDA. Besides overseeing marijuana cultivation, NIDA also plays a role in determining which researchers may obtain marijuana for medical or scientific use. *See* 21 U.S.C. § 823(f).

B. The 2016 Policy Statement and Petitioners' applications to grow marijuana for research

In 2016, in response to increasing public interest in marijuana research, DEA announced a new policy (the "Growers Program") reflecting its intention to increase the number of federally authorized growers. *See Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States*, 81 Fed. Reg. 53846, 53847 (Aug. 12, 2016) (the "2016 Policy Statement"); FOIA Dkt. No. 1-1 at 2.[3] Under the 2016 Policy Statement, licensed growers would "be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA." *Id.* at 53,848; FOIA Dkt. No. 1-1 at 3. NIDA would not be involved in monitoring the additional licensees.

DEA then invited the public to apply to register to manufacture marijuana, noting that any person who applied to be registered would receive

[3] Petitioner SRI's recent lawsuit seeking to compel DOJ to disclose a secret opinion of the OLC discussed much of the same background relevant here. It also included many of the relevant documents and filings discussed here as exhibits. For efficiency's sake, Petitioners include those materials in the Appendix (RA1-RA651) and reference that complaint and its exhibits here where applicable. References to the FOIA complaint appear in the following format: FOIA Dkt. No. 1-[num] at [page].

"due process" protections under the APA. *Id.* More than 30 interested parties, including both Petitioners in this case, submitted applications to grow marijuana under the Growers Program.

Petitioner Craker ("Dr. Craker") is a Professor Emeritus of Botany and Plant Sciences at the University of Massachusetts, Amherst. Since 2001, he has sought a license from DEA to create a privately owned but DEA-regulated cannabis farm to supply FDA-regulated drug development. MAPS Comment for the Public Record at 2 (RA673). His partner in that effort has been the Multidisciplinary Association for Psychedelic Studies ("MAPS"). *Id.* MAPS is an IRS-approved 501(c)(3) research and educational organization. *Id.* Its mission includes developing FDA-approved medical uses of schedule I controlled substances. *Id.*

Having completed Phase 2 clinical trials of cannabis for use by veterans with PTSD, MAPS has an immediate need to produce cannabis for Phase 3 trials. *Id.* at 6 (RA677). Assurance of an uninterrupted supply at an economically feasible price is essential for privately-funded drug development. *Id.* at 3 (RA674). The supply of DEA-authorized cannabis has not been viable for commercial use and cannot be used in FDA-regulated Phase 3 trials. *Id.*

So, Dr. Craker spent 20 years forging a pathway to feasibly bring cannabis therapeutics to market. *Id.* at 2 (RA677). Dr. Craker submitted his first application to DEA for licensure in 2001, while still an active Professor of Botany. *Id.* DEA at first claimed to have lost the application and did nothing for the next three years. *Id.* at 5 (RA676). When Dr. Craker filed a lawsuit in federal court alleging unreasonable delay, the court ordered DEA to file responsive pleadings. *Id.* Instead, Respondents finally issued an order to show cause, indicating their intention to deny Dr. Craker's application. *Id.*

Dr. Craker exercised his right to an evidentiary hearing. *Id.* In February 2007, DEA Administrative Law Judge ("ALJ") Mary Ellen Bittner issued an 80-page opinion recommending that DEA grant Dr. Craker's application. *Id.* Respondents waited almost two years before issuing a final order rejecting ALJ Bittner's recommendation. 74 Fed. Reg. 2101 (2009).

When DEA announced in the 2016 Policy Statement that it was seeking new applications for licenses to grow marijuana to encourage and facilitate privately-funded cannabis drug development, Dr. Craker and MAPS prepared a new application to register to manufacture marijuana. Dr. Craker submitted his application to DEA on February 22, 2017. *Id.* at 6. Through an intervention by Senator Elizabeth Warren, he learned that DEA received his application in August 2017. *Id.* at 6, n.1 (RA677).

Petitioner SRI, a non-commercial Arizona limited liability company and clinical trials site located at 5436 E Tapekim Rd., Cave Creek, AZ 85331, is dedicated to advancing the state of medical care through clinical research. Its mission is to conduct high quality, controlled scientific studies to ascertain the general medical safety and efficacy of plant products, including marijuana, to treat pain and PTSD as well as for potential substitution of opioid dependence. Its clinical research is largely funded by grants. To date, it is the only entity federally approved to do clinical research into the effects of marijuana on veterans with treatment-resistant PTSD. SRI also has a nonprofit 501(c)(3) arm, the SRI Field to Healed Foundation, which shares in its mission and is also dedicated to raising awareness on the difficulties of medical marijuana research in this country. *See generally* FOIA Dkt. No. 1-5 at 74-85 (Declaration of Suzanne Sisley); SRI Comment for the Public Record at 1 (RA655).

SRI is run by Dr. Sue Sisley. An Arizona-licensed physician, Dr. Sisley has been treating veterans with PTSD in her private practice for over a decade. She has received many honors and awards for her work both in private practice and in research. In 2001, for example, she won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. She also received the Arizona Medical Association's highest honor,

the President's Distinguished Service Award. Dr. Sisley has received significant support from patient rights organizations and veteran groups around the country, including national veterans' organizations. As part of SRI's mission, Dr. Sisley travels across the country and internationally, educating the public on the difficulties of doing medical marijuana research in the United States. *See generally* FOIA Dkt. No. 1-5 at 74-85.

C. The Trump Administration secretly sidelines the Growers Program

Not long after President Trump took office, then-Attorney General Sessions ordered DEA to halt the Growers Program while DOJ conducted a policy review to determine whether DEA's regulations governing the registration of manufacturers of schedule I and II substances under § 823(a) were consistent with U.S. treaty obligations under the Single Convention. Neither he nor DEA informed the public, Congress, or the thirty-some parties, including Petitioners, with applications pending under the 2016 Policy Statement that DOJ had sidelined the Growers Program. *See generally* FOIA Dkt. No. 1 at 12-15.

Eventually, and again in secret, Attorney General Sessions referred the matter to OLC. On June 6, 2018, OLC responded with a 25-page Opinion ("OLC Opinion" or "OLC Op.") on the subject of "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs."

OLC Op. (Add. 66). The OLC Opinion, which was signed by Henry C. Whitaker, Deputy Assistant Attorney General, OLC, and addressed to Robert C. Gleason, Acting Chief Counsel, DEA, explained that DEA's regulations implementing § 823(a), had been in open violation of the Single Convention since the day DEA was established as an agency in 1973. OLC Op. 5. ("Since its founding in 1973, DEA has licensed only one such grower to supply researchers with marijuana—the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi."). That was so, OLC explained, for three reasons:

> First, the division of responsibilities between DEA and NIDA, a component of the Department of Health and Human Services ("HHS"), contravenes Article 23(2)'s requirement that all Article 23 functions be carried out by a single government agency. Second, neither of the two government agencies "take[s] physical possession" of the marijuana grown by the National Center, as required by Article 23(2)(d). Third, no federal agency exercises a monopoly over the wholesale trade in marijuana, as required by Article 23(2)(e). We discuss each departure in turn.

OLC Op. at 8. OLC also reviewed DEA's 2016 Policy Statement and concluded that "[f]or similar reasons, [it] also fails to establish a framework that would fully comply with Articles 23 and 28 of the Single Convention." OLC Op. at 23.

While OLC acknowledged that "[t]here may well be more than one way to satisfy those obligations under the Single Convention," "licens[ing] the

cultivation of marijuana without complying with the minimum requirements of that agreement" was not an option. OLC Op. at 2. Accordingly, OLC "conclude[ed] that DEA must alter the marijuana licensing framework to comply with the Single Convention." OLC Op. at 24.

In the Final Rule at issue here, DEA acknowledges that "[t]he Attorney General determined that adjustments [to DEA's regulations controlling the registration of manufacturers of marijuana] were necessary after receiving the aforementioned advisory OLC Opinion." Final Rule at 82,335 n.7. Yet DEA did not mention the OLC Opinion in the Proposed Rule, nor did it include the OLC Opinion in the rulemaking docket or publish it in the Federal Register. In fact, until April 29, 2020—over a month after the 60-day comment window on the Proposed Rule began running—*no one* outside the Executive Branch even knew the OLC Opinion existed. As we explain next, that was not for want of asking.

D. Members of Congress express concern over DEA's unexplained refusal to process the applications it solicited in the 2016 Policy Statement.

Between April 12, 2018 and May 7, 2019, members of Congress from both parties sent letters to federal government officials inquiring about DEA's failure to act on the Growers Program and the need for robust medical marijuana research. FOIA Dkt. No. 1-3 at 62, 67, 74, 78; 1-4 at 2, 5, 8. These

members expressed "deep concern" with the delay, implored Respondents to act, and described the need for research-grade marijuana to do meaningful federally sanctioned research as "critical." FOIA Dkt. No. 1-3 at 78 & 1-3 at 6. They stated "[o]ur nation needs scientific research to analyze the medical applications of cannabis so we may determine appropriate federal marijuana policy in accordance with federal law." FOIA Dkt. No. 1-3 at 74.

By mid-2018, rumors were circulating that DOJ had sidelined the Growers Program. Several members of Congress inquired about these rumors in their letters, asking Defendants to "share DOJ's legal analysis of the CSA and Single Convention and if the opinion of the Justice Department is the same or similar to that of DEA's" and to "identify and explain" any "legal barriers" to prompt implementation of the Growers Program. FOIA Dkt. No. 1-3 at 67-68. Senators Schatz and Booker expressed "opposition to any attempt to reinterpret United States' obligation under the [Single Convention]." FOIA Dkt. No. 1-4 at 2-3.

Respondents did not answer any of these letters. Nor did DOJ share its legal analysis of the CSA and Single Convention or identify and explain any legal barriers that Respondents believed prevented them from implementing the Growers Program. Instead, in testimony before Congress, DOJ said it was

"moving forward" and would "add, fairly soon … additional suppliers of marijuana under the Controlled [Substances Act]." FOIA Dkt. No. 1-4 at 40.

E. SRI's mandamus action prompts DEA to initiate rulemaking.

Because of DEA's unexplained delays, SRI turned to the courts.

1. In June 2019, SRI filed a mandamus petition in the U.S. Court of Appeals for the D.C. Circuit, seeking an order compelling DEA to comply with its statutory obligation to publish a notice of SRI's application in the Federal Register. FOIA Dkt. No. 1-5 at 2. The court ordered DEA to respond to the petition by August 28, 2019. FOIA Dkt. No. 1 at 15. Two days before that response deadline, Attorney General Barr stated that he was "pleased that DEA is moving forward with its review of applications for those who seek to grow marijuana legally to support research" and that DOJ would "continue to work with our colleagues at [HHS] and across the Administration to improve research opportunities wherever we can." Dkt. No. 1-5 at 87. DEA added: "Before making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research. The new rules will help ensure DEA can evaluate the applications under the applicable legal standard and conform the program to relevant laws." Dkt. No. 1-5 at 88.

The day before the court deadline, DEA published in the Federal Register a notice of SRI's application as well all other applications then-pending. Dkt. 1-5 at 90. DEA explained it needed more time to promulgate new rules before it could further adjudicate the pending applications. Dkt. No. 1-5 at 91. The next day, in its court-ordered response, DEA did not defend its delay; it argued only that its notice the day before had mooted the case. Dkt. No. 1-5 at 100. The court agreed and dismissed the case, but without prejudice to renewal if DEA significantly delayed going forward. Dkt. No. 1-5 at 121. In the months that followed, members of Congress from both sides of the aisle continued to write letters to Respondents. Dkt. No. 1-6 at 6-16. Again, no response.

2. On March 23, 2020, DEA published the NPRM for new rules to govern the Growers Program. Dkt. No. 1-6 at 23. According to DEA, "this proposed rule would amend DEA regulations *only to the extent necessary* to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana." Dkt. No. 1-6 at 24; Proposed Rule at 16,298 (emph. added). DEA did not consider alternative constructions of the CSA or the treaty. *Id.* Missing from the NPRM was any explanation of DEA's legal rationale for deciding to overhaul its regulations, but DEA did mention that DOJ had "advised DEA that it must

adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single Convention." Proposed Rule at 16,294; Dkt. No. 1-6 at 78.

Realizing it would be impossible to comment meaningfully on DEA's Proposed Rule without access to DEA and DOJ's legal rationale for proposing the rules in the first place, SRI turned to the courts again. In April 2020, SRI filed a complaint in Arizona district court under FOIA's electronic-reading provision. *See* FOIA Dkt. No. 1. The case settled with DOJ agreeing to publicly release the OLC Opinion. It did so on April 29, 2020, midway through the Proposed Rule comment period.

DEA issued the Final Rule on December 18, 2020, 85 Fed. Reg. 82,333, and Petitioners each filed timely petitions for review.

STANDARD OF REVIEW

Under the APA, "a reviewing court shall … hold unlawful and set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Courts generally review agency interpretations of statutes they administer under *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). "Even under *Chevron*," however, courts "owe an agency's interpretation of the law no deference unless, after 'employing traditional

tools of statutory construction,' [they] find [them]selves unable to discern Congress's meaning." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) (cites omitted).

SUMMARY OF THE ARGUMENT

The Final Rule is substantively and procedurally invalid and must therefore be set aside. Beginning with procedure, in the Proposed Rule, DEA refused to disclose the legal rationale for its proposed dramatic overhaul of the agency's regulations governing the registration of marijuana growers under the CSA. Without access to the agency's reasoning in support of the proposal, the public did not have the meaningful opportunity to comment on it that § 553(b) of the APA requires.

DEA's Final Rule did not provide any explanation of *its* reasons for pursuing the rulemaking. Instead, DEA continued to insist that the policy shift was DOJ's idea and that it had no choice in the matter. The APA requires the agency promulgating a legislative rule—here, DEA—to offer *its* reasons for supporting the rule. As a result, DEA's claim that it was following another agency's orders was no substitute for the reasoned explanation the APA requires.

Substantively, the Final Rule is at odds with the text of the CSA in several respects, and its definition of "medicinal cannabis" violates the Single

Convention and ignores this Court's precedent. It is also impermissibly retroactive and internally incoherent.

For these reasons and others explained below, this Court should grant the petitions for review, vacate the Final Rule, and remand to DEA for reasoned decision-making.

ARGUMENT

I. DEA Failed to Comply with the APA Requirements Governing Notice and Comment Rulemaking.

The APA "prescribes a three-step procedure for so-called 'notice-and-comment rulemaking.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). First, an agency must issue a "[g]eneral notice of proposed rule making." 5 U.S.C. § 553(b). Second, it must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* at § 553(c). Third, "[a]fter notice" and "[a]fter consideration of the relevant matter presented" in the received comments, the agency may promulgate a rule. *Id.*

Undertaking these procedures in this sequence is no mere formality. "Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019). To achieve these

goals, however, "the opportunity to participate in the rule making," 5 U.S.C. § 553(c), "must be … *meaningful*," *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) (emphasis added). An opportunity for comment is not "meaningful" unless the proposed rule "include[s] sufficient detail on its content and basis in law and evidence to allow for meaningful and informed comment." *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132-33 (D.C. Cir. 1995). Courts have therefore held that "[a]n agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time for meaningful commentary." *Connecticut Light & Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C. Cir. 1982); *see also Home Box Office, Inc. v. FCC*, 567 F.2d 9, 55 (D.C. Cir. 1977) (proposed rule must provide sufficient information to permit informed "adversarial critique").

Once an agency adopts a course of action and issues a final rule, it must "articulate with reasonable clarity its reasons for the decision[ ] and identify the significance of the crucial facts[.]" *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970); *accord* 5 U.S.C. §§ 553(c), 706. Indeed, "the orderly functioning of the process of [judicial] review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained." *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). "Without such a requirement, effective judicial review would be

impractical if not impossible, and administrative litigants and the public generally would be set adrift on a potential sea of unconscious preference and irrelevant prejudice." *Columbia Broadcastinq Sys., Inc. v. FCC*, 454 F.2d 1018, 1025 (D.C. Cir. 1971); *accord Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

A. DEA did not provide a meaningful opportunity for comment on the Proposed Rule.

Nowhere in the Proposed Rule or anywhere else did DEA disclose the legal basis for DOJ's conclusion that the 2016 Policy Statement violated the CSA and the Single Convention. It gave interested persons notice, as of March 23, 2020, that they had just 60 days to submit comment on a sweeping proposed change to an important public health program but denied them access to the government's controlling legal reasoning supporting it. Respondents did not reveal the controlling legal reasoning until 36 days later, after it settled SRI's FOIA lawsuit against DOJ for failing to make the secret OLC Opinion containing the legal rationale for DEA's Proposed Rule publicly available in DOJ's electronic reading room under the affirmative-disclosure provisions of the FOIA. *See* 5 U.S.C. § 552(a)(2).

While the Proposed Rule explains that "DOJ advised DEA that it must adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single

Convention," Proposed Rule at 16,294, it left Petitioners and the public in the dark with respect to several critical considerations, including:

(1) what DOJ advised DEA to do;

(2) which parts of DEA's proposal are supposedly necessary to bring DEA's regulations in line with the CSA's requirement that DEA regulations be consistent with the Single Convention; and

(3) which parts of its proposal are supposedly necessary to bring DEA regulations in line with other CSA requirements.

The answers to these questions lay in the OLC Opinion that DEA and DOJ refused to disclose to Congress—much less the public—until April 29, 2020. *See* https://www.justice.gov/olc/opinion/licensing-marijuana-cultivation-compliance-single-convention-narcotic-drugs (showing publication on April 29, 2020). As DEA later admitted, that secret document was behind DOJ's decision to sideline the Growers Program while DEA embarked on this rulemaking process. Final Rule at 82335 n.7.

The APA "requires the agency to make available to the public, in a form that allows for meaningful comment, the data the agency used to develop the proposed rule." *Am. Med. Ass'n*, 57 F.3d at 1133 (quoting *Engine Mfrs. Ass'n v. EPA*, 20 F.3d 1177, 1181 (D.C. Cir. 1994) (notice must provide legal basis for agency rule)). Because the public cannot meaningfully comment on a rationale known only to the agency, notice is "not adequate where it fails to provide an accurate picture of the reasoning that has led the agency to the

proposed rule." 2 Am. Jur. 2d Administrative Law § 170. As a result, DEA's refusal to disclose the OLC Opinion that formed the sole legal basis for the Proposed Rule rendered the notice of the Proposed Rule inadequate under the APA. This Court should not tolerate DEA's attempt "to play hunt the peanut" with its rationale for a policy with important consequences for public health and safety. *See Connecticut Light & Power Co.*, 673 F.2d at 531-32. *See also, e.g.*, *United States v. Nova Scotia Food Prods, Corp.*, 568 F.2d 240, 251 (2d Cir. 1977).

The D.C. Circuit's decision in *American Medical Association* is instructive. 57 F.3d at 1129. There, DEA's failure to explain "how it had arrived at the total diversion control budget" that was the subject of another informal rulemaking violated § 553(b)'s notice requirement. *Id.* at 1132-33. By failing to provide "the data underlying" its proposal and "its basis for attributing particular costs to that program," the Court explained, DEA had deprived interested persons of "sufficient detail on [the proposed rule's] basis in law and evidence to allow for meaningful and informed comment." *Id.* (quoting *Engine Mfrs. Ass'n*, 20 F.3d at 1181).

DEA's refusal to disclose the legal basis for its Proposed Rule rendered the *notice*-and-comment process at issue here deficient for the same reasons. The vast majority of the 224 comments DEA received came from interested

persons who likely had no idea the OLC Opinion even existed. And those few that knew it existed did not actually see it until April 29, 2020, when the government posted it on DOJ's website. By that time, however, the window for comments on the Proposed Rule had dwindled to a mere 23 days.

Had DEA been concerned about ensuring that interested persons and the general public have a meaningful opportunity to comment on the legal basis for the Proposed Rule, it could have published the OLC Opinion in the Federal Register, supplemented the rulemaking record to ensure public awareness of its centrality to Proposed Rule, extended the comment period, and/or invited the public to review the OLC Opinion and submit any additional comments on the Proposed Rule before the new deadline. DEA did none of those things.

The APA was designed to facilitate public participation in the development of important regulations and to prohibit federal agencies from developing secret law. Attorney General's Manual on the APA (1947) ("In general the purpose of section 4 is to guarantee to the public an opportunity to participate in the rulemaking process."); *Renegotiation Bd.*, 415 U.S. at 9 ("Congress was … troubled by the plight of those forced to litigate with agencies on the basis of secret laws or incomplete information."). The Final Rule undermines those purposes and therefore must be set aside.

B. DEA did not give a contemporaneous reasoned explanation for the Final Rule.

DEA did not offer a reasoned explanation of its own for the new policy announced in the Final Rule. Instead, it characterized itself as bound to follow the directives of DOJ and OLC. Final Rule at 82346. This was consistent with its disclaimer of policy discretion in the Proposed Rule, *see* Proposed Rule at 16298, but not the APA's requirement that the agency decision-maker with delegated authority to promulgate rules with the force and effect of law be the one making the relevant policy choices and supplying the necessary reasoned explanation for them. *Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C. Cir. 2006) (Garland, J.) (internal quotation marks omitted).

DEA recognized in the Final Rule its delegated authority to promulgate legislative rules governing the registration of manufacturers of schedule I and II substances under § 823(a). Final Rule at 82,334. Yet in the Proposed Rule and Final Rule, DEA insisted, without explanation, that it was bound to follow the determinations DOJ and OLC announced in the wake of their "policy review." Proposed Rule at 16,294.

In fact, however, even OLC recognized that DEA retained significant discretion in rulemaking process. OLC Op. at 24. Thus, either DEA "did not … appreciate the full scope of [its] discretion," or it simply preferred to evade political accountability for the policy changes announced in the Final Rule.

Dep't of Homeland Sec. v. Regents of the Univ. of California, 140 S. Ct. 1891, 1911, (2020). Either way, its attempt to use the APA's notice-and-comment rulemaking process as a vehicle for passively announcing another agency's already-decided policy choices renders the Final Rule arbitrary and capricious. *Id.*

DEA's attempt to cast itself as a passive bystander in the rulemaking process is problematic for other reasons as well. It did not, for example, consider alternative approaches to the problem before it. An agency that is simply doing another's bidding will likely have little interest in alternative approaches. Nor did it provide any substantive explanation for the dramatic shift in long-settled policy occasioned by the Final Rule. Instead, it simply explained that DOJ had decided new rules were necessary before announcing DOJ's new interpretation of the CSA and Single Convention. Missing from the Final Rule is any explanation from DEA of *its* reasons for abandoning the old policy in favor of the new one. *E.g.*, *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. at 502, 515 (2009); *See also State Farm* at 48-51 (agency must provide reasons for abandoning old policy).

In short, DEA's attempt to use § 553's notice-and-comment procedures to convert a policy developed years ago by a *different* agency *in secret* into a legislative rule cannot stand. Fundamental administrative-law principles

prohibit "judges [from] uphold[ing] agency action on the basis of rationales offered by anyone other than the proper decisionmakers." *Alpharma, Inc.*, 460 F.3d at 6. In this way, the APA provides a structural assurance that the grounds for agency policy are publicly embraced by the most politically responsive actors in the administrative state. *Regents of the Univ. of California*, 140 S. Ct. at 1905 ("The APA 'sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.'") (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992)). As such, if DEA wants to elevate the views of another agency like DOJ or OLC to the status of a "legislative rule," it must exercise its discretion to propose the policy changes, open them to public inspection and criticism, and provide a reasoned explanation for them. Its failure to do so here renders the Final Rule invalid.

II. The Final Rule Contravenes the CSA.

A. The Final Rule is contrary to § 823(a).

Congress mandated that DEA "shall register an applicant to manufacture controlled substances in schedule I or II" if doing so "is consistent with the public interest and with [certain] United States [treaty] obligations." 21 U.S.C. § 823(a). In determining "the public interest," Congress instructed DEA to "consider" six enumerated "factors":

> (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
>
> (2) compliance with applicable State and local law;
>
> (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> (6) such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a)(1)-(6). DEA's Final Rule is contrary to Congress's instructions in § 823(a) in several respects.

First, instead of considering "compliance with applicable State and local law" as subsection (a)(2) instructs, the Final Rule focuses on *the applicant's past* "compliance with applicable State and local law." Final Rule at 82,335. Had Congress intended subsection (a)(2) to require consideration of an applicant's past behavior, it would have said so as it did elsewhere in § 823(a). Subsection (a)(4), for instance, instructs DEA to consider the "*prior* conviction record *of applicant* under [certain] Federal and State

laws." *Id.* § 823(a)(4) (emphasis added). And in § 823(h), which governs registration of distributors of a list I chemical, Congress directed DEA to consider "compliance *by the applicant* with applicable Federal, State, and local law." *Id.* § 823(h)(2) (emphasis added).

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Territory of Guam v. United States*, 141 S. Ct. 1608, 1615 (2021) (internal quotation marks and citations omitted). DEA's attempt to add language to subsection (a)(2) that Congress intentionally omitted defies settled principles of statutory interpretation. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020) ("It is a fundamental principle of statutory interpretation that 'absent provision[s] cannot be supplied by the courts.") (internal quotation marks and citations omitted).

Second, the Final Rule rewrites subsection (a)(4) to require consideration of an applicant's *compliance* with federal law when, in fact, subsection (a)(4) doesn't mention compliance at all. *Compare* Final Rule at 82,335 *and* 21 U.S.C. § 823(a)(4). Instead, Congress instructed DEA to make

a far more limited inquiry into an applicant's "prior conviction record under [certain] State and federal laws ...." 21 U.S. C. § 823(a)(4).

A review of § 823(a)(4) in its broader context confirms this interpretation. *E.g.*, *Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.") (internal quotation marks and citations omitted). Congress instructed DEA to consider "an applicant's compliance with ... federal ... law" twice in § 823—but not in § 823(a)(4). *See* 21 U.S.C. § 823(f)(4) (requiring DEA to consider "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances" when assessing the public interest in the context of "register[ing] practitioners ... to dispense, or conduct research with, controlled substances in schedule II, III, IV"); *id.* § 823(h)(2) (requiring DEA to consider "compliance by the applicant with applicable Federal, State, and local law" when assessing the public interest in registering an applicant to distribute a list I chemical). Unlike those directives, subsection (a)(4) is one of six provisions requiring DEA to make the more limited inquiry into an applicant's "prior conviction record" under federal law. *See id.* §§ 823(b)(3), 823(d)(4), 823(e)(3), 823(f)(3).

It strains credulity to think that Congress would deploy the distinct concepts of "compliance" with federal law on the one hand and "prior conviction record" under federal law on the other throughout § 823(a)(2) *without* intending them to be treated distinctly. That is especially so given that "in every fiscal year since 2015, Congress has prohibited the Department of Justice from spending funds prosecuting individuals for violations of federal marijuana laws that do not also run afoul of state law." *Standing Akimbo, LLC v. United States*, No. 20-645 (U.S. June 28, 2021) (statement of Thomas, J., respecting denial of petition for writ of certiorari) (citing *United States v. McIntosh*, 833 F. 3d 1163, 1168, 1175-1177 (9th Cir. 2016) (interpreting the relevant appropriation riders to prevent expenditures on the prosecution of individuals who comply with state law)).

DEA's arguments to the contrary are unpersuasive. DEA contends, for example, that "[s]uch activity [non-compliance with federal law] is relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety." Final Rule at 82,335. If the considerations DEA identifies swept broadly enough to reach mere non-compliance with federal law, however, then Congress would have had no reason to separately list an

applicant's "prior *conviction* record under … federal law[ ]" in subsection (a)(4) (emph. added).

DEA's argument that "prior conduct in violation of the CSA is relevant to determining whether the applicant can be entrusted with the responsibilities associated with being a DEA registrant," fails for the same reason. Final Rule at 82,335. Assuming, for purposes of argument, that DEA may consider "whether the applicant can be entrusted with responsibilities associated with being a DEA registrant" under § 823(a), DEA still could not consider an applicant's past *compliance* with federal law without impermissibly rendering subsection (a)(4)'s focus on an applicant's past *conviction record* under federal law surplusage.

Perhaps rewarding compliance with the CSA is good policy. But "[w]here a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer." *Iancu*, 138 S. Ct. at 1355.

Third, DEA misconstrues § 823(a)(1) again in insisting that it *requires* the agency to limit the number of manufacturers to a number of establishments that can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions. *See* Final Rule at 82,336-367. In fact, the statute merely instructs DEA to *consider* such a

limitation. 21 U.S.C. § 823(a)(1). The difference between instructing an agency to consider a certain restriction among several factors when deciding and requiring an agency to impose such a restriction each time it makes that determination is apparent.

Moreover, Congress was aware of the difference. It derived § 823(a)(1) from the Narcotics Manufacturing Act of 1960, 74 Stat. 55 (1960). Under the 1960 Act, a person seeking to manufacture a basic class of narcotic drugs was required to obtain a license from the Secretary of the Treasury Department. Within the Treasury Department, this function was delegated to the Commissioner of the Bureau of Narcotics (a predecessor of DEA). Section 8 of the 1960 Act set forth the criteria that the Commissioner was required to consider in determining whether to issue a narcotics manufacturing license. Paragraph (a)(1) of section 8 of the 1960 Act—the analog to paragraph 823(a)(1) of the CSA—provided that, in determining whether to issue a license to an applicant seeking to manufacture a basic class of narcotic drug, the Commissioner was required to consider:

> Maintenance of effective controls against the diversion of the particular basic class of narcotic drug and of narcotic drugs compounded therefrom into other than legitimate medical and scientific channels through limitation of manufacture of the particular basic class of narcotic drug to *the smallest number of establishments* which will produce an adequate and uninterrupted supply of narcotic drugs of or derived from such

> basis class of narcotic drugs for medical and scientific purposes, consistent with the public interest.

(emph. added).

DEA's interpretation of § 823(a)(1) as placing an upper limit on the number of manufacturer registrations nullifies Congress's decision to drop this "smallest number" restriction from the 1960 Act. Final Rule at 82,336. Indeed, DEA's interpretation is even more restrictive than the 1960 Act, which, like § 823(a), did not impose an across-the-board constraint on the number of manufacturers and instead merely instructed the agency to *consider* such a restriction.

DEA's overly-restrictive reading of § 823(a) also ignores the very agency precedent DEA itself relies on in the Proposed Rule. *See* Proposed Rule at 16,293 (discussing *Lyle E. Craker, Denial of Application*, 74 Fed. Reg. 2101 (Jan. 14, 2009) (denying an application for a bulk manufacturer of marijuana)). In denying Dr. Craker's application in 2009, DEA acknowledged that § 823(a)(1) merely requires that the agency *consider* limiting the number of manufacturers, expressly rejecting the interpretation DEA advances in the Final Rule:

> To be precise, the text of the CSA (in contrast to that of the 1960 Act) does not unambiguously impose an absolute ceiling on the number of registered manufacturers (that which can produce an adequate and uninterrupted supply under adequately competitive conditions). Rather, as indicated above, the text of

> the CSA requires DEA to "consider … limiting" the number of manufacturers to such a number (along with considering the other public interest factors).

74 Fed. Reg. at 2128 n.105.

Despite repeatedly relying on the *Craker* decision, DEA never acknowledges—much less supplies a reasoned explanation for—its abrupt departure from this more sensible view of the statute. "It is, of course, a fundamental precept of administrative law that agencies are under an obligation to follow their own regulations, procedures, and precedents, or provide a rational explanation for their departure." *Nat'l Ass'n of Cas. & Surety Agents v. Bd. of Gov'rs of the Fed. Reserve Sys.*, 856 F.2d 282, 287 (D.C. Cir. 1988).

B. The Final Rule impermissibly limits DEA's § 822(d) waiver authority.

DEA acknowledges it has authority under § 822(d) to waive § 823(a)'s registration requirements "if [it] finds it consistent with the public health and safety," *see* 21 U.S.C. § 822(d), but it "does not consider such a waiver of registration for a bulk manufacturer to be a legally viable option," for four reasons:

1. "DEA has never previously waived the registration requirement to allow controlled substances to be manufactured outside the closed system of distribution";

2. "doing so would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain";

3. "waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention"; and

4. "supplying marihuana to researchers does not demonstrate that the material being supplied has been produced in accordance with other Federal laws."

Final Rule at 82,336. None of these arguments is persuasive.

DEA's past practice under § 822(d) is entirely beside the point for two reasons. First, whether DEA has authority and whether it has ever exercised it are separate questions. Second, given DEA's commitment to the view that the Single Convention obligated it to license just one manufacturer of marijuana—a view that the OLC Opinion revealed to have been mistaken as a matter of law the entire time—its failure to exercise its § 822(d) waiver authority in this context is not surprising. The fact that DEA's mistaken view of the Single Convention and the CSA prevented it from entertaining the idea of granting a § 822(d) waiver in the past does not mean it ever lacked authority to grant such a waiver. Simply put, DEA cannot use its past practice under an admittedly wrongheaded view of the law to ignore an important aspect of the problem before it now.

DEA's conclusory claim that it cannot grant a waiver under § 822(d) because doing so "would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain" also makes no sense. First, § 822(d) is *part* of the framework of the CSA. Moreover, the Act's various "measures of accountability" have never prevented DEA from exercising its discretion to grant waivers and make exceptions to the Act's otherwise-strict terms in other contexts. For example, less than two weeks ago, it invoked § 822(d) to allow the operation of mobile components associated with DEA registered Narcotic Treatment Programs. 86 Fed. Reg. 33,861, 862 (Jun. 28, 2021). Given DEA's history of exception-making and waiver granting, its refusal even to entertain the idea of a waiver here requires a reasoned explanation.

DEA's claim that exercising its authority under § 822(d) would violate the Single Convention is wrong. Congress did not require DEA to consider compliance with the Single Convention when deciding whether to grant a waiver under § 822(d). Section 823(a) requires DEA to consider compliance with the Single Convention, but § 822(d) authorizes DEA to *waive* the registration requirements of § 823(a). It is precisely the point of § 822(d) that

the Single Convention does not excuse DEA's failure to consider a waiver under § 822(d).

DEA's final argument—that "supplying marihuana to researchers does not demonstrate that the material being supplied has been produced in accordance with other Federal laws"—fares no better. DEA never explains why it matters whether "the material being supplied has been produced in accordance with other Federal laws." In any case, if it does matter, it cannot help DEA's cause regarding § 822(d). As a result of DEA's longstanding wrongful adherence to the NIDA monopoly on cannabis production, *none* of the material DEA has permitted the National Center to manufacture, including under licenses DEA has granted *since* the OLC issued its June 2018 opinion, has ever been produced in accordance with federal law. That has not stopped DEA from continuing to permit the National Center to manufacture cannabis under a regulatory regime that OLC has condemned. Without some explanation of why such compliance with federal law should matter for potential recipients of a § 822(d) waiver but not the National Center, DEA's refusal even to consider exercising its § 822(d) discretion renders the Final Rule contrary to law.[4]

[4] Section 822(d) also illustrates precisely why the untimely disclosure of the OLC Opinion was prejudicial. On its face, it gives the Attorney General

III. DEA's Interpretation of Medicinal Cannabis Violates the Single Convention and Federal Law.

DEA erroneously asserts that "medicinal cannabis" is limited to "a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act." Rule at 82,340. DEA's interpretation of "medicinal cannabis" is arbitrary, capricious, and contrary to law because it contravenes the plain and ordinary meaning of the text and is inconsistent with statutory text and scheme.

A. DEA's interpretation cannot be squared with the ordinary public meaning of "medicinal."

The Single Convention defines "medicinal opium" as "opium which has undergone the processes necessary to adapt it for medicinal use." Single Convention, ¶ 1(o) (Add. 92). Presumably, "medicinal cannabis" means the same thing but regarding cannabis: "cannabis which has undergone the

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the flexibility, unconstrained by the Single Convention, to relax registration requirements, like § 823(a), when doing so would be "consistent with the public health and safety." The Single Convention and § 823(a) were executed more than fifty years ago, before the rise of medicinal marijuana programs in more than two-thirds of the United States, when the structure described by the OLC Opinion might be consistent with public health interest. Today, something different is needed. Using § 822(d), the Attorney General could waive registrations to fit contemporary public health and safety needs (for example, permitting researchers to obtain and study state-legal medical marijuana). Had the OLC Opinion been disclosed, Petitioners and the public could have provided more detailed proposals about how § 822(d) could permit a scheme that would be consistent with the public health and safety.

processes necessary to adapt it for medicinal use.". *See A. Scalia & B. Garner*, Reading Law: The Interpretation of Legal Texts, 170-74 (2012) (presumption of consistent usage).

DEA's interpretation, however, adds an additional, nonsensical requirement that to be "medicinal" the cannabis product must be approved by the FDA. DEA defines medicinal cannabis as "drug products derived from cannabis in a form that the United States has approved for medical use," which is "most effectively captured in this rule by requiring that the product be able to be legally marketed under the Food Drug and Cosmetic (FD&C Act)." Final Rule at 82,340. Because a drug cannot be used medicinally until FDA-approved, however, FDA approval cannot be one of the "processes necessary to adapt it for medicinal use."

Start with "medicinal." Around the time that the Single Convention and the CSA became law, "medicinal" meant "adapted to the cure or alleviation of bodily disorders." Webster's New Twentieth Century Dictionary Unabridged (2d ed.) (1970). A "medicinal" drug, therefore, contrasts with a recreational drug. A "[m]edicinal" drug is a drug that has been "adapted to the cure or alleviation of bodily disorders." "Medicinal cannabis" means "cannabis that is adapted to the cure or alleviation of bodily disorders."

For over a century, courts have interpreted "medicinal" in a manner consistent with this plain meaning and inconsistent with DEA's interpretation. In *Fink v. United States*, 170 U.S. 584, 585-86 (1898), for example, the Supreme Court explained that "the commercial meaning of the term 'medicinal preparation' is the same as its ordinary meaning, *viz.* a substance used solely in medicine, and prepared for the use of the apothecary or physician, to be administered as a remedy in disease." *Id. See also, e.g.*, *United States v. Wm. Cooper & Nephews*, 22 C.C.P.A. 31, 35 (1934) (similar). Decades later, in *Biddle Sawyer Corp. v. United States*, 320 F.2d 416, 423 (C.C.P.A. 1963), the court applied a dictionary definition nearly identical to the one referenced above: "curative or alleviative; used for the cure or alleviation of bodily disorders; as, medicinal tinctures, plants, or springs." And recently, in *Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1309 (Fed. Cir. 2004), the Court described a "medicinal preparation" as a preexisting product administered to treat disease.

The commentary to the Single Convention, which DEA does not address, underscores this interpretation. "The Single Convention follows earlier narcotics treaties in defining 'medicinal opium' as a special form of opium in which that drug is used in medical treatment" Commentary, ¶ 1(o)(1) (Add. 102-03). Something is "medicinal," therefore, if it is used in

medical treatment—not if it has been proven to be safe and effective according to FDA standards for interstate marketing. The Single Convention commentary also contrasts "medicinal opium" with pharmaceutical preparations of opium like codeine and morphine, further refuting DEA's attempt to equate the word "medicinal" with FDA-approved pharmaceutical products. Commentary, Art. 24, ¶ 2(a), No. 5 (Add. 105). It states that medicinal "applies not only to opium as base drug, but also to preparations of opium, including medicinal opium, but not to other drugs made from opium, e.g. morphine or codeine." *Id.*

DEA offers neither reason nor explanation for its restrictive FDA-centric interpretation. It says "medicinal" means a drug "has undergone the processes necessary to adapt it for medicinal use," and from this text, "understands 'medicinal cannabis' to mean drug products derived from cannabis in a form that the United States has approved for medical use." Final Rule at 82,340. How or why DEA arrived at that understanding is left unsaid. But because DEA's syllogism does not follow from any ordinary meaning of the term "medicinal," it cannot withstand scrutiny.

B. DEA's interpretation of medicinal ignores this Court's decision in *Grinspoon*.

In *Grinspoon v. DEA*, 828 F.2d 881, 891 (1st Cir. 1987), this Court carefully examined similar language in the CSA—"accepted medical use"—

and rejected DEA's attempt to equate that phrase with FDA-approval for interstate marketing. Based on an examination of the statutory text and scheme, this Court instructed DEA that it could not treat the absence of FDA interstate marketing approval as conclusive evidence that a drug has "no currently accepted medical use." *Id.* at 888, 891. In so holding, this Court explained that "the absence of FDA approval for interstate commerce does not foreclose the possibility that a substance might still possess an accepted medical use or even be considered safe for use under medical supervision." *Id.* at 888.

If, as *Grinspoon* holds, the text and scheme preclude DEA from interpreting "accepted medical use" to require FDA-approval, *a fortiori*, "medicinal cannabis" cannot require FDA approval. In *Grinspoon*, this Court emphasized that "accepted" limited "medical use"; in fact, DEA's equating "accepted medical use" with FDA-approval hinged more on the word "accepted" than "medical." As this Court noted, accepted means "generally approved" or "generally agreed upon." *Id.* at 886 & n.7. DEA used FDA approval as a proxy for general approval. But here, the use of "medicinal" is unlimited and unqualified. The Single Convention does not say "approved medicinal cannabis" or even "accepted medicinal cannabis."

C. DEA's interpretation conflicts with the CSA and the FDCA.

DEA states that "its definition excludes an investigational new drug containing cannabis; such products may eventually become approved for *full medical use* in the United States (as opposed to research), but have not yet obtained such approval." Final Rule at 82,340 (emph. added). This statement alone should doom the Rule, for implicit in it is an admission that situations exist where a drug can be used medicinally absent FDA approval. Indeed, the limited sort of medical use, as opposed to "full," is expressly contemplated by the CSA: "currently accepted medical use with severe restrictions." *See* 21 U.S.C. § 812(b)(2)(B).

Years before *Grinspoon* explained that "accepted medical use" under the CSA does not mean "FDA-approved," FDA recommended that THC remain in schedule I as a drug with "no currently accepted medical use in treatment in the United States" because it could not be lawfully marketed under the FDCA. *See* 47 Fed. Reg. 10,080 at 10,085 (Mar. 9, 1982). Importantly, however, FDA also concluded that THC could be placed in schedule II as a drug with "a currently accepted medical use with severe restrictions." *Id.*

FDA reasoned that drugs "in the later stages of the investigational process may fall within this statutory language." In the case of THC,

development had progressed sufficiently far to be termed "currently accepted medical use with severe restrictions." *Id.* There, the National Cancer Institute's inclusion of THC in a "group C distribution scheme represents an example of clinical research that has progressed sufficiently far to be termed." The Surgeon General had announced THC's placement in group C, making THC available to an estimated 4,000 cancer specialists for use in combating nausea and vomiting in cancer patients undergoing chemotherapy. *Id.* FDA authorized this broader distribution plan because, among other reasons, the close supervision required by the study protocol appeared to provide adequate safeguards for patient safety and sufficient evidence of effectiveness existed to support broader availability for treatment of patients. *See id.*

FDA did not propose to define "accepted medical use with severe restrictions" as limited to group C drugs because that definition would improperly limit the statutory language to drugs involved in cancer therapy. *See id.* But it believed that THC's placement in group C fit the statutory language of "accepted medical use with severe restrictions." *See id.* Therefore, according to FDA, under certain circumstances, a substance that is not approved for interstate marketing but is available on a limited basis for

investigation can be deemed to have a "currently accepted medical use with severe restrictions." *Id.*

Today, FDA's expanded access program squarely fits the bill. *See* 21 C.F.R. § 312.300 *et seq.* (regulations "to facilitate the availability of [unapproved] drugs to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition"). Under regulated conditions, FDA permits the use of drugs medicinally without full FDA approval. In the Rule, DEA characterizes such access as mere "research." Rule at 82,340. It is wrong. The regulations that outline expanded access demonstrate beyond cavil that it is medicinal use. *See, e.g.*, 21 C.F.R. § 312.305 (explaining that submissions must include, among other items, "an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options"); *id.* § 312.310 (explaining when FDA may permit medical use of an investigation drug).

DEA admits its "definition excludes an investigational new drug containing cannabis" and thus excludes cannabis and cannabis-based drugs being used in the later-stage FDA clinical trials, even though these products:

(1) by definition, undergo "processes necessary to adapt it for medicinal use,"

(2) might, according to FDA, be deemed as having a "currently accepted medical use with severe restrictions," and

(3) might be eligible for FDA expanded access programs.

DEA offers no reasonable explanation for excluding drugs that could meet these criteria. It merely states that such developmental drugs are not approved for "full medical use." But whether a drug is approved for "full medical use"—whatever that might mean—is irrelevant to whether a cannabis product is "medicinal" because it does not speak to whether a product "has undergone the processes necessary to adapt it for medicinal use." And for the reasons previously stated, it is plainly possible for a such a product to exist and be used medically and legally before it has been approved by FDA.

Because the Final Rule contradicts the statutory text and arbitrarily precludes legal medicinal products, it must be set aside. *Cf. Manhattan Gen. Equip. Co. v. Comm'r of Internal Revenue*, 297 U.S. 129, 134 (1936) ("A regulation which … operates to create a rule out of harmony with the statute, is a mere nullity."); *Clifton v. Fed. Election Comm'n*, 114 F.3d 1309, 1312 (1st Cir. 1997) ("Agencies often are allowed through rulemaking to regulate beyond the express substantive directives of the statute," but only "so long as the statute is not contradicted."); *Wilcox v. Ives*, 864 F.2d 915, 918 (1st Cir.

1988) (invalidating regulation "in direct conflict with the plain meaning of the statute").

D. DEA's interpretation of "medicinal" impermissibly narrows legitimate medical practice.

Petitioners do not suggest that DEA, a federal agency, must adopt a position on "medicinal cannabis" that effectively aligns it in assisting violations of federal law. For example, Petitioners' objection is not rooted in the fact that DEA's interpretation excludes cannabis authorized for use as "medical marijuana" under State law. *See* Rule at 82,340 (discussing exclusion of state "medical marijuana"). DEA may, for example, define medicinal cannabis as cannabis that has been "adapted to the cure or alleviation of bodily disorders, and whose use is consistent with federal law." What it cannot do, however, is interfere with the practice of medicine by unduly limiting "medicinal" or medical practice to something FDA has approved for interstate marketing to the exclusion of developmental and medicinal cannabis products that could be used legally under federal law.

Boiled down, DEA's attempt to codify its narrow view of medicine as binding federal law is just the latest in a long series of attempts by a federal law-enforcement agency to use its "limited and specific" rulemaking authority under the CSA to bootstrap itself into the role of regulator of the medical profession—a practice this Court rebuked in *Grinspoon* and that the

Supreme Court resoundingly rebuked in *Gonzales v. Oregon*, 546 U.S. 243 (2006). There, the Court explained that the CSA does not empower DEA to define the substantive standards of medical practice. *Id.* at 264. *See also id.* at 265-66. To the contrary, the Court declared, "[t]he structure of the CSA … conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise." *Id.* at 266. Nor does the CSA "impliedly authorize[ ] an Executive officer to bar a [medical] use simply because it may be inconsistent with one reasonable understanding of medical practice." *Id.* at 272-73. Indeed, the Court explained that § 823(a)(1)—the very authority DEA invokes as the basis for the Final Rule—does *not* give DEA "authority to define diversion based on [its] view of legitimate medical practice." *Id.* at 260.

DEA has no delegated authority to regulate medical practice. Its job is to prevent diversion and drug abuse. As long as legitimate, non-theoretical pathways for medicinal use of cannabis products that have yet to be approved by FDA exist, DEA may not regulate them out of existence. *Cf. The Judge Rotenberg Educational Center v. FDA*, 20-1087, Slip. Op. at 15 (D.C. Cir. July 6, 2021) (Sentelle, J.) ("In this case, [FDA] attempts to regulate the practice of medicine, not only without explicit authorization from Congress, but in the face of an explicit congressional command not to do so."). And

because DEA offers no persuasive explanation for the unduly narrow limitation it adopted in the Final Rule, for the reasons stated above and in *Gonzales*, its arbitrary limitation of "medicinal cannabis" must be set aside.

IV. The Final Rule Is Arbitrary and Capricious.

A. The Final Rule is impermissibly retroactive.[5]

Absent express congressional approval, newly promulgated agency rules may not be applied retroactively. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (citations omitted) ("[C]ongressional enactments .... will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."). By ensuring that regulated parties have a chance to know what the law requires of them before they are bound to follow it, the presumption against retroactivity serves the due process interests of "fair notice, reasonable reliance, and settled expectations." *De Niz Robles v. Lynch*, 803 F.3d 1165, 1169 (10th Cir. 2015) (Gorsuch, J.) (quoting *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994)). And by "preventing the state from singling out disfavored individuals or groups and

[5] Petitioner SRI does not join this argument.

condemning them for past conduct they are now powerless to change," the presumption serves an important equal protection interest as well. *Id.* (citing Adrian Vermeule, Essay, *Veil of Ignorance Rules in Constitutional Law*, 111 Yale L.J. 399, 408 (2001)).

DEA's Final Rule is impermissibly retroactive because it "seeks to impose 'new legal consequences to events completed before its' announcement." *Id.* at 1168 (quoting *INS v. St. Cyr*, 533 U.S. 289, 321 (2001)). Petitioner Craker and the 30-some other applicants who responded to DEA's solicitation of applications in the 2016 Policy Statement prepared their applications in reliance on the standards DEA had in place at the time. For many, that meant tailoring not just their application forms, but also their business affairs and priorities to optimize their ability to satisfy DEA's then-existing standards for registering manufacturers of marijuana. They did all this in reliance on DEA's express public pledge to provide each applicant "due process in the consideration of the[ir] application." 2016 Policy Statement at 53848.

The Final Rule upsets those reasonable reliance interests as DEA has applied or will apply entirely different standards when finally evaluating the long-pending applications. The Supreme Court has declared it "hard to imagine a more violent breach of [the reasoned decisionmaking]

requirement than [when an agency] appl[ies] a rule of primary conduct or a standard of proof which is in fact different from the rule or standard formally announced." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359 (1998). Yet that is precisely what DEA's Final Rule does.

Furthermore, the Final Rule renders the pending applications, most of which DEA declared "complete" years ago under then-existing standards, suddenly "incomplete," not because of anything the applicants did in the meantime but because DEA's Final Rule imposed new requirements that all applicants submit a form that did not even exist when they submitted their applications. *See* Proposed Rule at 16305 ("Persons seeking to become registered with DEA to grow marihuana as bulk manufacturers would still apply for registration using the same DEA Form 225 as other bulk manufacturers, but DEA would use a new supplemental questionnaire unique to marihuana manufacturers in order to gather additional information about applicants."). Changing the legal status of past conduct is another tell-tale sign of impermissible retroactivity. *See, e.g.*, *Ass'n of Accredited Cosmetology Schs. v. Alexander*, 979 F.2d 859, 864 (D.C. Cir. 1992) (quotes omitted) ("An administrative rule is retroactive if it takes away or impairs vested rights acquired under existing law, or creates a new

obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already past.").

As a final example, the Final Rule subjects those applicants DEA eventually registers to additional fees and administrative duties that DEA never mentioned until long after the agency had accepted the pending applications for filing. Many of these requirements bear on the actual mechanics of cultivating, harvesting, and storing the applicants' would-be research-grade marijuana crops. Had applicants and the public known of these issues before they made decisions to submit—or not submit—applications to manufacture in response to the 2016 Policy Statement, they might have changed their assessment of the pros and cons of applying. Such considerations may well have altered those decisions, resulting in DEA receiving a more or less competitive set of applications than the set currently before the agency. This, in turn, would have impacted the competitive process of selecting additional manufacturers of marijuana.

Where, as here, a rule imposes new obligations or disadvantages a person's prospects in an ongoing adjudication based on past conduct the person can longer change, it is impermissibly retroactive. *E.g.*, *Nat'l Min. Ass'n v. U.S. Dep't of Interior*, 177 F.3d 1, 8 (D.C. Cir. 1999) (rule impermissibly retroactive because it "impose[d] a new disability, permit

ineligibility, based on transactions or considerations already past, namely pre-rule violations by mine operators over whom permit applicants acquired control before the rule's effective date") (quotes omitted).

B. DEA failed to consider relevant alternatives.

In the Proposed Rule, DEA admitted it did not consider alternatives to its proposed approach because it was only amending its regulations to the extent necessary to comply with the CSA and U.S. treaty obligations. Proposed Rule at 16298. But DEA overlooked several viable alternatives, including ones suggested by OLC. *See* OLC Op. at 24. DEA's failure to consider relevant alternatives renders the Final Rule arbitrary and capricious. *State Farm*, 463 U.S. at 43.

C. DEA's refusal to permit the study of state-dispensary marijuana is arbitrary and capricious.

In the Final Rule, DEA responded to comments calling for DEA-registered researchers to be allowed to obtain marijuana and marijuana products from State-authorized sources for the purpose of Federal research. Final Rule at researchers to be able to study marijuana grown in compliance with state law but in violation of federal marijuana laws. Final Rule at 82,338. According to DEA, permitting researchers to study marijuana grown in violation of the CSA and/or Single Convention is out of the question. *Id.*

The problem with that reasoning is that taken seriously, it would also mean federally registered researchers could not study NIDA marijuana either. After all, the OLC Opinion concludes that *all* marijuana grown under the NIDA contract since the enactment of the CSA in 1970 was grown in violation of federal law and the Single Convention. OLC Op. 24. Yet DEA has no problem with researchers using NIDA marijuana. Indeed, despite the OLC Opinion's conclusion that marijuana manufacturing under DEA's previous regulations (or the 2016 Policy Statement) would violate the Single Convention (and therefore the CSA), DEA has continued to grant the National Center's applications to register as a marijuana manufacturer. *E.g.*, "Bulk Manufacturer of Controlled Substances Application: National Center for Natural Products Research NIDA MPROJECT," 84 Fed. Reg. 49,556 (Sept. 20, 2019).

DEA does not and cannot explain why the National Center's violations of federal law and the Single Convention are tolerable when the same sorts of violations by companies complying with state laws are not. Nor can it explain why it had to halt the ongoing adjudication of all 30-some applications it received in response to the 2016 Policy Statement while it promulgated the Final Rule and yet it had no problem granting the National

Center's applications to register. In short, DEA's bias against research of state-dispensary marijuana is irrational.

CONCLUSION

Petitioners request that the Court grant the Petitions for Review, hold the Final Rule unlawful, and set it aside.

Date: July 9, 2021

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 12,699 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Matthew C. Zorn
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CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system.

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ADDENDUM

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85 FR 82333-01, 2020 WL 7406680(F.R.)
RULES and REGULATIONS
DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Parts 1301 and 1318
[Docket No. DEA-506]
RIN 1117-AB54

Controls To Enhance the Cultivation of Marihuana for Research in the United States

Friday, December 18, 2020

AGENCY: Drug Enforcement Administration, Department of Justice.

***82333** ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to facilitate the cultivation of marihuana for research purposes and other licit purposes to enhance compliance with the Controlled Substances Act, including registering cultivators consistent with treaty obligations. This final rule adopts, with minor modifications, the notice of proposed rulemaking published on March 23, 2020, including regulations that govern applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and regulations related to the purchase and sale of this marihuana by DEA.
DATES: This final rule is effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152-2639; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

The Controlled Substances Act (CSA) requires all persons who seek to manufacture a controlled substance to obtain a DEA registration.[FN1] 21 U.S.C. 822(a)(1). The CSA defines "manufacture" to include the "production" of a controlled substance, which in turn includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. 21 U.S.C. 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marihuana [2] 3 ***82334** to supply researchers or for other uses permissible under the CSA (such as product development) must obtain a DEA manufacturing registration. Because marihuana is a schedule I controlled substance, applications by persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. 823(a). See generally 76 FR 51403 (2011); 74 FR 2101 (2009), pet. for rev. denied, Craker v. DEA, 714 F.3d 17 (1st Cir. 2013). DEA's Administrator has the authority to grant a registration under section 823(a). To do so, the Administrator must determine that two conditions are satisfied: (1) The registration is consistent with the public interest (based on the enumerated factors in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 ("Single Convention" or "Treaty"), 18 U.S.T. 1407.[FN4]

In 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marihuana for research purposes. See Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the requirement of section 823(a) that a registration to bulk manufacture a schedule I or II controlled substance must be consistent with United States obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed. As part of this review, in June 2018, the

DOJ Office of Legal Counsel (OLC) prepared an opinion ("OLC Opinion"), now publicly available, examining DEA's policies and practices for granting bulk manufacturing registrations to marihuana growers in light of the CSA's requirement that DEA register manufacturers of schedule I and II controlled substances in a manner consistent with the Single Convention.[FN5]

This rule is being implemented pursuant to the Administrator's authority under the CSA "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA]," 21 U.S.C. 871(b).

Summary of the Notice of Proposed Rulemaking

On March 23, 2020, DEA published a notice of proposed rulemaking (NPRM) in the Federal Register to (1) facilitate the cultivation of marihuana for research and licit purposes in compliance with the CSA, including a provision requiring consistency with the Single Convention; (2) amend DEA regulations pertaining to applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers; and (3) establish regulations related to the purchase and sale of this marihuana by DEA. 85 FR 16292. This final rule responds to comments received concerning the proposed rule, and DEA is adopting the proposed rule with minor modifications to the regulations to be codified at 21 CFR 1318.04, as described below.

Discussion of Public Comments

DEA received comments from the general public, DEA registrants, applicants for registration to manufacture marijuana, organizations, associations, and a United States Senator. Some commenters expressed general support of the proposed rule because it will increase the number of DEA-registered bulk manufacturers of marihuana for research. Some commenters expressed general concern about the impact of the proposed rule. Other commenters expressed specific concerns about, among other things, the application process and applicant criteria, quality of marihuana produced, DEA's ability and authority to lead the program, controls for the purchase and sale of marihuana, harvest time, quota, and costs. Other commenters submitted comments that are outside of the scope of this rule.

Application Process and Criteria

Commenters expressed concerns about the application process and the criteria for applicants. The following issues raised by the commenters, and DEA's response to each, fall under this category.

Issue 1: Many commenters stated that the approval process for applications takes too long and needs to be streamlined, suggesting that a timeframe for the approval or denial of applications should be determined, specifically within 30 days, 90 days, or six months of receipt of the application.

Response 1: DEA has a process for receiving, reviewing, and acting on applications for a DEA registration or re-registration, as described in 21 CFR part 1301. The process involves applicants submitting applications online or on paper and DEA evaluating all applications and supporting documentation submitted in accordance with the factors specified in 21 U.S.C. 823. The length of this process varies due to the detailed review performed by DEA, and as explained in the NPRM, a review of pending applications to manufacture marihuana has been delayed due to the need to establish the additional policies reflected in this rule. After receiving an application, DEA will send a questionnaire to the applicant to be completed and returned to DEA within 10 business days. DEA uses the information from the questionnaire and the application to determine whether the application should be granted under the factors specified in 21 U.S.C. 823. After the completed questionnaire is processed, DEA publishes a notice of application in the Federal Register, and current registrants and applicants for bulk manufacture of the same class of substance have 60 days to comment on, or object to, the application, as required by 21 CFR 1301.33. During the application process, DEA investigators also complete site visits and submit the appropriate reports to aid in the determination of whether to grant a registration. Because the process of evaluating an application to manufacture a schedule I controlled substance includes a 60-day public comment period, DEA cannot act on the application in a shorter timeframe, such as 30 days. Likewise, DEA must

balance limited resources to conduct pre-registration vetting of numerous applicants, which impacts the length of time needed to complete the application process. As a result, DEA declines to adopt a specific approval date applicable to all applications for registration to bulk manufacture marihuana.

However, in accordance with 21 U.S.C. 823(i), for applications to manufacture a schedule I or II controlled substance for use only in a clinical trial, DEA will issue a notice of application not later than 90 days after the application is accepted for filing. Additionally, DEA will register the applicant, or serve an order to show cause upon the applicant in accordance with 21 U.S.C. 824(c), not later than 90 days after the date on which the period ***82335** for comment pursuant to such notice ends, unless DEA has granted a hearing on the application under 21 U.S.C. 958(i). An applicant that believes it qualifies for review under these procedures should identify itself as an 823(i) applicant in its initial application for registration submitted to DEA. DEA will then determine whether the applicant qualifies for the review timeline specified under section 823(i).

Issue 2: Some commenters suggested that when there is a denial, DEA should provide notice and allow a hearing.

Response 2: Pursuant to 21 U.S.C. 824(c) and 21 CFR 1301.37, when DEA proposes to deny an application, DEA must serve the applicant with an order to show cause setting forth the factual and legal basis for the proposed denial. The applicant may file a request for a hearing, in accordance with 21 CFR 1301.43. If a hearing is requested, DEA will hold the hearing in accordance with the provisions for formal adjudications set forth in the Administrative Procedure Act and DEA regulation found at 21 CFR 1316 subpart D.

Issue 3: Another commenter stated that DEA used an internal memorandum to delay approval of applications to bulk manufacture marihuana.

Response 3: As mentioned in the NPRM, after the 2016 marihuana grower policy statement issued by DEA,[FN6] DOJ reviewed DEA's policies and practices for issuing bulk marihuana manufacturing registrations in light of the CSA and determined that DEA needed to amend its policies.[FN7] DEA has acted as expeditiously as possible to amend its policies to ensure consistency with the Single Convention as required by the CSA, while increasing the number of marihuana growers for research purposes. DOJ and DEA fully support research into the effects of marihuana and the potential medical utility of its chemical constituents, and DEA is working to expand the number of DEA-registered bulk manufacturers of marijuana, including through the finalization of this rule.

Issue 4: One commenter requested that DEA make the revised Form 225 and updated questionnaire available online for applicants.

Response 4: As required by the Paperwork Reduction Act (PRA), DEA must receive approval from the Office of Management and Budget (OMB) when a rule creates a new information collection or modifies an existing collection. This approval must be granted before an agency can use a revised form. In the NPRM, DEA discussed the modification of the existing information collection which would revise Form 225 and add questionnaires to the registration application process. Within the PRA section of the NPRM, DEA explained that an interested party could contact DEA for a copy of the form and questionnaires. The revision of the collection is awaiting approval; and, as such, DEA cannot yet post the proposed revisions to the form online for applicants. However, after the form has been approved, DEA will post the application to its website, and an applicant can complete and submit it online. DEA will then send the applicable questionnaires to the applicant after the application has been received.

Issue 5: Some commenters believe that DEA's consideration of an applicant's compliance with Federal marihuana law would exclude qualified applicants, specifically those who operate in compliance with State laws that are inconsistent with Federal law.

Response 5: Congress has established by statute the factors that DEA must consider when evaluating whether to grant an application for registration. For an applicant to manufacture a schedule I or II controlled substance, DEA must consider, among other factors, the applicant's "compliance with applicable State and local law;" "prior conviction record . . . under Federal and

State laws relating to the manufacture, distribution, or dispensing of such substances;" "past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;" and "such other factors as may be relevant to and consistent with the public health and safety." 21 U.S.C. 823(a). An applicant that has manufactured marijuana without obtaining a DEA registration has violated Federal law, see 21 U.S.C. 841(a), regardless of whether that manufacturer has violated the laws of the State in which the applicant is located. Such activity is relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety. Moreover, prior conduct in violation of the CSA is relevant to determining whether the applicant can be entrusted with the responsibilities associated with being a DEA registrant. Indeed, DEA registration is a fundamental component of the CSA, and it is wholly appropriate to consider an applicant's past noncompliance with the CSA when deciding whether to grant a registration under the Act. DEA will consider all relevant factors for each individual applicant, on a case-by-case basis, when determining whether to grant registration, as provided for in 21 U.S.C. 823(a) and the regulatory text at 21 CFR 1318.05. While the DEA Administrator has discretion to weigh the statutory factors and any one factor need not be dispositive, an applicant's prior compliance with Federal law is a relevant consideration when determining whether to grant an application for registration.

Issue 6: A commenter suggested that a notice of exemption for a new drug application issued by the Food and Drug Administration (FDA) be an alternative to obtaining a DEA registration.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). Using FDA's authorization of a notice of exemption for a new drug application would not be in compliance with the CSA and therefore cannot be considered an alternative for obtaining a DEA registration.

Issue 7: A commenter opined that applicants should only be required to submit proof of State-issued marihuana licenses to DEA, after DEA approves the application.

Response 7: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). In assessing the application, DEA also weighs the applicant's compliance with applicable State law. 21 U.S.C. 823(a)(2). DEA has always required applicants seeking to manufacture a controlled substance to obtain and submit a valid State pharmaceutical manufacturer's license to demonstrate compliance with State law. Likewise, an applicant seeking to manufacture marihuana must submit evidence that it possesses a valid State manufacturer's license as part of its application, or explain why no such license is required by the State to manufacture marihuana for use in research. This evidence must be submitted to DEA as part of the determination of whether to grant a registration.

Issue 8: Some commenters suggested that the registration requirement be waived for marihuana growers (manufacturers) who will be supplying ***82336** marihuana to researchers under 21 U.S.C. 822(d).

Response 8: DEA-registered researchers are not currently allowed to obtain marihuana from entities that are not registered with DEA. DEA is permitted to waive the registration requirement if it finds that doing so is "consistent with the public health and safety," pursuant to 21 U.S.C. 822(d), and acting under authority delegated by the Attorney General. However, DEA has never previously waived the registration requirement to allow controlled substances to be manufactured outside the closed system of distribution, and doing so would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention.[FN8] It should also be noted that supplying marihuana to researchers does not demonstrate that the material being supplied has been produced in accordance with other Federal laws. As a result, DEA does not consider such a waiver of registration for a bulk manufacturer to be a legally viable option.

The scope of this rule addresses the registration of manufacturers of marihuana, not researchers of marihuana. To the degree that the commenters were seeking to exempt marihuana researchers, rather than manufacturers, from registration, in addition to

the foregoing concerns about adherence to treaty obligations, DEA does not at this time conclude that there is a public health need to exempt schedule I researchers from DEA registration. DEA notes that over the last several years, there has been a 149 percent increase in the number of active researchers registered with DEA to perform bona fide research with marihuana, marihuana extracts, and marihuana derivatives (from 237 in November 2014 to 589 in June 2020). At present, more researchers are registered to conduct research in the United States on marihuana, marihuana extracts, and marihuana derivatives than on any other schedule I substance, and more than 72 percent of DEA's total schedule I research registrant population (589 of 808 as of June 2020) is registered to conduct research on these substances. As a result, DEA concludes that there is not currently a public health need to exempt researchers from the registration requirement.

Issue 9: Other commenters suggested that DEA-registered researchers should be exempt from applying for DEA manufacturer registrations if the researchers are growing marihuana for their own studies and not for distribution.

Response 9: As reflected in this rule, any person lawfully growing marihuana must be registered with DEA to allow DEA to fulfill its obligations under the CSA. For the reasons discussed above, DEA has concluded that this requirement cannot be waived for researchers. Thus, under this final rule, when an applicant, including a researcher growing for his or her own use, is approved to grow marihuana, the applicant is registered as a bulk manufacturer. After the applicant is approved as a bulk manufacturer, the registrant must apply for and be issued an individual manufacturing quota (IMQ) for the amount of marihuana it needs to manufacture to meet the legitimate research and scientific needs of its customers. If the manufacturer plans to use the marihuana grown in bulk for its own research, it will also need to apply for a procurement quota. Under this rule, the DEA registrant must sell their harvest to DEA and then purchase from DEA the amount that they are allowed to procure based on the procurement quota issued to them. As such, DEA cannot exempt a researcher from the requirement of a DEA manufacturing registration even if they plan to use the marihuana grown for their own studies.

Issue 10: A few commenters suggested applicants who applied to be registered to grow marihuana soon after DEA published its 2016 marihuana growers policy should receive priority over more recent applicants. On the other hand, some commenters suggested that DEA should not delay consideration of new marihuana grower applications submitted after this rule is promulgated, as 21 CFR 1318.05(c) provides. In particular, some commenters expressed confusion about the "limited exception" to this delay noted in the NPRM and suggested that the limited exception should apply to all applicants.

Response 10: As previously stated in the NPRM, applications received after the date the final rule becomes effective will not be considered until all of the applications currently pending have been approved or denied, unless an application requires action under 21 U.S.C. 823(i). Applications already submitted will receive priority, and as a result, DEA will not have to restart its consideration of the pool of pending applications whenever a new application is submitted.

As described in the NPRM, the "limited exception" refers to the review of applications claiming the benefit of the statutory timeline of 21 U.S.C. 823(i). Congress has set the timeline for review of such applications by statute. That timeline will apply in lieu of the provision at 21 CFR 1318.05(c) for applicants that clearly identify themselves as 823(i) applicants in their original application, and for which DEA determines that the applicant qualifies for review under 823(i).

Issue 11: Another commenter suggested that the number of applicants selected to bulk manufacture marihuana should be unlimited and that DEA should consider the bulk manufacture of marihuana as a coincident activity to a researcher registration.

Response 11: The CSA mandates that DEA consider the maintenance of effective controls against diversion by limiting the bulk manufacture to a number of establishments which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 U.S.C. 823(a)(1). By statute, DEA is not allowed to register an unlimited amount of manufacturers, and DEA must perform an analysis of each application to determine whether the addition of the applicant is necessary to provide the adequate and uninterrupted supply of marihuana for research needs or whether the legitimate need will be met by the registration of others.

Currently, researchers are only permitted to manufacture as a coincident activity in limited quantities as set forth in a protocol approved by DEA in the researcher's registration application (or re-registration application), and to the extent that manufacture is not for the purposes of dosage form development. 21 CFR 1301.13(e)(1). A researcher's planting, cultivating, growing, or harvesting of marihuana does not constitute such a coincident activity to research. Rather, the planting, cultivating, growing, or harvesting of marihuana requires a manufacturer registration obtained under 21 U.S.C. 823(a), even when the researcher is growing the marihuana for his or her own research use. See 21 CFR 1301.33(d). As described in response to Issue 9, and in the section on quota that follows, international treaties require that DEA control manufacturing of marijuana and other schedule I and II controlled substances by means of quota. Although regulatory provisions allow for the approval of certain small- ***82337** scale manufacturing pursuant to a DEA-approved protocol, significant manufacturing, including for research purposes, must be performed pursuant to a quota to maintain effective controls against diversion. As a result, researchers must register with DEA as manufacturers to engage in significant manufacture of controlled substances, even if the manufactured substances will exclusively be used in the grower's own research.

In addition, the Single Convention obligates a single government agency of the United States to purchase and take possession of all marihuana manufactured, and DEA has concluded this includes marihuana manufactured for research even when manufactured for use in research by the grower. By requiring all planting, cultivating, growing, and harvesting of marihuana be performed by DEA registered manufacturers, DEA can ensure that the controls set forth in the Single Convention are properly applied to all registrations to manufacture marihuana for research.

Issue 12: Other commenters suggested that the criteria for applicants should include the applicant's ability to produce high quality marihuana while another commenter suggested that applicants should have prior experience producing quality cannabis or hemp.

Response 12: The CSA provides that two conditions must be satisfied for an applicant to become a registrant: (1) The registration must be consistent with the public interest, and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs. Congress defined the factors for DEA to evaluate whether granting a registration is consistent with the public interest in 21 U.S.C. 823(a), and the burden lies with the applicant to demonstrate that the application meets those factors. Under those factors, DEA will consider the applicant's "past experience in the manufacture of controlled substances" and its "promotion of technical advances in the art of manufacturing these substances," including the applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition. § 1318.05(b)(2). DEA must also consider the applicant's overall past experience with controlled substances in relation to preventing diversion.

Issue 13: Some commenters suggested DEA establish application requirements or committees that ensure diversity and inclusion of minority applicants. Other commenters suggested DEA provide regulatory provisions that afford economic opportunities to communities that have been disproportionately impacted by substance abuse and illicit drug markets and make application selection inclusive to include rural farmers, racial minorities, and disabled persons.

Response 13: DEA gives all applicants equal treatment regardless of the gender, race, socioeconomic status, or disabled status of the applicant. The only criteria used to evaluate the application for registration are those factors defined by Congress at 21 U.S.C. 823(a). See 21 CFR 1318.05.

Issue 14: Another commenter inquired whether manufacturers would be permitted to develop contracts, partnerships, or cooperative agreements with international research and development firms.

Response 14: Registrants are permitted to import and export controlled substances, including marihuana, in accordance with the criteria defined at 21 U.S.C. 952(a) (import) and 21 U.S.C. 953(a) (export), and after obtaining registration in accordance with 21 U.S.C. 958. After obtaining a registration to manufacture marihuana, the applicant may form agreements with international firms, but, if the importation or exportation of marihuana or another controlled substance will be involved as part of the agreement, it must ensure that any such importation or exportation complies with 21 U.S.C. 952, 953, and 958, and the relevant

implementing regulations. Moreover, in addition to these general regulatory requirements, § 1318.04(b) of this rule specifically requires prior written notice to DEA of each proposed importation or exportation of marihuana, and DEA's express written authorization for the importation or exportation.

Quality of Marihuana

DEA received a number of comments that expressed concerns about the quality of marihuana that will be produced under this rule.

Issue 1: Some commenters stated that the current quality of marihuana produced for Federal research is of poor quality.

Response 1: The purpose of this rule is to increase the number and variety of marihuana growers in order to diversify the supply available to researchers. As proposed in the NPRM and finalized in this rule, one of the selection criteria for marijuana grower applicants is the "applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition." 21 CFR 1318.05(b)(2).

Issue 2: A few commenters suggested that samples of marihuana should be tested to determine the quality prior to sales transactions and that manufacturers should be allowed to send samples of crops before and after harvest to analytical labs for testing, prior to DEA taking possession.

Response 2: DEA has no objection to DEA-registered marihuana growers and buyers exchanging samples or sending such samples to analytical labs for testing so long as this exchange occurs in a manner consistent with the CSA, and is amending the rule to make this clear. DEA understands that it is necessary for registered growers to engage in sampling and testing prior to harvest or DEA taking possession of the crop for growers to demonstrate compliance with contractual specifications to their researcher customers. Prior to the agency taking possession of the marihuana harvest, a registered grower may collect samples and distribute those samples to a DEA-registered analytical laboratory for analysis. It is consistent with the Single Convention to permit growers to conduct sampling and exclude the samples from the total crop that DEA is required to purchase and possess because the Single Convention plainly contemplates that growers will be able to harvest and sell their marijuana crops, and without sampling, sales would be practically impossible because the final intended purchaser could not know whether the marijuana is acceptable for purchase.

DEA is thus modifying the regulations proposed in the NPRM to add a new section at 21 CFR 1318.04(d). This new section explicitly permits DEA-registered manufacturers of marihuana to collect samples and distribute them to DEA-registered analytical laboratories for chemical analysis prior to DEA taking possession of the marihuana grown. However, to limit the risk of diversion and keep the distribution within the legitimate purposes permitted by the CSA, the quantity of samples collected and distributed must be small.

Issue 3: Some commenters stated that the time it takes DEA to take possession of the marihuana could negatively impact the quality of marihuana.

Response 3: To minimize the risk of diversion and delays that may impact the quality of the crop, DEA intends to take physical possession of the crop after harvest and distribute marihuana to the purchaser as soon as practicable.

Issue 4: Many commenters expressed concerns that DEA is excluded from liability for any damage to crops that may occur while in DEA's possession, and that there are no regulations to ensure the quality of marihuana while ***82338** in DEA's possession. Other commenters stated that there is no process or remedy for the damage or loss of crops that could occur while in DEA's possession.

Response 4: DEA assesses the risk of marihuana crops being lost or damaged while in DEA's possession to be low. DEA does not anticipate retaining possession of marihuana crops for long periods of time; in most instances, they will be transferred quickly

from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. In addition, crops in DEA's possession are largely expected to be maintained at the manufacturer's registered location, in a secure location designated by DEA. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. To avoid costly and unnecessary disputes related to any loss or damage of crops, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this rule makes clear that buyers and sellers should structure their marihuana transactions to minimize the risk of damage or disputes over quality, rather than expecting DEA to mediate or bear the costs of such disputes.

DEA recognizes that some growers and buyers may wish the DEA to assume a greater role in assuring the quality of marihuana supplied to researchers. Doing so, however, could significantly increase DEA's costs for operating the marihuana grower program, which would then be transferred to growers and buyers in the form of increased administrative fees. Thus, given the relatively low risk that crops will be lost or damaged in DEA's possession, DEA has concluded that the program will provide marihuana to researchers most efficiently if DEA does not assume any role in quality assurance and accordingly does not assume liability for such risks.

Issue 5: One commenter inquired how DEA will ensure availability of different strains of marihuana for research.

Response 5: DEA does not have the authority to dictate the strains of marihuana to be produced by growers. Rather, DEA believes that market forces will drive the strains of marihuana materials that growers will produce, and the purchasers will be able to choose which DEA-registered grower they believe will best produce the strains or quality of marihuana that will meet their needs. The factors that the Administrator will consider in granting a registration to grow marihuana will be consistent with the public interest factors set forth in section 21 U.S.C. 823(a), including the applicant's ability to consistently produce and supply high quality marihuana and defined chemical composition and other criteria as specified in 21 CFR 1318.05.

Issue 6: Some commenters suggested that DEA-registered researchers be allowed to obtain marihuana and marihuana products from State-authorized sources for the purpose of Federal research.

Response 6: The CSA requires anyone seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). State licenses to manufacture marijuana do not satisfy the requirements of Federal law. See id.; 21 U.S.C. 841(a)(1). Therefore, possession of a license to manufacture marijuana issued by a State government or agency does not meet the requirements of the CSA and cannot be accepted in lieu of DEA registration to manufacture or distribute. Registrants, including researchers, are only authorized to possess, manufacture, distribute, or dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions" of the CSA. 21 U.S.C. 822(b).

DEA does not view the receipt of a schedule I substance from a non-registrant, distributed in violation of § 841(a), to be "in conformity with the other provisions" of CSA as required of registrants by § 822(b). The receipt of controlled substances from outside the CSA's closed system of distribution is incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. In addition, as discussed above, the CSA—including a provision that requires consistency with the Single Convention—requires DEA to, among other things, register marihuana growers and take possession of all marihuana crops. Thus, authorizing researchers to obtain marihuana from unregistered sources is inconsistent with the Single Convention, and with DEA's CSA enforcement duties. Authorizing such research using marihuana from unregistered sources may also be inconsistent with the requirements of other Federal laws, as well as DEA's broader obligation to authorize controlled substances research in a manner consistent with the public safety.

Moreover, such a change is unnecessary. By registering additional marihuana growers pursuant to this rule, DEA will expand researchers' access to marihuana in accordance with the CSA, and in a manner that supports the public health.

Issue 7: Some commenters suggested that growers should be allowed to perform marihuana-related activities that are State-sanctioned but violate Federal law, such as distributing marihuana to recreational users, in the same facilities as DEA-authorized marihuana-related activities to save costs.

Response 7: As previously explained, DEA cannot authorize marihuana growers to violate the CSA or other Federal laws. Endorsing the production of marihuana outside the CSA's closed system of distribution would be incompatible with the framework of the CSA, which is predicated on registration, recordkeeping, and other measures of accountability throughout the distribution chain. Authorizing such activities would also be inconsistent with the Single Convention, and with DEA's CSA enforcement duties, as well as contrary to other Federal laws.

Federal Agency Obligations Pertaining to Cannabis Controls

DEA received several comments regarding the division of authority between agencies in regulating the growing of marijuana for scientific research.

Issue 1: DEA received comments asserting that scientific or public health-based agencies such as the Department of Health and Human Services (HHS), National Institutes of Health (NIH), FDA, or Department of Agriculture should oversee the marihuana grower program. Some of these commenters also suggested that the CSA be amended by Congress to allow a health-related agency to be in charge of this program. Similarly, a commenter suggested that DEA contract with a private third party and authorize that contractor to carry out the functions described in this rule.

Response 1: DEA agrees that HHS and other Federal agencies can offer valuable insights into how the Federal government can best oversee the provision of marihuana for legitimate scientific research. DEA is committed to collaborating with HHS and other Federal agencies to ensure marihuana is available to meet the research and scientific needs of the United States, and that this rule is implemented with minimal disruption of the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP). That said, as a matter of current law, any registration and coordination of legitimate marihuana growing in the United States will be overseen solely by DEA, not ***82339** other Federal agencies. In other words, even if DEA preferred other Federal agencies to carry out these functions, as DOJ has interpreted the CSA, including a provision requiring that registrations be consistent with U.S. obligations under the Single Convention, it would be unlawful for DEA to transfer these functions to another Federal agency. Commenters' suggestions that the law should be changed are beyond the scope of this rulemaking: This rulemaking must follow the law, as enacted by Congress.[FN9]

As discussed above and in the NPRM, under the CSA, DEA may only grant a person a registration to grow marihuana if: (1) The registration is consistent with the public interest, and (2) the registration is consistent with U.S. obligations under the Single Convention. See 21 U.S.C. 823(a). Accordingly, DEA may only grant marihuana grower registrations which are consistent with U.S. obligations under the Single Convention. Article 23(2) of the Single Convention, which is applicable to the cultivation of marihuana through Article 28, describes five functions related to the distribution, supervision, and licensing of marihuana cultivation [FN10] that the United States is obligated to fulfill as part of a regulatory scheme that authorizes the growing of marihuana.

The Single Convention requires that these five functions “be discharged by a single government agency if the constitution of the Party concerned permits it.” Single Convention art. 23(3).[FN11] Nothing in the U.S. Constitution precludes the United States from discharging all five of those controls through one government agency, so a single U.S. Federal agency must perform all five of the controls. Further, by requiring that the functions be discharged by a government agency, the Single Convention prohibits the United States from assigning them to a private government contractor.

Through the CSA, Congress assigned the first three of the Single Convention functions to DEA by authorizing DEA—and, at least at the Federal level, DEA alone—to register and regulate marihuana growers: Under the CSA, DEA effectively designates the area in which the marihuana cultivation is permitted, limits marihuana growers to those it licenses, and specifies the extent of the land on which marihuana cultivation is permitted as required by the Single Convention. Thus, to fully comply with the CSA

provision requiring consistency with the Single Convention, DEA also must perform the remaining two functions of Article 23: Taking possession of marihuana crops after harvest and maintaining the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana and its resin. Congress granted DEA the power to enforce these provisions by directing DEA to grant registrations if the registrations are consistent with U.S. obligations under the Single Convention. 21 U.S.C. 823(a).[FN12]

Therefore, Congress has assigned DEA the duty and authority to carry out the five functions the Federal government is required to perform under the Single Convention if it authorizes the production of marihuana. DEA has no authority to assign these functions to another agency or a private contractor outside the government. Rather, DEA must perform the functions itself, and this rule will enable DEA to do so more effectively.

Issue 2: Another commenter suggested that NIDA be completely removed from any role in supplying marihuana to researchers.

Response 2: Marihuana research can be enhanced by allowing other growers to supply marihuana to researchers. However, scientific and medical research is likely to benefit from the NIDA DSP's continued involvement in these efforts. As discussed in the NPRM and further discussed below, the NIDA DSP has long played a fundamental role in supplying marihuana to researchers. In doing so, the NIDA DSP has acquired valuable experience and expertise in the production of marihuana. Moreover, because researchers currently obtain their marihuana though the NIDA DSP, the continued operation of the NIDA DSP will allow researchers who wish to continue to receive such NIDA DSP marihuana to do so with minimal disruption. Ultimately, the purpose of this rule is to expand researchers' options for obtaining marihuana, not eliminate them, a result best achieved by allowing the NIDA DSP to continue to operate, while also registering additional marihuana growers.

Issue 3: Some commenters suggested that DEA and DOJ misinterpreted the Single Convention. Some commenters stated that DEA is inappropriately using the Single Convention requirements as a justification to maintain exclusive control over marihuana sales/purchases. Another commenter suggested that DEA's view of the Single Convention is too narrow and not aligned with other parties to the Single Convention with respect to Article 23. This same commenter suggested that the United States withdraw from the Single Convention and rejoin with a formal reservation opting out of the cannabis related provisions of the Single Convention. Some other commenters suggested DEA initiate the process to amend the treaty to accomplish its intent of allowing robust research to be performed.

Response 3: As a matter of law, the CSA requires that registrations to manufacture schedule I and II controlled substances be consistent with U.S. obligations under the Single Convention, which requires a single government agency to regulate the cultivation of and certain trading in marihuana, including taking possession of marihuana after harvest.[FN13] The CSA assigns this function to the Attorney General, who has delegated this statutory authority to the DEA Administrator. The CSA therefore requires DEA to grant registrations that are consistent with U.S. obligations under the Single Convention, which includes regulating the cultivation of and certain trading in marihuana. DEA acknowledges some may disagree with these legal conclusions, but DEA is bound by the law as DOJ and DEA understand it. Whether the Single Convention's or the CSA's controls of marihuana should be amended and whether the United States should withdraw from the Single Convention ***82340** are beyond the scope of this rulemaking and DEA's authority. This rulemaking must be consistent with DEA's obligations under the CSA, including granting registrations which are consistent with the Single Convention as it currently stands.

Issue 4: Some commenters believe that DEA's increased involvement in the provision of marihuana to researchers would have an adverse impact on clinical research, clinical trials, and the creation of cannabis preparations.

Response 4: As explained elsewhere in this rulemaking, DEA anticipates this rule will increase researchers' access to marihuana for medical and scientific research. At present, researchers must obtain marihuana for researchers through the NIDA DSP, and researchers who wish can continue to do so with minimal disruption. However, this rule will also allow researchers to legally obtain marihuana from other DEA-registered growers. DEA's involvement in that process will be limited, as set forth in these regulations, to those activities required by the CSA.

Issue 5: Another commenter suggested that DEA allow researchers to possess marihuana without restriction and that DEA's role in regulating the growing of marihuana be completely eliminated.

Response 5: As explained above, the CSA requires any person seeking to manufacture or distribute controlled substances to apply for and obtain a DEA registration. 21 U.S.C. 822(a)(1). More broadly, marihuana remains a schedule I controlled substance, and as such has a high potential for abuse and no currently accepted medical use in treatment in the United States. See, e.g., Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 FR 53687 (Aug. 12, 2016). Allowing the cultivation of marihuana for research without a DEA registration or otherwise regulating this activity would be incompatible with the CSA and its requirement of consistency with the Single Convention; it would also fail to protect public health and safety from the danger of that marihuana being diverted and abused.

Issue 6: One commenter suggested that the NPRM is incompatible with the Administrative Procedure Act (APA) on the grounds that DEA did not sufficiently explain the reasoning underlying the proposed rule.

Response 6: The NPRM satisfied the requirements of the APA, as does this final rule. The NRPM and this rule both set out the legal and practical reasons why DEA is promulgating this rule to increase the availability of marihuana for research consistent with the legal requirements of the CSA, as well as with DEA's duty to protect the public interest by preventing its diversion and abuse.

Issue 7: Two commenters requested that DEA extend the comment period given the current coronavirus disease 2019 public health emergency.

Response 7: DEA recognizes the challenges applicants and registrants may be facing during the public health emergency. However, DEA has decided not to extend the comment period beyond the 60 days generally required under Executive Order 12866 to avoid any further delays in registering additional marihuana growers. DEA, therefore, decided that extending the comment period would have unnecessarily delayed the registering of additional marihuana growers without meaningfully enhancing the rulemaking process.

The Meaning of "Medicinal Cannabis"

Issue 1: Some commenters expressed concern about the definition of medicinal cannabis. Specifically, they argued that "medicinal cannabis" should include any cannabis that State law authorized for use as "medical marijuana." One commenter requested DEA amend the definition of medicinal cannabis to include investigational marihuana for an investigational new drug.

Response 1: Under this rule, DEA will have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. [FN14] The term "medicinal cannabis" in this rule is limited to "a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act," and DEA continues to believe this is the most appropriate definition for the term.

Through this rule, DEA is asserting an exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana so as to ensure compliance with the CSA, including a provision requiring registrations to be consistent with the Single Convention. The exclusion of medicinal cannabis from this function is based on Single Convention Article 23's exclusion of medicinal opium from parties' obligation to maintain an exclusive right over opium trading (as applied to cannabis through Article 28). The Single Convention does not define medicinal cannabis, but its definition of "medicinal opium" is limited to opium that "has undergone the processes necessary to adapt it for medicinal use." Single Convention art. 1(o).

Thus, DEA understands "medicinal cannabis" to mean drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured in this rule by requiring that the product be able to be legally

marketed under the Food Drug and Cosmetic (FD&C Act). The United States, not State governments, is the relevant party to the Single Convention, and thus "medicinal cannabis" should only include cannabis-derived products that the United States has approved for medical use, not products States may have approved.

For similar reasons, this definition excludes an investigational new drug containing cannabis; such products may eventually become approved for full medical use in the United States (as opposed to research), but have not yet obtained such approval. The finished dosage form of such a substance may qualify as a "cannabis preparation," which is outside of DEA's exclusive right to engage in the wholesale trade in cannabis, but remains subject to control under the CSA. It should be emphasized, however, that the bulk material from which any cannabis preparation is manufactured must be obtained from DEA.

Security Costs and Requirements Applicable to the Manufacture of Marihuana

Issue 1: Some commenters inquired about the packaging requirements necessary prior to the transport of purchased marihuana and once that marihuana is sent from a grower to a seller. Many commenters suggested DEA use tracking technology, similar to that used by some States, to monitor the movement of marihuana seeds, marihuana plants, and other marihuana products. Some commenters suggested that the use of such tracking technology would eliminate the need for the security measures proposed in the NPRM and required by DEA regulations more generally.

Response 1: DEA registrants are required to maintain effective controls against diversion. DEA registered manufacturers are responsible for providing proper security during the growing process. The crops must either be delivered and stored in a secure storage mechanism at the manufacturer's registered location, if one is designated by DEA, or delivered ***82341** to a location designated by DEA. In either case, the registrant must comply with security requirements specified in 21 CFR part 1301. A DEA registrant is also required to adhere to the recordkeeping and reporting requirements set forth in 21 U.S.C. 827 and 21 CFR part 1304, including the requirement to maintain records of all controlled substances which it manufactures, sells, and delivers. Although this regulation does not specify any special measures imposed on a grower for the packaging of a marihuana crop for purchase by DEA, DEA may develop packaging requirements as part of separate agreements between DEA and individual manufacturers; [FN15] but in all cases, DEA's general security regulations shall apply.

With regard to tracking technology, DEA recognizes that security technology is always evolving, and that in some circumstances tracking technology may present a useful means of protecting against diversion. In addition to security measures specifically required by DEA regulations, registrants should take the appropriate measures to guard against diversion of their crops, which may include the use of new technologies. At this time, however, DEA has concluded that it is not necessary to update its security regulations in this regard, and has not yet seen evidence that tracking technology can adequately replace security measures required by current regulations.

Issue 2: Other commenters suggested that the procedures for inspection of crops and harvests, and physical security requirements are expensive and would discourage applicants.

Response 2: As noted, DEA requires all applicants and registrants to maintain effective controls against the diversion of controlled substances as set forth in 21 CFR part 1301. The proposed rule and this final rule do not impose new or amended regulations for the security requirements set forth in 21 CFR part 1301. Furthermore, DEA registrants are subject to routine scheduled investigations conducted by DEA diversion investigators and other administrative requirements such as those specified in 21 CFR part 1304. DEA understands there will be costs incurred in meeting these administrative requirements; however, these requirements and costs are comparable to those applicable to bulk manufacturers of other controlled substances. Requiring such security controls is a critical part of DEA's efforts to fulfill its duties under the CSA to reduce the diversion and abuse of controlled substances, including marihuana.

Harvest

Issue: One commenter suggested that DEA expand the amount of time to deliver a harvest to DEA. This commenter also suggested DEA change the time period for providing notice of a harvest to five days, instead of 15 days beforehand, and suggested that the amount of harvests per year should be changed from three to five. Other commenters suggested manufacturers provide DEA with notice more than 15 days prior to harvest. Another commenter agreed that DEA should take possession of the crop no later than four months after harvest to maintain chemical composition of the crop.

Response: DEA understands the importance of taking possession of harvested crops in a timely manner to expedite the re-distribution of those crops to researchers and to reduce any potential for changes in the crops' chemical composition. As stated in the NPRM, and to comply with a CSA provision requiring consistency with the Single Convention, DEA must take physical possession of the crops within four months after the end of harvest. The requirement that a grower notify DEA at least 15 days prior to the commencement of a harvest is intended to provide DEA with sufficient time to make the necessary arrangements for traveling to the grower's registered location and to take possession of the crops. DEA has concluded that a five-day notice period will not provide sufficient time to make the arrangements needed to travel to a grower and attend a harvest.

With respect to this commenter's statement that DEA should change the number of harvests per year from three to five, DEA is not regulating the number of growing cycles that a registered grower may conduct. A grower may conduct as many growing cycles as is necessary to meet customer demand, so long as it does not exceed its IMQ for the year. The NPRM used three harvests per year as the estimated average number of harvests only for the purpose of conducting its regulatory analysis.

Quotas

Issue 1: A commenter stated there is a significant lag time from when quota is issued to harvest time. This same commenter inquired as to whether the cultivation of marihuana can begin prior to the issuance of quota. Another commenter suggested that DEA provide a deadline by which DEA must review or approve bona fide supply agreements and make quota determinations based upon them. A commenter also suggested that each manufacturer should be issued IMQ. One commenter suggested that DEA issue a multi-year license for new bulk manufacturers to meet quota needs.

Response 1: Pursuant to 21 U.S.C. 826, DEA is required to "determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States [and] for lawful export requirements." This figure, which is known as the aggregate production quota (APQ), is then allocated to individual registered manufacturers based on each manufacturer's application for an IMQ as set forth in 21 U.S.C. 826(c). Pursuant to section 826(c), DEA is required to issue IMQ "[o]n or before December 1 of each year" for the following year.

While there may be significant lead time between the date on which an IMQ is issued and the date of harvest, a grower's lead time is dependent upon the growing techniques it uses. It should also be noted that non-botanical manufacturers of controlled substances frequently deal with significant lead times and have been able to manage them. In any event, Federal law prohibits the manufacturing of a controlled substance by a registrant which "is not expressly authorized . . . by a quota assigned to him pursuant to" 21 U.S.C. 826. 21 U.S.C. 842(b).

Thus, a registered manufacturer cannot commence growing marihuana until it has been granted its IMQ. Furthermore, because the CSA expressly requires that both the APQ and an IMQ be determined on a calendar year basis; DEA is not authorized to issue an IMQ other than on a single year basis.

As stated above, the CSA requires that DEA issue IMQ "[o]n or before December 1 of each year" for the following year. Thus, the CSA already sets the deadline by which DEA must review a bona fide supply agreement and make a quota determination. Each registered manufacturer of marijuana who produces evidence that it has entered into a bona fide supply agreement with a researcher will be issued an IMQ. In the event a registered manufacturer enters into additional bona fide supply agreements after receiving its IMQ, which would result in an increase in its estimated net disposal for the calendar year, it may apply for an increase in its IMQ for that calendar year. 21 CFR 1303.25.

***82342** Issue 2: A commenter suggested that the price and quantity of extracts is not based on dried flower weight and that different strains of marihuana will yield different extract weights from the same weight of marihuana. Thus, this commenter argued, DEA should set marihuana quotas based on the amount of marihuana extract produced from a harvested marihuana crop, not the weight of the harvested marihuana itself.

Response 2: Under the CSA, IMQ limits the quantity of controlled substances a manufacturer may produce. See, e.g., 21 U.S.C. 826(c). Marihuana itself, not just its extract, is a schedule I controlled substance. Accordingly, when a marihuana grower cultivates a marihuana crop, that grower has produced a schedule I controlled substance. Thus, under the CSA, marihuana growers require an IMQ for the entire marihuana crop, regardless of the value or quantities of other controlled substances produced from that crop. Setting marihuana quota based solely on the amount of extract eventually produced would also inhibit quota enforcement, as DEA may not be able to determine if a marihuana grower was complying with its IMQ until the grower processed the marihuana into an extract. Finally, not all marihuana grown will necessarily be used to produce extracts—some marihuana research makes use of the plant material itself. Thus, not all marihuana production quotas could be tied to the quantity of extract produced from it, because not all marihuana grown for research is converted into an extract.

Costs, Pricing, and Fees of Marihuana for DEA Registrants

Issue 1: A commenter inquired how the purchase price is established when DEA purchases cannabis from a registrant that the registrant intends to use for his/her own research.

Response 1: This scenario was addressed in the NPRM by proposed 21 CFR 1318.06(b)(4), which this rule promulgates without change. Normally, under the rule, the seller and buyer may negotiate their own purchase price, to which DEA will add its administrative fee. When a registrant grows marihuana for its own use, the purchase price is irrelevant, given that the grower is effectively negotiating the price with itself. Thus, the rule will allow the grower to set any "nominal price" it chooses, given that the grower will purchase the marihuana back from DEA at the same price at which it is sold to DEA. In this scenario, the only net cost of the transaction is the per-kilogram administrative fee that grower must pay to DEA.

Issue 2: Several commenters suggested the purchase price of cannabis should be the registrant's average purchase price of the last six months or the average U.S. price for high grade commercial cannabis, plus 20 percent due to its research grade. Another commenter suggested a cap on the wholesale value of cannabis.

Response 2: DEA recognizes that supply and demand for the cultivation of marihuana for research and other licit purposes may fluctuate based on the lawful needs of the U.S. market. As such, DEA believes that allowing the buyer and seller to negotiate the purchase price of the marihuana provides more flexibility in determining appropriate prices driven by market forces. Attempting to set a universal price—or schedule of prices—for cannabis, or limiting a registrants' ability to change its prices in response to new circumstances, would unduly restrict the varieties of marihuana grown and may unduly limit growers' ability to produce marihuana to satisfy new research needs. Similarly, setting a price cap may prevent growers from meeting researchers' need for cannabis that is unusually expensive given its strain or the conditions in which it must be grown.

Issue 3: A commenter inquired whether the administrative fees are paid by the purchasing researchers or the selling growers.

Response 3: Under the rule, the administrative fee is considered part of the price of the cannabis DEA sells to the purchasing researcher. That said, the rule requires the "parties" to pay the fee to DEA upon entering into a contract for the provision of cannabis, but before the cannabis is actually delivered to the researcher. In other words, DEA is not charging the administrative fee to either party in particular, but to the parties jointly as part of the transaction. The parties are free to apportion the fee among themselves in any way they choose.

Issue 4: Some commenters suggested that the administrative fee be waived for DEA-registered manufacturers who cultivate and research their own marihuana, and do not sell their marihuana. Similarly, some commenters suggested that the administrative fee would discourage research and thus suggested that the administrative fee be waived for researchers in general.

Response 4: As explained in the NPRM, the purpose of the administrative fee is to allow DEA to recover the operational costs of administering the program, as required under 21 U.S.C. 886a(1)(C). Because DEA anticipates the vast majority of marihuana will be sold to researchers, a waiver of the administrative fee in transactions involving researchers would not allow DEA to properly recover its costs of administering the marihuana growers program under 21 U.S.C. 886a(1)(C).

DEA nonetheless continues to encourage lawful cultivation of marihuana for research and other licit purposes through the administration of this program. As discussed in the NPRM and below, DEA does not expect this administrative fee to be a barrier to research. Nothing in this rule prohibits NIH—or any other third-party funder of research grants—from funding marihuana research by covering the cost of marihuana materials used in research, including these administrative fees, via grants to researchers.

DEA also cannot waive the administrative fee for researchers growing marihuana for their own use because that too would prevent DEA from recovering its operational costs. The provisions of this rule—and the CSA and DEA regulations more broadly—apply not only when a grower is selling to a third party, but also when a grower is producing marihuana for its own use. DEA must still register the grower, and purchase and take possession of the marihuana, even if the marihuana is being used for the grower's own research. Thus, DEA does not anticipate its operational costs to be significantly less when it is regulating a grower's cultivation of marihuana for its own research or for another party's use. Accordingly, DEA will charge the same fees in both situations.

Issue 5: One commenter requested that DEA clarify administrative fees.

Response 5: The nature and purpose of the administrative fee, as well as how it is set, are explained both in the rule itself and throughout the NPRM. In sum, an administrative fee for each transaction will be added to the sales price of the marihuana. The administrative fee is a variable fee based on the quantities, in kilogram (not quality, grade, potency, etc.) of bulk marihuana distributed. The parties to the transaction will pay DEA the administrative fee upon entering into a contract for the provision of the marihuana and prior to the delivery of the marihuana. DEA will set the administrative fee rate at least annually at a level adequate to allow DEA to recover the costs of administrating the marihuana growers program under 21 U.S.C. 886a(1)(C).

Issue 6: One commenter suggested that DEA waive the administrative fee ***82343** for any crops that are damaged or lost while in DEA's possession.

Response 6: Such a fee waiver is unnecessary and inconsistent with DEA's obligations under the CSA and this rule. As explained elsewhere, DEA generally does not anticipate retaining possession of crops for significant periods of time; in most instances, they should be transferred quickly to the buyer. Accordingly, crops are unlikely to be damaged or lost in DEA's possession. Moreover, as explained above, the administrative fee must be set at a rate that allows DEA to recover the costs of operating the marihuana growers program under 21 U.S.C. 886a(1)(C). Every marihuana transaction under this rule will impose costs on DEA. Thus, if DEA waived fees for some marihuana buyers and sellers, it would have to increase fees on other buyers and sellers to compensate for the amounts lost due to the waiver. DEA has concluded that it is most equitable to base the administrative fee on the weight of marihuana produced, and not other factors.

Out of Scope

Issue: DEA received comments that are outside the scope of this final rule. Some comments raised general concerns regarding the treatment of marihuana under Federal law. Others raised specific issues regarding, among other things, medical illnesses, medical treatments, the scheduled class of marihuana, marihuana-related activities permitted and prohibited in specific States, and the status of previous congressional inquiries.

DEA Response: DEA acknowledges receipt of these comments; however, such comments are outside the scope of the NPRM and the final rule. These comments ultimately have no bearing on the rule under consideration, or on the regulatory decisions DEA is making as part of this rulemaking.

Section-by-Section Summary of the Final Rule

The purposes and functions of this rule were discussed in the NPRM. Aside from a minor amendment to 21 CFR 1318.04, this rule adopts the proposed rule without change. DEA's reasoning was fully explained in the NPRM. However, in addition to describing the amendment—in particular, the added section at § 1318.04(d)—DEA will summarize this rule's various changes to DEA regulations and the reasoning behind these changes for the sake of clarity and convenience.

§ 1301.33: Applying the Marihuana Grower Regulations to All Marihuana Growers

This rule makes two technical changes to 21 CFR 1301.33 to account for the addition of part 1318, which in turn provides regulations specific to the growing of marihuana in accordance with the CSA.

As discussed above, part 1301 of DEA's regulations governs the registration of manufacturers, distributors, and dispensers of controlled substances. It also includes various sections governing how entities are to apply to become registered with DEA. See, e.g., 21 CFR 1301.13-17. These sections include § 1301.33, which contains certain provisions unique to applications to become registered to manufacture schedule I and II substances in bulk. For example, § 1301.33(a) requires that DEA publish a notice of application after receiving a schedule I and II bulk manufacturer application. Previously, § 1301.33(c) provided that the other provisions of § 1301.33 do not apply when the manufacturing at issue is "as an incident to research or chemical analysis as authorized in § 1301.13(e)(1)," i.e., when the bulk manufacture is a coincident activity of a DEA-registered researcher or chemical analyst.

This rule amends § 1301.33(c) to modify this exception in the case of marihuana growing. Specifically, under this rule, § 1301.33(c)'s exclusion applies to manufacturing as an incident to research and chemical analysis, except as provided in the newly added § 1301.33(d). And the new § 1301.33(d) provides that an application to manufacture marihuana "that involves the planting, cultivating, growing, or harvesting of marihuana" (as opposed to, for example, marihuana manufacturing that merely involves processing marihuana grown by another party into a new marihuana product) shall be subject both to the general requirements of § 1301.33 as well to the newly added requirements of part 1318.

This change serves two purposes. First, by cross-referencing part 1318 in part 1301, this change ensures that marihuana grower applicants reviewing the general registration and application requirements in part 1301 are made aware of the regulations specific to marihuana growers in part 1318. Second, the Single Convention does not distinguish marihuana grown by a researcher or chemical analyst from that grown by other manufacturers; under the Single Convention, a government agency is required to purchase and take possession of that marihuana and then oversee its distribution. Thus, both to ensure that DEA complies with the CSA, including a provision requiring consistency with obligations under international treaties such as the Single Convention, and to ensure that these applications are treated as equitably as possible, DEA is amending its regulations to ensure that all marihuana growers are subject to the requirements of both § 1301.33 and part 1318.

§ 1318.01: The Scope of the New Marihuana Grower Regulations

New 21 CFR part 1318 adds a series of new provisions to ensure that DEA can register additional marihuana growers in a way consistent with its obligations under the CSA, including a provision requiring consistency with the Single Convention. New § 1318.01 clarifies the scope of these new provisions, stating that they govern "the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana."

Among other things, this serves to make clear that part 1318 only applies to those manufacturers involved in activities related to the cultivation of marihuana, not all forms of marihuana manufacturing. The CSA defines "manufacturing" broadly as "the production, preparation, propagation, compounding, or processing of a drug or other substance," including extraction from plant products and certain forms of packaging. 21 U.S.C. 802(15). Thus, under the CSA, entities involved in a variety of marihuana-related activities, not just marihuana growers, are required to register with DEA as marihuana manufacturers.

Section 1318.01 emphasizes that part 1318 does not apply to all marihuana manufactures, but only to those involved in the planting, growing, cultivating, or harvesting of marihuana.[FN16] Part 1318 limits itself to marihuana growers, rather than all manufacturers, given the unique obligations the Single Convention places on the United States with regard to the growing of marihuana and the unique diversion risks growing presents.

§ 1318.02: Definitions

Part 1318 contains a number of terms that are not used elsewhere in DEA regulations or have a unique meaning when used in the context of part 1318. Thus, to avoid any ambiguity about the meaning of those terms and the regulations in which they are used, ***82344** § 1318.02 specifically defines those terms for the purposes of part 1318.

Most of the definitions in § 1318.02 are self-explanatory. For example, "cannabis" means any plant of the genus Cannabis (unless otherwise excepted, as discussed below), and "cannabis resin" (with one exception discussed below) means the separated resin, whether crude or purified, obtained from the cannabis plant. Similarly, the definition of "Single Convention" includes a citation to eliminate any possible confusion about the Single Convention at issue, and the definition of "bona fide purchase agreement" specifies the broad type of agreements DEA is seeking to encompass by this term.

Several provisions of § 1318.02, however, warrant further discussion. First, as discussed in the NPRM and above, the Single Convention exempts "medicinal cannabis" and "cannabis preparations" from certain of its requirements. Following suit, part 1318 likewise exempts these substances from certain of its provisions, and, to facilitate this exemption, § 1318.02 defines "medicinal cannabis" and "cannabis preparations." Under § 1318.02, "medicinal cannabis" means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the FD&C Act. "Cannabis preparation" means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis or cannabis resin. These definitions track those of the Single Convention, as adapted to account for Federal law.[FN17]

Finally, § 1301.02(e) clarifies that, when used in part 1318, none of these cannabis-related terms—cannabis, cannabis preparation, cannabis resin, or medicinal cannabis—include substances that fall outside the CSA's definition of marihuana. Among other things, § 1301.02(e) is intended to reflect the CSA amendments made by the Agriculture Improvement Act of 2018 (AIA), Public Law 115-334. The AIA amended the definition of marihuana to exclude "hemp," defined as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. 1639*o*(1). Thus, under the AIA, anything that meets this definition of hemp is no longer a controlled substance, and the CSA's requirements no longer apply to it. This rule is designed to regulate marihuana growers, not hemp growers; and thus § 1301.02(e) ensures that part 1318 does not apply to the cultivation of substances do not meet the definition of marihuana under the CSA, such as hemp.

§ 1318.03: Implementation of the CSA's Requirements

This section reiterates the requirements of certain other provisions of the CSA and DEA regulations, both to make clear that these requirements apply to marihuana grower applications and as background for other provisions of part 1318. Specifically, § 1318.03(a) reiterates the requirement of 21 U.S.C. 823(a) that the DEA Administrator may only grant an application to cultivate marihuana if he determines that such registration is both consistent with the public interest and with U.S. obligations under the Single Convention. Section 1318.03(b) states that, in accordance with both 21 U.S.C. 823(a) and 21 CFR 1301.44, the applicant has the burden of demonstrating that these requirements are satisfied.

§ 1318.04: Specific Control Measures Applicable to the Cultivation of Marihuana

This section adds a series of control measures designed to ensure that, once DEA registers additional marihuana growers, their marihuana cultivation occurs in accordance with the CSA, including the provision that requires registrations be granted consistent with the Single Convention. In particular, this section adds regulations that will ensure that DEA is able to purchase and take possession of marihuana crops within four months of harvest, and also that DEA has the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana (other than medicinal cannabis or cannabis preparations)—both functions that the Single Convention expressly requires a single agency of the Federal government to perform. This section also contains provisions describing how DEA will perform these functions, provisions that are designed both to guide DEA's performance of these duties (and growers' expectations) as well as to ensure that these functions are performed in a way that protects against diversion of marihuana without placing an undue burden on growers. These provisions—and how they apply to particular scenarios—are discussed in greater depth both above and in the NPRM.

Finally, this section adds a provision that explicitly provides an allowance for registered bulk manufacturers of marihuana to distribute samples to registered analytical laboratories. Because these samples are small, distributed to the laboratory solely for the purpose of analysis, and consumed in the course of the analysis or destroyed upon completion of the testing, DEA has determined that DEA is not required to take possession of these samples to satisfy U.S. obligations under the Single Convention. This allowance permits registered bulk manufacturers to monitor the cannabinoid content of their crop in order to properly time their harvest and demonstrate compliance with contract specifications to their customers.

§ 1318.05: Applying the CSA's Public Interest Factors to Marihuana Grower Applicants

As indicated above, in addition to ensuring registration is consistent with its Single Convention obligations, DEA may grant a registration to manufacture a schedule I or II controlled substance only where the Administrator determines that the registration is consistent with the public interest, based on the factors listed in 21 U.S.C. 823(a).

This section both reiterates these public interest factors and explains how DEA will evaluate whether a particular marihuana grower application is consistent with them. For example, under 21 U.S.C. 823(a)(1), DEA must weigh, as one of the registration factors, the need to maintain effective controls against diversion by limiting the number of registered bulk marihuana growers to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Section 1318.05 states that, for the purpose of assessing this factor, a bona fide supply agreement between a marihuana grower and a duly registered schedule I researcher or manufacturer provides evidence that an applicant's registration is necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. An applicant proposing to grow marihuana to supply its own research may also be deemed to have satisfied this aspect of public interest factor 823(a)(1) upon the presentation of evidence that it possesses a registration to conduct ***82345** research with marihuana under 21 CFR 1301.32.

The rule also provides that, when selecting marihuana grower registrants, the DEA Administrator will place particular emphasis on an applicant's ability to consistently produce and supply marihuana of a high quality and defined chemical composition, and whether the applicant has demonstrated prior compliance with the CSA and DEA regulations. These factors are designed to result in registration of those manufacturers of marihuana that can most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality. These factors are further aimed at selecting applicants that can be entrusted with the responsibility of a DEA registration and complying with the corresponding obligations under the CSA and DEA regulations.

Section 1318.05(c) provides that, aside from any applications governed by 21 U.S.C. 823(i), applications DEA accepts for filing after the date this rule becomes effective will not be considered pending until all applications accepted for filing on or before this effective date have been granted or denied by the Administrator. This is because, as explained above, the CSA requires DEA to consider the need to maintain effective controls against diversion by limiting the total number of registered marihuana growers to that necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. Thus, DEA must consider all pending applicants together when deciding which applications to grant. Given this requirement, DEA

is including this provision to avoid a situation in which the agency is in the midst of evaluating these applications and has to begin its evaluation anew each time it accepts a new marihuana grower application for filing.

§ 1318.06: Factors Affecting Marihuana Prices

As discussed in the NPRM and above, to ensure compliance with the CSA, including a provision requiring consistency with the Single Convention (and as specified in § 1301.04 of this rule), DEA will purchase all lawfully grown marihuana crops within four months of harvest and then sell the marihuana to DEA registrants who seek to acquire it for research, product development, or other lawful purposes under the CSA. To do so, DEA will establish purchasing and selling prices: § 1318.06 describes how DEA will do this—and more broadly explains how certain aspects of these transactions will work, as well as how DEA will fund its expenses from carrying out these duties.

As explained elsewhere in the NPRM and this rule, in purchasing such marihuana, DEA will use the Diversion Control Fee Account established in 21 U.S.C. 886a. Thus, DEA must take into account its obligation under 21 U.S.C. 886a(1)(C) to charge fees under its diversion control program "at a level that ensures the recovery of the full costs of operating the various aspects of that program." There are two potential categories of fees that could be used to recover the costs of carrying out the new aspects of the diversion control program relating to marihuana: (1) Fees charged to persons who apply for, and seek to renew, a DEA registration to manufacture marihuana, and (2) fees charged for the sale of marihuana by DEA. Under this rule, DEA intends to recover its basic operating costs primarily through the latter means, by recovering these costs through an administrative fee set based on these costs. Section 1318.06 describes how this will occur.

Under § 1318.06, DEA will allow market forces to direct prices for marihuana grown by the manufacturer and purchased by DEA, allowing the marihuana grower and ultimate purchaser to negotiate a sales price. Where the grower and the buyer are the same entity (or related entities), § 1318.06 allows the entity to set a nominal price.

In addition to that negotiated price, § 1318.06 provides that DEA will add an administrative fee (per kilogram (kg)) to the sales price of the marihuana it sells to end users. As provided in § 1318.06(a), DEA will calculate this administrative fee no less than annually by taking the preceding fiscal year's cost to operate the program and dividing it by the quantity in kg of the total of the IMQs for marihuana issued during the current quota year. Section 1318.06(c) requires DEA to make the updated administrative fee available on DEA's website.

As discussed elsewhere, DEA does not intend for this rule to interfere with HHS's funding of marihuana for use in research. Thus, to avoid any possibility of confusion, § 1318.06(d) notes that this section does not prohibit HHS from funding the purchase cost or associated administrative fees for marihuana purchased for research.

§ 1318.07: DEA's Disclaimer of Liability

As explained above, DEA generally does not anticipate retaining possession of marihuana crops for significant periods of time: In most instances, they should be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marihuana from buyer to seller. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. That said, if a buyer concludes that a crop is unacceptable, it is conceivable that a grower could claim that the damage is attributable to DEA, leading to costly and unnecessary disputes. To avoid disputes, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana. In effect, this puts buyers and sellers on notice that it is their obligation to structure their marihuana transactions in such a way as to minimize the risk of damage or disputes over quality, rather than looking to DEA to mediate or bear the costs of such disputes.

Regulatory Analyses

***Executive Orders 12866** (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)*

This rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. Section 3(f) of Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of ***82346** recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

OMB's Office of Information and Regulatory Affairs (OIRA) has determined that, although this rule is not economically significant, it is a significant regulatory action under section 3(f) of Executive Order 12866, and it therefore has been reviewed by OMB.

I. Need for the Rule

This rule is needed to ensure that DEA complies with the CSA and grants registrations that are consistent with relevant treaty provisions as DEA seeks to increase the number of registered growers of marihuana. Specifically, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. These amendments will ensure that DEA carries out all five functions under Article 23 and Article 28 of the Single Convention pertaining to marihuana, thus facilitating the planning and coordinated management of marihuana production necessary as the number of registered marihuana manufacturers increases.

II. Alternative Approaches

This rule amends DEA regulations only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana. In areas where DEA has discretion, such as in setting a fee structure to recover the cost of this rule, alternative approaches normally would be discussed. However, because DEA does not have sufficient information at this time to discuss alternatives for either the future registration fees or the fees for the sale of marihuana, the alternative approaches for such provisions are not included in this rule. Consistent with past agency practice, any changes to registration fees will be the subject of a separate rulemaking proceeding, including a discussion of alternative approaches.

III. Analysis of Benefits and Costs

There are two key benefits associated with this rule. First, DEA believes it is possible that the approval of new growers may increase the variety (quality, potency, etc.) of bulk marihuana for research, leading to more effective research and potentially resulting in the development of FDA-approved drug products. Second, this rule ensures that DEA's regulations comply with the requirements of the CSA by granting registrations that are consistent with the Single Convention relating to marihuana. DEA is unable to quantify these benefits at this time.

DEA analyzed the costs of this rule and estimates an annual cost of $651,318.[FN18] The details of the analysis are below.

This rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights do not extend to medicinal cannabis or cannabis preparations. The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies,[FN19] and purchasers (generally medical and scientific researchers). To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

Current System

To date, DEA has authorized one grower, the National Center for Natural Products Research (National Center), to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.[FN20] The National Center has designated a secure plot of land or indoor grow facility where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[FN21] NIDA obligated approximately $1.5 million in Fiscal Year 2015 under this contract.[FN22] This amount included costs unrelated to growing and cultivating marihuana, such as extracting chemical components and producing marihuana cigarettes and other marihuana-related material. However, based on recent discussion with NIDA,[FN23] DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[FN24] The $2.9 million includes compensation for the cultivating and the 2019 manufacturing quota (MQ) of 2,000 kgs for NIDA (National Center) as well as all other duties required in the contract.[FN25]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is currently available at no cost to research investigators supported by a NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a "cost-reimbursement basis," [FN26] the current policy is to provide the marihuana at no charge.[FN27]

Changes to Growers

Upon promulgation of this rule, DEA anticipates approving more than one ***82347** entity to cultivate and harvest bulk marihuana. As explained earlier in this document, the CSA imposes limitations on the number of registrations that DEA may issue to bulk manufacturers of a given schedule I or II controlled substance. In addition, in deciding whether to grant an application for any such registration, the CSA requires DEA to consider the other public interest factors of 21 U.S.C. 823(a), which must be evaluated on an applicant-by-applicant basis. Further, DEA cannot accurately predict in advance which particular applications will be granted, or how many. Accordingly, DEA is unable to accurately estimate the number of registered bulk marihuana growers. As a result, to allow for this analysis, DEA estimated the economic impact of this rule under two different hypothetical scenarios, the first in which the number of growers expands to three growers, and the second in which the number of growers expands to 15 growers. It should be understood that this range of potential registrants is not necessarily reflective of the actual number of applications that DEA will grant.

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[FN28] Since the publication of the 2016 policy statement, DEA has received approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of three to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[FN29] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and the reimbursement of production cost through sales) is transferred from the single incumbent grower to new growers. This means that there is only a transfer of economic activity rather than any new cost. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[FN30]

Transitioning from one large grower to multiple growers may introduce inefficiencies, driving up production or facility costs. Some growers may introduce more costly growing techniques to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down costs. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. In particular, one of the goals of this new rule is to enhance marijuana availability for product development, which may have the effect of increasing the MQ. However, DEA does not have a basis to estimate the impact of these possibilities. Therefore, for the purposes of this analysis, DEA estimates that an increase in the number of approved growers does not impact the MQ. In summary, there is no new cost to growers.

Changes to Authorizing Agencies—Cost to DEA

DEA anticipates that there will be a transfer of economic activity from NIDA to DEA as well as several new costs as a result of this rule. This analysis should not be construed as a proposal to modify agency funding or funding sources.

As discussed above, assuming a constant MQ for bulk marihuana of 2,000 kgs, DEA estimates the cost of all the activities the National Center performs under its contract with NIDA and the purchase of the entire aggregate crop, regardless of the number of growers, is $2.9 million. This $2.9 million is not a new cost; it is a transfer. Rather than NIDA paying the current single grower, DEA will pay the multiple new growers. In practice, DEA anticipates crops from multiple growers will be purchased at different times of the year, allowing funds from sales of earlier purchases to pay for subsequent purchases. Therefore, to purchase and distribute $2.9 million in bulk marihuana, a working capital of a lesser amount is likely needed. However, due to many unknowns and to be conservative, for the purposes of this analysis, the estimated transfer and working capital requirement is assumed to be $2.9 million.

DEA anticipates incurring new costs associated with the following activities: Taking title to the crops and employing personnel to administer the program. The growers, purchasers, and DEA will already understand, prior to growing and harvesting, the quantities of marihuana to be distributed and to whom the distribution will be made, because the bona fide supply agreements presented during the registration application process will provide such information. In most instances, DEA is expected to purchase and take title to the crop, then sell and distribute the crop to the purchaser on the same day at the grower's registered location. For the purposes of this analysis, DEA assumes the following process:

1. After marihuana is harvested and prepared for delivery to DEA, the registered manufacturer will contact DEA to inform it that the marihuana is ready for collection.

2. Within a reasonable timeframe, but in no event later than four months after the harvest, DEA will purchase and take title to the marihuana. Two DEA Special Agents from the nearest local DEA field office will drive an estimated 100 miles (200 miles roundtrip) to the registered manufacturer to take title. Any marihuana that is not immediately distributed is stored in a designated secure storage mechanism at the grower's registered location for later distribution. The number of trips by the two DEA Special Agents equals the number of harvests.

3. For marihuana distributed from storage at the grower's registered location, the grower distributes marihuana on DEA's behalf. If DEA deems it necessary to be present at such distribution, the distribution is scheduled to coincide with DEA's visit to take title to the next crop, requiring no additional trips by DEA to the grower.

4. Each grower has three harvests, requiring DEA to collect three times per year per grower.

For each collection, DEA estimates $2,071 of labor cost [FN31] and $116 of vehicle cost [FN32] for a total of $2,187 per ***82348** collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of $2,187 per collection, DEA estimates a transport cost of $19,683 and $98,415 for scenarios with three and 15 growers, respectively.

Additionally, DEA anticipates it will need additional personnel resources to operate this program. There are many unknowns and no decisions have been made on hiring. However, for the purposes of this analysis, DEA estimates three full-time-equivalent (FTE) professional staff in the Diversion Control Division will be needed, consisting of two FTE diversion investigator (DI), and one FTE professional/administrative (PA) resources.

Applying the fully loaded annual cost of $211,981 per DI and $168,307 per PA, the estimated total cost of the three FTE employees is $592,269. For the purposes of this analysis, this cost does not vary with the number of growers. Table 1 below summarizes the costs associated with increased staffing.

Table 1—Cost of Personnel Resources

Position	Job category	Modular cost/unit cost ($)	Number of FTEs	Cost ($)
Staff Coordinator	DI	211,981	2	423,962
Program Analyst	PA	168,307	1	168,307
Total	N/A	N/A	3	592,269

In summary the estimated cost to DEA is:

• $19,683 or $98,415 per year to purchase and take title to the bulk marihuana for scenarios with 3 or 15 authorized growers, respectively;

• $592,269 per year for three DEA FTE employees;

• The estimated total annual cost is $611,952 with three growers and $690,684 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is $651,318. Table 2 summarizes the costs.

Table 2—DEA Cost Summary

	Low ($)	High ($)	Average ($)
Transport Cost	19,683	98,415	N/A
Personnel Cost	592,269	592,269	N/A
Total Cost	611,952	690,684	651,318

Changes Affecting Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that some researchers will acquire the bulk marihuana from DEA, rather than from NIDA. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, an average of high and low scenarios, which will be recovered by adding an administrative fee of $326 per kg. The administrative fee was updated from $304 per kg in the NPRM to $326 per kg in this final rule because there is a change in the personnel required to administer the program.[FN33] As discussed earlier, the administrative fee will be adjusted annually.

While the purchaser will purchase marihuana from DEA, this rule does not in any way affect the purchaser's source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase. In particular, NIH has long served as a third-party funder for research through grants, including grants to researchers studying marihuana. Nothing in this rule prohibits NIH from continuing to fund such research by continuing to cover the cost of marihuana materials used in research, via grants to researchers.

Cost Summary

DEA estimates the cost of producing the 2019 MQ for bulk marihuana of 2,000 kgs and operating NIDA's marihuana DSP is $2.9 million per year. Under the rule, DEA anticipates more bulk marihuana producers will be approved. DEA estimates the $2.9 million in economic activity will be transferred across multiple growers, without introducing new costs.

DEA's purchase of bulk marihuana is not a new cost (to the economy); it is a transfer from NIDA to DEA. However, $611,952 to $690,684 in operating costs will be incurred by DEA. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated ***82349** sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis.

The net present values (NPV) of the low cost estimate of $611,952 per year over 10 years are $5.2 million and $4.3 million at a three percent discount rate and seven percent discount rate, respectively. The NPVs of the high cost estimate of $690,684 over 10 years are $5.9 million and $4.9 million at a three percent discount rate and seven percent discount rate, respectively. The average of the estimated low and high costs is $651,318. The NPVs of the average of $651,318 over 10 years are $5.6 million and $4.6 million at three percent and seven percent discount rates, respectively. Table 3 summarizes the estimated annual effect and NPVs calculation for each of the transfers and the three scenarios.

Table 3—Summary of Annual Effect and NPVs

	Annual effect	NPVs at 3%	NPVs at 7%

	($)	($M)	($M)
Cost (Low)	611,952	5.2	4.3
Cost (Average)	651,318	5.6	4.6
Cost (High)	690,684	5.9	4.9

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule is a deregulatory action for the purposes of Executive Order 13771. The rule is an enabling rule which, coincidentally with other provisions, expands the number of authorized bulk marihuana growers.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens on regulated parties and the court system.

Executive Order 13132 (Federalism)

This rule does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless the agency can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and a discussion of its findings is below.

As discussed in the section of this rulemaking relating to Executive Orders 12866, 13565, and 13771, this rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana; DEA will purchase and take physical possession of crops; and DEA will, with respect to marihuana, have the exclusive right of importing,

exporting, wholesale trading, and maintaining stocks. These changes, as explained above, mean that authorized purchasers of bulk marihuana may only purchase from DEA, except that DEA's exclusive right will not extend to medicinal cannabis or cannabis preparations as these terms are defined in paragraphs (b) and (c), respectively, of § 1318.02 of this rule.

The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies (including NIDA and DEA), and purchasers (generally researchers). Because any economic impact on Federal agencies is outside the scope of the RFA, the transfer of economic activity between the agencies is excluded from this discussion. To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the two affected non-Federal groups: Growers (bulk manufacturers of marihuana) and researchers.

Current System

To date, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for use in research studies.[FN34] The National Center designates a secure plot of land where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[FN35] As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately $2.9 million.[FN36] The $2.9 million includes compensation for the cultivating and the 2019 MQ of 2,000 kgs for NIDA as well as all other duties required in the contract.[FN37]

***82350** Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marihuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marihuana on a "cost-reimbursement basis," [FN38] the current policy is to provide the marihuana at no charge.[FN39]

Impact on Growers

Upon promulgation of this rule, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[FN40] Since the publication of the 2016 policy statement, there are approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacture and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[FN41] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and reimbursement of their production cost through sales) is transferred from the incumbent grower to new growers. This means that there is no new cost; instead, there is only a transfer of economic activity. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[FN42]

Transitioning from one large grower to multiple smaller growers may reduce production efficiency, driving up cost. Some growers may introduce more costly growing techniques in order to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down cost. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. However, DEA does not have a basis to estimate the impact of these possibilities.

Impact on Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that the researcher will acquire the bulk marihuana from DEA, rather than from NIDA or the National Center. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of $651,318, which will be recovered by adding an administrative fee of $326 per kg. As discussed earlier, the administrative fee will be adjusted annually. While purchasers will purchase marihuana from DEA, this rule does not in any way affect the purchasers' source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase.

Affected Number of Small Entities

This rule affects the current and prospective bulk manufacturers of marihuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this rule. Additionally, based on a discussion with NIDA,[FN43] DEA estimates 40 researchers are affected by this rule. The 40 researchers represent the approximate number of researchers that receive marihuana from NIDA's marihuana DSP.

Based on a review of representative North American Industry Classification System (NAICS) codes for bulk manufacturers and researchers, the following number of firms may be affected: [FN44]

• 421 firms related to ‘Medicinal and Botanical Manufacturing’ (325411) [FN45]

• 9,634 firms related to ‘Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)’ (541712) [FN46]

The United States Small Business Administration (SBA) sets size standards that determine how large an entity can be and still qualify as a small business for Federal government programs. For the most part, size standards are based on the average annual receipts or the average number of employees of a firm. The SBA size standard for both industries identified by the NAICS codes above is 1,000 employees.[FN47]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates the following number of small entities and percent of firms that are small entities by industry:

• 392 (93.1 percent of total) firms in the area of ‘Medicinal and Botanical Manufacturing’ (325411)

• 9,090 (94.4 percent of total) firms in the area of ‘Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)’ (541712)

Table 4 details the calculation for the number of small entities by industry.

Table 4—Number of Small Entities by Industry

NAICS description	Firm size by average employees	Firms	SBA size standard	Small entities	% small

					entities
325411—Medicinal and Botanical Manufacturing	<500	384	1,000	384	100
	500-749	3		3	100
	750-999	5		5	100
	1,000-1,499	6			0
	1,500-1,999	2			0
	2,000-2,499	1			0
	2,500-4,999	7			0
	5,000+	13			0
	Total	421		392	93.1
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	<500	8,972	1,000	8,972	100
	500-749	68		68	100
	750-999	50		50	100
	1,000-1,499	70			0
	1,500-1,999	40			0
	2,000-2,499	35			0
	2,500-4,999	132			0
	5,000+	267			0
	Total	9,634		9,090	94.4

***82351** Applying the calculated respective percentage for small entities to the number of affected bulk manufacturers and researchers, DEA estimates 14 (15 x 93.1 percent) bulk manufacturers and 38 (40 x 94.4 percent) researchers, for a total of 52 small entities, will be affected by this rule. The 14 affected small entity bulk manufacturers represent four percent of the estimated 392 small entities in the 'Medicinal and Botanical Manufacturing' (325412) industry, and the 38 affected small entity researchers represent 0.4 percent of the estimated 9,090 small entities in the 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) industry. Table 5 summarizes the calculations for the percentage of small entities that are affected by the rule.

Table 5—Percent of Small Entities Affected by Industry

NAICS description	Number of firms	SBA size standard	Estimated	Estimated	Percentage of

			number of small entities	number of affected small entities	small entities affected
325411—Medicinal and Botanical Manufacturing	421	1,000	392	14	4
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	9,634	1,000	9,090	38	0.4
Total	10,055	N/A	9,482	52	N/A

DEA generally uses a threshold of 30 percent as a "substantial" number of affected small entities. Thus, the above analysis reveals that a non-substantial amount of small bulk manufacturer entities (4 percent) and of small researcher entities (0.4 percent) will be affected by this rule.

DEA generally considers impacts that are greater than three percent of annual revenue to be a "significant economic impact" on an entity. As discussed earlier, DEA estimates that there will be a new cost to DEA of $611,952 to $690,684 per year, or the average of the high and low estimates of $651,318 per year. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis. Based on the average of the high and low estimates of $651,318 and MQ of 2,000 kgs, the administrative fee is $326 per kg, adjusted annually.

Furthermore, NIH-funded or other third-party funded researchers are likely to request and receive enough funding for the full price of marihuana, including the administrative fee. There will be no impact to these researchers. However, DEA does not have sufficient information to estimate the number of small entity researchers that will fall under this category. Although DEA is unable to quantify the economic impact for the estimated 14 small entity bulk manufacturers and 38 small entity researchers, the number of affected small entity manufacturers and researchers is not a substantial number of small entities in their respective industries.

Based on the analysis above, and because of these facts, DEA believes this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., DEA has determined that this action will not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." See 2 U.S.C. 1532(a). Therefore, neither ***82352** a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501-3521, DEA is revising existing information collection 1117-0012. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at https://www.reginfo.gov/.

A. Collections of Information Associated With the Rule

Title: Application for Registration (DEA Form 225); Renewal Application for Registration (DEA Form 225A); Affidavit for Chain Renewal (DEA Form 225B).

OMB control number: 1117-0012.

Form numbers: DEA-225, DEA-225A, DEA-225B.

Type of information collection: Revision of a currently approved collection.

Applicable component of the department sponsoring the collection: Department of Justice/Drug Enforcement Administration, Diversion Control Division.

Affected public who will be asked or required to respond: Business or other for-profit.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, or conduct research and laboratory analysis with controlled substances to register with DEA. 21 U.S.C. 822; 21 CFR 1301.11, 1301.13. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring that the closed system of distribution of controlled substances can be monitored by DEA, and that the businesses and individuals handling controlled substances are accountable.

This rule amends the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Persons seeking to become registered with DEA to grow marihuana as bulk manufacturers will still apply for registration using the same DEA Form 225 as other bulk manufacturers, but there will be a new supplemental questionnaire unique to marihuana manufacturers in order to gather additional information about applicants. There will also be new questionnaires used for importer applicants and non-marihuana bulk manufacturer applicants. Forms 225, 225A, and 225B will all receive minor revisions to improve clarity and usability for registrants.

DEA estimates the following number of respondents and burden associated with this collection of information:

• Number of respondents: 15,919.

• Frequency of response: 1 per respondent per year.

• Number of responses: 15,919.

• Burden per response: 0.1304 hours.

• Total annual burden in hours: 2,076.

If you need a copy of the proposed information collection instruments with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152-2639; Telephone: (571) 362-3261.

At this point, any comments related to this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB54/Docket No. DEA-506.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. DEA submitted a copy of the final rule to both Houses of Congress and to the Comptroller General.

National Environmental Policy Act

DEA has analyzed the impacts of this Final Rule on the human environment pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 et seq., and has determined that it is categorically excluded under 28 CFR part 61, Appendix B. Categorical exclusions are actions identified in an agency's NEPA implementing procedures that normally do not have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant preparation of an EA or EIS. This action is covered by the categorical exclusion for registration of persons authorized to handle controlled substances listed in 28 CFR part 61, Appendix B.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1318

Administrative practice and procedure, Drug traffic control.

For the reasons stated in the preamble, DEA amends 21 CFR chapter II as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.
21 CFR § 1301.33

2. In § 1301.33, revise paragraph (c) and add paragraph (d) to read as follows:
21 CFR § 1301.33

§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

* * * * *

(c) Except as provided in paragraph (d) of this section, this section shall not apply to the manufacture of basic classes of controlled substances listed in Schedule I or II as an incident to research or chemical analysis as authorized in § 1301.13(e)(1).

(d) An application for registration to manufacture marihuana that involves the planting, cultivating, growing, or harvesting of marihuana shall be subject to the requirements of this section and the additional requirements set forth in part 1318 of this chapter.

3. Add part 1318 to read as follows:

PART 1318—CONTROLS TO SATISFY THE REQUIREMENTS OF THE ACT APPLICABLE TO THE MANUFACTURING OF MARIHUANA

Sec.

Authority: 21 U.S.C. 801(7), 821, 822(a)(1), (b), 823(a), 871(b), 886a.

21 CFR § 1318.01

§ 1318.01 Scope of this part.

Procedures governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana are set forth by this part.

21 CFR § 1318.02

§ 1318.02 Definitions.

(a) Except as provided in paragraph (e) of this section, the term cannabis means any plant of the genus Cannabis.

(b) Except as provided in paragraph (e) of this section, the term medicinal cannabis means a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act.

(c) Except as provided in paragraph (e) of this section, the term cannabis preparation means cannabis that was delivered to the Administration and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis.

(d) Except as provided in paragraph (e) of this section, the term cannabis resin means the separated resin, whether crude or purified, obtained from the cannabis plant.

(e) As used in this part, the terms cannabis, medicinal cannabis, and cannabis preparation do not include any material, compound, mixture, or preparation that falls outside the definition of marihuana in section 102(16) of the Controlled Substances Act (the Act) (21 U.S.C. 802(16)).

(f) The term Single Convention means the Single Convention on Narcotic Drugs, 1961 (18 U.S.T. 1407).

(g) The term bona fide supply agreement means a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act.

(h) The term registered researcher or manufacturer means a person registered under the Act to perform research or manufacture of marihuana in Schedule I.

21 CFR § 1318.03

§ 1318.03 Implementation of statutory requirements.

(a) As provided in section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator may grant an application for a registration to manufacture marihuana, including the cultivation of cannabis, only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention.

(b) In accordance with section 303(a) of the Act and § 1301.44(a) of this chapter, the burden shall be on the applicant to demonstrate that the requirements for such registration have been satisfied.

21 CFR § 1318.04

§ 1318.04 Specific control measures applicable to the bulk manufacture of marihuana.

For a registration to manufacture marihuana that involves the cultivation of cannabis, the following provisions must be satisfied:

(a) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to the Administration, except as provided in paragraph (d). The Administration shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. The Administration may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against diversion. In such cases, the Administration shall designate a secure storage mechanism at the registered location in which the Administration may maintain possession of the cannabis, and the Administration will control access to the stored cannabis. If the Administration determines that no suitable location exists at the registered location of the registered manufacturer authorized to cultivate cannabis, then the Administration shall designate a location for the authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in part 1301 of this chapter.

(b) The Administration shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. The Administration may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. The Administration shall require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with part 1312 of this chapter, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of the Administration.

(c) A registered manufacturer authorized to grow cannabis shall notify in writing the Administration of its proposed date of harvest at least 15 days before the commencement of the harvest.

(d) A registered manufacturer authorized to grow cannabis may distribute small quantities of cannabis to a registered analytical lab for chemical analysis by such analytical lab prior to the Administration purchasing and taking physical possession of the crop. The cannabis delivered to the analytical lab under such circumstances need not be delivered to the Administration pursuant

to paragraph (a), provided such cannabis is destroyed by the analytical lab upon completion of the testing. Any such distribution of cannabis by a registered manufacturer to a registered analytical lab must comply with all applicable requirements of the Act and this subchapter, including but not limited to security and recordkeeping requirements.
21 CFR § 1318.05

§ 1318.05 Application of the public interest factors.
(a) In accordance with section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator shall consider the public interest factors set forth in paragraphs (a)(1) through (6) of this section:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these ***82354** substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(b) The Administrator's determination of which applicants to select will be consistent with the public interest factors set forth in section 303(a), with particular emphasis on the following criteria:

(1) Whether the applicant has demonstrated prior compliance with the Act and this chapter;

(2) The applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition; and

(3)(i) In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall place particular emphasis on the extent to which any applicant is able to supply cannabis or its derivatives in quantities and varieties that will satisfy the anticipated demand of researchers and other registrants in the United States who wish to obtain cannabis to conduct activities permissible under the Act, as demonstrated through a bona fide supply agreement with a registered researcher or manufacturer as defined in this subpart.

(ii) If an applicant seeks registration to grow cannabis for its own research or product development, the applicant must possess registration as a schedule I researcher with respect to marihuana under § 1301.32 of this chapter. As specified in § 1301.13 of this chapter, chemical analysis and preclinical research (including quality control analysis) are not coincident activities of a manufacturing registration for schedule I substances, including cannabis. In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall consider the holding of an approved marihuana research protocol by a registered schedule I researcher seeking to grow cannabis for its own research or product development as evidence of the necessity of the applicant's registration under this factor.

(c) Applications accepted for filing after January 19, 2021 will not be considered pending for purposes of paragraph (a) of this section until all applications accepted for filing on or before January 19, 2021 have been granted or denied by the Administrator. Where an application is subject to section 303(i) of the Act (21 U.S.C. 823(i)), that section shall apply in lieu of this paragraph (c).

(d) In determining the legitimate demand for cannabis and its derivatives in the United States, the Administrator shall consult with the U.S. Department of Health and Human Services, including its components.

21 CFR § 1318.06

§ 1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.

(a) In accordance with section 111(b)(3) of Public Law 102-395 (21 U.S.C. 886a(1)(C)), seeking to recover the full costs of operating the aspects of the diversion control program that are related to issuing registrations that comply with the Controlled Substances Act, the Administration shall assess an administrative fee. To set the administrative fee, the Administration shall annually determine the preceding fiscal year's cost of operating the program to cultivate cannabis and shall divide the prior fiscal year's cost by the number of kgs of cannabis authorized to be manufactured in the current year's quota to arrive at the administrative fee per kg. The administrative fee per kg shall be added to the sale price of cannabis purchased from the Administration. The administrative fee shall be paid to the Diversion Control Fee Account.

(b) As set forth in § 1318.04, the Administration shall have the exclusive right of, among other things, wholesale trading in cannabis that it purchases from registered manufacturers. The Administration will, therefore, buy from such manufacturer, sell cannabis to registered researchers and manufacturers, and establish prices for such purchase and sale. The Administration will set such prices in the following manner:

(1) Bulk growers of cannabis shall negotiate directly with registered researchers and manufacturers authorized to handle cannabis to determine a sale price for their cannabis. Upon entering into a contract for the provision of bulk cannabis and prior to the exchange of cannabis, the parties shall pay to the Administration an administrative fee assessed based on the number of kgs to be supplied. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(2) The Administration shall sell the cannabis to the buyer at the negotiated sale price plus the administrative fee assessed on a per kg basis. Prior to the purchase of the cannabis by the Administration, the buyer shall pay the negotiated purchase price and administrative fee to the Administration. The Administration shall hold funds equal to the purchase price in escrow until the delivery of the cannabis by the grower to the Administration. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(3) After receiving the purchase price and administrative fee from the buyer, the Administration shall purchase the cannabis from the grower, on behalf of the buyer, at the negotiated sale price. The Administration shall retain the administrative fee. In the event the buyer fails to pay the purchase price and the administrative fee, the Administration shall have no obligation to purchase the crop and may order the grower to destroy the crop if the grower cannot find an alternative buyer within four months of harvest.

(4) In instances where the grower of the cannabis is the same entity as the buyer of the cannabis, or a related or subsidiary entity, the entity may establish a nominal price for the purchase of the cannabis. The Administration shall then purchase the entity's cannabis at that price and sell the cannabis back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee.

(c) Administrative fees set in accordance with this part will be made available, on an updated basis, on the Administration's website, no later than December 15th of the year preceding the year in which the administrative fee will be collected.

(d) Nothing in this section shall prohibit the U.S. Department of Health and Human Services from continuing to fund the acquisition of cannabis for use in research by paying, directly or indirectly, the purchase cost and administrative fee to the Administration.

21 CFR § 1318.07

§ 1318.07 Non-liability of Drug Enforcement Administration.

The Administration shall have no liability with respect to the performance of any contractual terms agreed to by a grower and buyer of bulk cannabis, including but not limited to the quality of any cannabis delivered to a buyer. In ***82355** the event that a buyer deems the delivered cannabis to be defective, the buyer's sole remedy for damages shall be against the grower and not the Administration.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020-27999 Filed 12-17-20; 8:45 am]

BILLING CODE 4410-09-P

Footnotes

1 All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

2 This document uses both the CSA spelling "marihuana" and the modern spelling "marijuana" interchangeably.

3 As defined in Section 802(16).

4 Section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be "consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." The Single Convention entered into force for the United States on June 24, 1967. See Single Convention, 18 U.S.T. 1407.

5 That opinion is available at http://www.justice.gov/olc/opinion/licensing-marijuana-cultivation-compliance-single-convention-narcotic-drugs.

6 Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States," 81 FR 53846 (Aug. 12, 2016).

7 The Attorney General determined that adjustments were necessary after receiving the aforementioned advisory OLC Opinion.

8 See OLC Op., supra note 5, at 7.

9 The relevant law is briefly summarized here but is discussed in greater depth in the aforementioned OLC Opinion.

10 The five functions of Article 23(2) of the Single Convention are as follows: (1) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis or cannabis resin shall be permitted; (2) ensure that only cultivators licensed by the agency shall be authorized to engage in such cultivation; (3) ensure that each license shall specify the extent of the land on which the cultivation is permitted; (4) require all cultivators of the cannabis plant to deliver their total crops of cannabis and cannabis resin to the agency and ensure that the agency purchases and takes physical possession of such crops as soon as possible, but not later than four months after the end of the harvest; and (5) have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin, except that this exclusive right need not extend to medicinal cannabis, cannabis

preparations, or the stocks of cannabis and cannabis resin held by manufacturers of such medicinal cannabis and cannabis preparations.

11 The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed to perform these tasks on constitutional grounds, administrative arrangements should be made to ensure the required coordination.

12 These issues are discussed further in the OLC Opinion.

13 As noted, the relevant legal considerations are explored in greater detail in the aforementioned OLC Opinion.

14 The exception that allows DEA registered manufacturers of medicinal cannabis and cannabis preparations to maintain stocks of cannabis materials for the purpose of producing such drugs or preparations only applies where the raw cannabis material was previously delivered to DEA.

15 DEA routinely enters into memoranda of agreement with certain registrants.

16 The rule refers to those "seeking to plant, grow, cultivate, or harvest marihuana" rather than just to "grow" or "cultivate," to ensure that all activities related to growth and cultivation are included.

17 Article 1 of the Single Convention defines "medicinal opium" and "opium preparations." These definitions apply to cannabis through Article 28, which, with limited exception, subjects the cultivation of cannabis to the system of controls set forth in Article 23 with regard to the cultivation of opium. DEA adapted the Single Convention's definitions to reflect governing Federal law, including the FD&C Act and the CSA.

18 This is an increase from the estimated cost of $607,644 in the NPRM. The increase is due to change in estimated personnel requirements as described below.

19 The "authorizing agency" refers to federal government agencies, including NIDA and DEA.

20 Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.

21 NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.

22 Information on Marijuana Farm Contract, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research/information-marijuana-farm-contract.

23 Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

24 Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10%-15% meet the definition of "hemp" under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million for marihuana, excluding hemp. The figures are based on a general discussion, and actual figures may differ.

25 The 2019 APQ for all marihuana is 2,450 kgs. 2,000 of the 2,450 kgs are for the NIDA (National Center) cultivating and manufacturing quota of bulk marihuana. See 83 FR 67348.

26 Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.

27 Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

28 Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). This rule supersedes the 2016 policy statement.

29 21 CFR 1303.11(a).

30 The phrase "multiple growers" includes the possibility that the current grower is one of "multiple growers."

31 DEA's loaded hourly rate of a Special Agent is $103.54. Assuming 10 hours each (full work-day) for two agents, the total labor cost associated with collection from a registered manufacturer is $2,071. "Loaded hourly rate" includes wages, benefits, and "loading" of "non-productive" hours, i.e., leave, training, travel, etc.

32 $116 is based on Internal Revenue Service standard mileage rates for 2019 of $0.58 per mile multiplied by the estimated 200 miles driven, roundtrip.

33 In the NPRM, DEA estimated personnel requirements to administer the program was one DEA Diversion Investigator and two Professional/Administrative personnel. After further review, DEA has estimated in this final rule that two DEA Diversion Investigators and one Professional/Administrative personnel are needed to administer the program. The two Diversion Investigators are needed to provide adequate oversight of reporting and recordkeeping requirements associated with distribution.

34 Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.

35 NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.

36 Estimated spending for the marihuana DSP for 2019 was $3.3 million to $3.4 million, of which 10 percent to 15 percent meet the definition of "hemp" under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million. The figures are based on a general discussion, and actual figures may differ.

37 The 2019 APQ for all manufacturers of marihuana is 2,450 kgs. 2,000 kgs are for cultivating and manufacturing of bulk marihuana. See 83 FR 67348.

38 Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.

39 See note 23.

40 Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (2016). This rule supersedes the 2016 policy statement.

41 21 U.S.C. 826(a).

42 The phrase "multiple growers" includes the possibility that the current grower is one of the "multiple growers."

43 Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

44 For the purposes of this analysis, the term "firms" is synonymous with "entities."

45 2015 SUSB Annual Datasets by Establishment Industry, U.S. & States, NAICS, Detailed Employment Sizes (U.S., 6-digit and States, NAICS Sectors), United States Census Bureau, https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.

46 Ibid.

47 Table of Small Business Size Standards Matched to North American Industry Classification System Codes, United States Small Business Association (Oct. 1, 2017). The NAICS code was updated for 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' from 541712 to 541715. The 2015 SUSB data uses 541712 and the 2017 SBA size standard uses 541715 for the same industry.

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(Slip Opinion)

Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs

Under the Controlled Substances Act, the Drug Enforcement Administration may register an applicant to cultivate marijuana only if the registration scheme is consistent with the Single Convention on Narcotic Drugs. To comply with the Single Convention, DEA's licensing framework must provide for a system in which DEA or its legal agent has physical possession and ownership over the cultivated marijuana and assumes control of the distribution of marijuana no later than four months after harvesting.

June 6, 2018

MEMORANDUM OPINION FOR THE ACTING CHIEF COUNSEL
DRUG ENFORCEMENT ADMINISTRATION

Under the Controlled Substances Act, the Attorney General is authorized to license marijuana cultivation if he determines that it would be "consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a). Such obligations include those under the Single Convention on Narcotic Drugs ("Single Convention"), Mar. 30, 1961, 18 U.S.T. 1407. As relevant here, the Single Convention requires parties either to prohibit marijuana cultivation altogether or, if they permit cultivation, to establish "a single government agency" to oversee marijuana growers and generally to monopolize the wholesale trade in the marijuana crop. *Id*. arts. 22, 23(3), 28(1). That single agency must strictly regulate any lawful cultivation of marijuana by, among other things, "purchas[ing] and tak[ing] physical possession of [the] crops as soon as possible, but not later than four months after the end of the harvest." *Id*. art. 23(2)(d).

This opinion considers whether the Drug Enforcement Administration ("DEA"), which exercises the Attorney General's licensing authority, must alter existing licensing practices to comply with the Single Convention. At present, DEA does not purchase or take physical possession of lawfully grown marijuana at any point in the distribution process. Instead, the only currently licensed marijuana cultivator grows and distributes the marijuana itself pursuant to a contract with, and under the supervision of, the National Institute on Drug Abuse ("NIDA"), a component of the Department of Health and Human Services' National Institutes of Health. In 2016, DEA revised this process and announced that it would increase the number of licensees and supervise the additional growers itself.

See Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,848 (Aug. 12, 2016) ("Applications To Manufacture Marijuana"). Under the new policy, DEA would not purchase or possess the marijuana before licensees distributed it to government-approved researchers. Several entities have applied for licenses under the new policy, but no applications have been approved.

We conclude that DEA must change its current practices and the policy it announced in 2016 to comply with the Single Convention. DEA must adopt a framework in which it purchases and takes possession of the entire marijuana crop of each licensee after the crop is harvested. In addition, DEA must generally monopolize the import, export, wholesale trade, and stock maintenance of lawfully grown marijuana.[1] There may well be more than one way to satisfy those obligations under the Single Convention, but the federal government may not license the cultivation of marijuana without complying with the minimum requirements of that agreement.

I.

The Single Convention entered into force for the United States on June 24, 1967, after the Senate had given its advice and consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The Convention requires parties to impose stringent controls on the cultivation, manufacture, and distribution of narcotic drugs, including "cannabis," which it defines as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the

[1] In preparing this opinion, we considered the views of DEA, the Office of the General Counsel of the Department of Health and Human Services, and the Department of State's Office of the Legal Adviser. *See* Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846–48 (discussing requirements of the Single Convention applicable to licensing marijuana cultivation); Lyle E. Craker, PhD, 76 Fed. Reg. 51,403, 51,409–11 (DEA Aug. 18, 2011) (same); Lyle E. Craker, 74 Fed. Reg. 2101, 2114–18 (DEA Jan. 14, 2009) (same); Memorandum for Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, from Matthew S. Bowman, Deputy General Counsel, Department of Health and Human Services (Apr. 13, 2018) ("HHS Mem."); Office of Law Enforcement and Intelligence and Office of Treaty Affairs, *Single Convention Analysis* (Jan. 29, 2018) ("State Mem."); Letter for Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, from Jennifer G. Newstead, Legal Adviser, Department of State (Apr. 17, 2018) ("State Supp. Mem.").

resin has not been extracted, by whatever name they may be designated." Single Convention art. 1(1)(b). Parties must, among other things, establish quotas on the import and manufacture of cannabis, generally prohibit the possession of cannabis, and adopt penal provisions making violations of those controls punishable offenses. *Id*. arts. 21, 33, 36.

Article 28 of the Single Convention requires that any lawful cultivation of the cannabis plant be subject to the same system of strict controls "as provided in article 23 respecting the control of the opium poppy." *Id*. art. 28. The cross-referenced provisions in Article 23 provide as follows:

> 1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
>
> 2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
>
> a. The Agency shall designate the area in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
>
> b. Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
>
> c. Each license shall specify the extent of the land on which the cultivation is permitted.
>
> d. All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
>
> e. The agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium, or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

> 3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

The agency's "exclusive right[s]" over the harvested marijuana need not extend to "medicinal" marijuana or marijuana "preparations," but the national cannabis agency must still purchase and take physical possession of all marijuana grown for such purposes. *Id*. art. 23(2)(d)(e); *see* Report of the International Narcotics Control Board for 2014, at 35 (Mar. 3, 2015) ("2014 INCB Report"); Secretary-General of the United Nations, *Commentary on the Single Convention on Narcotic Drugs, 1961*, at 284, 314 (1973) ("*Commentary*").[2]

Three years after the United States acceded to the Single Convention, Congress in 1970 enacted the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*., "a comprehensive statute designed to rationalize federal control of dangerous drugs." *Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977). "[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention." *Control of Papaver Bracteatum*, 1 Op. O.L.C. 93, 95 (1977); *see, e.g*., 21 U.S.C. §§ 801(7), 811(d)(1), 958(a); *see also* S. Rep. No. 91-613, at 4 (1969) ("The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.").

The CSA imposes strict controls on marijuana, which is defined to include "all parts of the plant Cannabis sativa L." and all compounds and derivatives thereof, with certain exceptions not relevant here. 21 U.S.C. § 802(16). The statute classifies marijuana as a schedule I substance, the most stringent classification available, reflecting a determination that marijuana "has a high potential for abuse" and "no currently accepted medical use." 21 U.S.C. § 812(b); *see Craker v. DEA*, 714 F.3d 17, 19 (1st Cir. 2013); 21 C.F.R. § 1308.11. The CSA makes the unauthorized

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[2] The United Nations' Economic and Social Council requested that the Secretary-General prepare the *Commentary* "in the light of the relevant conference proceedings and other material" in order to aid governments in applying the Single Convention. Economic and Social Council Resolution 1962/914(XXXIV)D (Aug. 3, 1962).

possession, manufacture, and distribution of marijuana a crime punishable by severe penalties. 21 U.S.C. §§ 841, 844.

Although federal law recognizes no currently accepted medical use for marijuana, *see United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 491 (2001), it does permit the cannabis plant to be cultivated lawfully for research purposes pursuant to a DEA license. *See* 21 U.S.C. §§ 822(a)(1), 823(a); 21 C.F.R. pt. 1301.[3] Since its founding in 1973, DEA has licensed only one such grower to supply researchers with marijuana—the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi. *See* Lyle E. Craker, 74 Fed. Reg. at 2104; Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846. The National Center cultivates marijuana pursuant to a contract administered by NIDA. Besides overseeing the cultivation of marijuana, NIDA also plays a role in determining which researchers may obtain marijuana for medical or scientific use. *See* 21 U.S.C. § 823(f); Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999, 80 Fed. Reg. 35,960 (June 23, 2015).

The current contract between NIDA and the National Center, which became effective on March 23, 2015, provides that the National Center will, among other things, "cultivate and harvest, process, analyze, store, and distribute cannabis . . . for research." Award/Contract Issued by Nat'l Inst. on Drug Abuse, to the University of Mississippi, Contract No. HHSN271201500023C, at 4 (effective Mar. 23, 2015) ("2015 NIDA Contract"). The National Center must also "[p]rovide an adequate DEA approved storage facility" for the harvested cannabis and may ship it to researchers only "as required by NIDA." *Id.* at 17. All work under the contract is to be "monitored" by the Government Contracting Officer's Representative, an employee at NIDA's headquarters in Bethesda, Maryland. *Id.* at 16, 34. The contract requires the NIDA representative to monitor technical progress based on the National Center's monthly progress reports, to evaluate the National Center's work, to perform technical evaluations and inspections of a sample of the marijuana shipped to NIDA, and to assist in resolving technical problems. *Id.* at 17, 26, 34.

[3] Sections 822(a) and 823(a) vest authority over registration for such licenses in the Attorney General. Pursuant to 21 U.S.C. § 871(a), the Attorney General delegated this function to DEA. 28 C.F.R. § 0.100(b).

In 2016, in response to increasing public interest in marijuana research, DEA announced a new policy reflecting its intention to increase the number of federally authorized growers. *See* Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,846–48. Under the new policy, a grower, if approved for a license, would "be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA." *Id*. at 53,848. NIDA would not be involved in monitoring the additional licensees. We understand that DEA has several currently pending requests from entities that seek to register as marijuana growers under that policy.

II.

Under the CSA, DEA may register an applicant to cultivate marijuana only if the registration scheme is consistent with the Single Convention. We address whether DEA's practices and policy for licensing marijuana cultivation comply with the Single Convention and, if not, what changes DEA must make to conform to the treaty.

A.

An international agreement has the force of domestic U.S. law if it is self-executing or if Congress has implemented it by legislation. *See Medellín v. Texas*, 552 U.S. 491, 504–05 (2008). Here, Congress has executed the Single Convention in the CSA. In that Act, Congress provided that the Attorney General "shall" license the cultivation of marijuana "if he determines that such registration is consistent with . . . United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a).[4] The Attorney General is thus required to determine that the licensing scheme is consistent with the Single Convention before exercising his authority to register an applicant to cultivate marijuana. *See Control of Papaver Bracteatum*, 1 Op. O.L.C. at 99; Memorandum for John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Petition to Decontrol Marihuana—*

[4] The Single Convention was amended by a 1972 protocol, but the amendments are not material to the obligations discussed in this opinion. *See* Protocol Amending the Single Convention on Narcotic Drugs, Mar. 25, 1972, 26 U.S.T. 1439.

Interpretation of Section 201 of the Controlled Substances Act of 1970, at 4 (Aug. 21, 1972) ("[I]n making determinations as to the fitness of registrants to receive licenses for manufacture or export and import of controlled substances, the Attorney General is instructed to ensure consistency 'with United States obligations under international treaties.'").

Article 23(2) of the Single Convention, made applicable to marijuana cultivation by Article 28, contains five requirements for the supervision, licensing, and distribution of marijuana. *See* Single Convention art. 23(2)(a)–(e). Under current regulations and practice, DEA satisfies the first three requirements. The Convention specifies that the agency must designate the land on which cannabis cultivation is permitted, limit cultivators to those licensed by the agency, and specify the extent of the land on which cultivation is permitted. *Id*. art. 23(2)(a), (b), (c). Federal regulations implement those requirements by mandating that a marijuana manufacturer obtain a DEA license annually for each physical location at which marijuana is grown. 21 U.S.C. § 822(a)(1); 21 C.F.R §§ 1301.11(a), 1301.12(a). DEA establishes annual production quotas for lawful marijuana cultivation, and it has exercised that authority by setting the annual quotas for the National Center, the only entity ever registered by DEA to grow marijuana to supply researchers in the United States. 21 U.S.C. § 826; 21 C.F.R. § 1303.11. DEA has ample authority under this framework to specify the areas and circumstances under which a licensee may cultivate marijuana and in fact satisfies the first three requirements of Article 23(2) of the Single Convention in registering applicants under the CSA pursuant to those requirements.

Article 23 of the Single Convention also imposes control requirements beyond those currently carried out by DEA. Under Article 23(2)(d), "all cultivators shall be required to deliver their total crops" to the agency, and the agency "shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest." Article 23(2)(e) requires the agency to "have the exclusive right of importing, exporting, wholesale trading and maintaining stocks." The United States currently attempts to comply with those requirements through NIDA's contract with the National Center, under which NIDA's contracting officials supervise the National Center's cultivation of marijuana and distribution of marijuana to researchers. Article 23's final requirement, however, provides that the "governmental functions" in Article 23(2) must be "discharged by a single government agency if the constitution of the Party concerned permits it." Single Convention art. 23(3).

We conclude that the existing licensing framework departs from Article 23 in three respects. First, the division of responsibilities between DEA and NIDA, a component of the Department of Health and Human Services ("HHS"), contravenes Article 23(2)'s requirement that all Article 23 functions be carried out by a single government agency. Second, neither of the two government agencies "take[s] physical possession" of the marijuana grown by the National Center, as required by Article 23(2)(d). Third, no federal agency exercises a monopoly over the wholesale trade in marijuana, as required by Article 23(2)(e). We discuss each departure in turn.

1.

Current practice diverges from the Single Convention's requirement that a single agency undertake each of the listed control functions unless the constitution of the treaty party forbids it. As explained, DEA is responsible for the controls required by Article 23(2)(a), (b), and (c) because it effectively designates the area where marijuana cultivation is permitted, limits cultivators to those licensed by the agency, and specifies the extent of the land on which cultivation is permitted. NIDA, for its part, attempts to satisfy the physical-possession and government-monopoly-control requirements of Article 23(2)(d) and (e) by supervising cultivation under its contract with the National Center. That division of authority is contrary to Article 23(3), because nothing in the Constitution would preclude the United States from discharging all of those controls through one government agency.

DEA agrees that "the United States fails to adhere strictly" to the single government agency provision because "both DEA and HHS carry out certain functions set forth in article 23, paragraph 2." Lyle E. Craker, PhD, 76 Fed. Reg. at 51,409.[5] For the current framework to be in compli-

[5] Members of Congress and the American Bar Association have also recognized that the division of regulatory responsibilities among federal agencies fails to comply with the Single Convention. *See* 129 Cong. Rec. 7434 (Mar. 24, 1983) (Rep. McKinney) (recognizing that the current division of responsibilities is in "violation of the [S]ingle [C]onvention" and introducing a bill that would create an "Office for the Supply of Internationally Controlled Drugs" within the Department of Health and Human Services to "comply[] with the [S]ingle [C]onvention on [N]arcotic [D]rugs"); *Report No. 1 of the Section of Administrative Law*, 109 Ann. Rep A.B.A. 447, 482 (1984) (noting that the Single Convention "requires that a *single* government agency license all domestic pro-

ance with the single-agency requirement of the treaty, we would have to view NIDA as performing the physical-possession and government-monopoly functions on behalf of DEA. *See* State Mem. at 5. But we do not believe that NIDA acts for DEA, and it is unlikely that DEA could lawfully supervise NIDA in the performance of its functions. We are aware of no statute that gives DEA that authority. And the President may not delegate to DEA his constitutional authority to supervise NIDA in the exercise of its statutory responsibilities. *See Centralizing Border Control Policy Under the Attorney General*, 26 Op. O.L.C. 22, 24–25 (2002).

2.

We turn next to the requirement that the single government agency "purchase and take physical possession" of the marijuana. Single Convention art. 23(2)(d). As noted above, NIDA contracts with, and partially oversees, the cultivation of marijuana by the National Center, which is licensed by DEA. But under that contractual arrangement, neither NIDA nor DEA takes physical possession of the marijuana. Rather, the National Center itself stores the marijuana on the premises of the University of Mississippi and ships it to researchers approved by DEA. Neither NIDA nor DEA accepts delivery of the harvested crops. That contractual arrangement does not satisfy the United States' obligations under Article 23(d). The contract at most results in a federal government agency's having constructive, rather than physical, possession of the marijuana crop.

a.

The Single Convention does not define "physical possession." In construing that term we should "begin with the text of the treaty and the context in which the written words are used." *Water Splash, Inc. v. Menon*, 137 S. Ct. 1504, 1508–09 (2017) (internal quotation marks omitted); *see also Restatement (Third) of the Foreign Relations Law of the United States* § 325(1) (Am. Law Inst. 1987) ("*Restatement of Foreign Relations*") ("An international agreement is to be interpreted in good faith according to the ordinary meaning to be given to its terms in their context and in light of its object and purpose."); Vienna Convention on the Law of

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duce[r]s of marijuana, specify the particular plots of land on which it is to be grown, and collect the crops of all domestic producers of marijuana" and that "at present the authority to control marijuana production is split between" government agencies).

Treaties art. 31(1), *opened for signature* May 23, 1969, 1155 U.N.T.S. 331("Vienna Convention") (similar).[6]

We think it evident from the treaty's text and context that "physical possession" requires growers licensed under the CSA to transfer the crops to the physical, and not merely legal, control of the federal government. Article 23(2)(d) says that "cultivators" must "deliver their total crops" to the government—a clear indication that the treaty contemplates the physical transfer of control from one party to another. The Single Convention's *Commentary* reinforces that point in emphasizing that "the time between the harvest and *delivery of the crop* should be as short as possible" and recommending that parties "set a final date after which possession of harvested [crops] by a private cultivator is in any event illegal and [the crop] subject to confiscation." *Commentary* at 283 (emphasis added). And this understanding of the words used in the Single Convention is further confirmed by the decisions of U.S. courts, which have consistently distinguished constructive possession from physical possession, with the latter requiring direct physical control over the item in question.[7]

One might argue that NIDA, through its contract, satisfies the treaty requirements of physical possession via the pervasive influence and control NIDA exercises over the National Center's cultivation operations. *See* State Mem. at 5; State Supp. Mem. at 2. NIDA's contract does provide that the National Center serves as "NIDA's cannabis drug repository." 2015 NIDA Contract at 16. DEA regulations also include detailed specifications for the material, size, and accessibility of the storage facility. *See* 21 C.F.R. §§ 1301.71–1301.76. The contract further specifies particular temperatures for the storage facility and notes that "[l]ocal DEA agents will determine the exact type of security required." 2015 NIDA

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[6] The United States is not a party to the Vienna Convention, but this Office has relied on Article 31 as generally reflecting customary international law and practice. *See Interpretation of Article 17* Bis *of the US-EU Air Transport Agreement*, 40 Op. O.L.C. __, at *5 (Apr. 14, 2016); *"Protected Person" Status in Occupied Iraq Under the Fourth Geneva Convention*, 28 Op. O.L.C. 35, 53 n.21 (2004).

[7] *See, e.g.*, *United States v. Hunter*, 558 F.3d 495, 503–04 (6th Cir. 2009) ("Actual possession exists when an individual knowingly has direct physical control over a thing at a given time[.]"); *United States v. Derose*, 74 F.3d 1177, 1185 (11th Cir. 1996) (defining "actual possession" as "physical possession or . . . actual personal dominion over the thing allegedly possessed"); *United States v. Raper*, 676 F.2d 841, 848 (D.C. Cir. 1982) (finding constructive possession even though the drugs were in another's "physical possession"); *United States v. Moreno*, 649 F.2d 309, 313 (5th Cir. Unit A June 1981) (same).

Contract at 17. And the contract provides for federal monitoring of compliance by the NIDA representative, although that supervision occurs primarily from NIDA's headquarters in Bethesda, Maryland. *Id*. at 16, 26, 34. But the control that NIDA exercises through these contractual provisions amounts at most to constructive possession of the marijuana, and is thus insufficient to meet the treaty requirement of physical possession by the federal government.

In particular, this requirement demands that the government have physical control over the crop. Because a government acts through its agents, that mandate means the marijuana must be delivered to government agents who must have personal and direct physical access to the crops in question, and not simply the ability or power to obtain access to them.

b.

It could be argued that the National Center's employees are acting as federal government agents, and that the federal government physically possesses marijuana grown by the National Center through those employees. But in a similar context, for purposes of asking whether the federal government is liable for the actions of a contractor under the Federal Tort Claims Act, the Supreme Court has emphasized that requiring compliance with "federal standards and regulations" or contract terms that "fix specific and precise conditions to implement federal objectives" does not suffice to "convert the acts of [contractors] into federal governmental acts." *United States v. Orleans*, 425 U.S. 807, 815–16 (1976). A contractor's employees may become federal agents only if the government has the authority "to control the detailed physical performance of the contractor" and supervise its "day-to-day operations." *Id*. at 814–16 (internal quotation marks omitted).

For analogous reasons, the National Center's employees are not agents of the federal government. The parameters of the contract do not provide for DEA or NIDA to supervise closely the day-to-day physical operations of the National Center's distribution and storage functions. And the NIDA contract disavows the notion that it creates an agency relationship. It provides that the National Center operates "[i]ndependently, *and not as an agent* of the Government" and, further, that the National Center "shall be required to furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government." 2015 NIDA Contract at 15 (emphasis added). There is simply no indica-

tion that the federal government, rather than the National Center, exercises the kind of close supervision of the National Center's employees that would make them federal agents.

We are also not persuaded by a similar line of argument contending that the National Center "could be considered an extension of" the federal government. Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,847. The suggestion is that the National Center itself operates as the federal government in carrying out the controls required by the Single Convention. The question of whether an entity is part of the federal government turns on a variety of factors, including whether the government owns the entity; whether the government appoints its officers and directors; whether Congress has defined its corporate purposes or appropriated funds for its operations; and whether the entity is controlled by or operates for the benefit of the federal government. *See Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 51–55 (2015); *United States v. New Mexico*, 455 U.S. 720, 739–40 (1982); Memorandum for Edward A. Frankle, General Counsel, National Aeronautics & Space Administration, from Randolph D. Moss, Assistant Attorney General, Office of Legal Counsel, *Re: Applicability of Government Corporation Control Act to Gain Sharing Benefit Agreement* at 7–9 (Sept. 18, 2000).

Under those factors, the National Center is not an extension of the federal government. The National Center is part of the University of Mississippi, located on campus in a university-owned building, and run by its own employees. It does not operate solely for a federal purpose, but instead was established to help the University conduct "research to discover and develop natural products for use as pharmaceuticals, dietary supplements and agrochemicals, and to understand the biological and chemical properties of medicinal plants." National Center for Natural Products Research, About NCNPR, https://pharmacy.olemiss.edu/ncnpr/about-ncnpr/ (last visited June 6, 2018). While the federal government pays the National Center to grow marijuana and exercises some supervision over its growing operations, the government does not generally fund or control the National Center. That the National Center may physically possess the marijuana it grows, then, does not satisfy the federal government's obligation to do so.[8]

[8] The Supreme Court has cautioned against applying "background principle[s] of American law" that are "relevant to the interpretation of federal statutes" but were not necessarily adopted by the signatories to a treaty (for example, the presumption in favor

c.

In addition to taking "physical possession," Article 23(2)(d) requires that the national agency "purchase" the marijuana from the cultivator. That requirement provides for the government to pay for and take legal title to the marijuana. The *Commentary* advises that the payment of money was meant to encourage the delivery of the crops because "[p]rompt payment, a good price and other favourable conditions of purchase may be incentives to producers to deliver speedily their total" crops to the agency. *Commentary* at 283. The exchange of payment for the harvested crops encourages each grower to deliver its full inventory to the government.

Neither NIDA nor DEA "purchases" the harvested crops from the National Center, but it could be said that NIDA does not need to do so if it already has title to the marijuana. *See* State Mem. at 4–5; HHS Mem. at 5–6. Although the contract between NIDA and the National Center includes some provisions discussing government property, they do not expressly address or otherwise make clear where title to the marijuana crops lies.[9] But we need not decide whether NIDA has title to the crops. The requirement that the federal government physically possess the marijuana crops is distinct from the requirement that it "purchase" the crops and thus secure title. *See* Single Convention art. 23(d). Physical possession is not conferred by mere "transfer of title or risk of loss." *In re World Imports, Ltd*., 862 F.3d 338, 344 (3d Cir. 2017) (interpreting the Bankruptcy Code's reference to "receipt of goods" as requiring "physical

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of equitable tolling of federal statutes of limitations). *Lozano v. Montoya Alvarez*, 572 U.S. 1, 12 (2014). Here, we have sought help from analogies drawn from U.S. law to interpret the Single Convention "in good faith in accordance with the ordinary meaning to be given to its terms in their context and in light of its object and purpose." *Restatement of Foreign Relations* § 325(1).

[9] The current NIDA contract incorporates a clause of the Federal Acquisition Regulation dealing with government title to property. 2015 NIDA Contract at 55. That clause states that "[t]itle to property (and other tangible personal property) purchased with funds available for research and having a unit acquisition cost of less than $5,000 shall vest in the Contractor upon acquisition or as soon thereafter as feasible; provided that the Contractor obtained the Contracting Officer's approval before each acquisition." 48 C.F.R. § 52.245-1 Alternate II (2012). If the unit acquisition cost is $5,000 or more, title vests "as set forth in this contract." *Id*. The application of this clause to marijuana the contractor grows rather than purchases is ambiguous and the contract does not otherwise expressly address title to the crops.

possession"); *see Matter of Brio Petroleum, Inc*., 800 F.2d 469, 472 (5th Cir. 1986) (same); *Matter of Marin Oil, Inc*., 740 F.2d 220, 225 (3d Cir. 1984) (same). Moreover, DEA certainly does not have title to the crops. Even if NIDA had formal legal title to the crops, the current arrangement would still have to be adjusted to comply with the treaty's requirements that a single government agency be charged with licensing cultivators, purchasing, and physically possessing the crops. In the course of making those adjustments, DEA could enter into a contract that expressly states that it owns the marijuana crops, should the agency seek to obviate the need for a purchase and claim ownership in the marijuana from its inception, rather than buying back the crops shortly after the harvest.

3.

Finally, we do not believe that the current arrangement provides for the federal government to exercise "the exclusive right of importing, exporting, wholesale trading and maintaining stocks" in the drug, as required by Article 23(2)(e). DEA has authority to control the lawful distribution of the crops in certain respects. But just as with the physical possession requirement, the Single Convention contemplates that the government monopoly will involve more than the exercise of regulatory authority. The *Commentary* on the Convention stresses that wholesale trade "must be undertaken by governmental authorities," rather than private parties, because of the risk of diversion. *Commentary* at 278. The Convention contemplates an actual "monopoly," *id*. at 284, i.e., "[t]he market condition existing when only one economic entity produces a particular product or provides a particular service." *Black's Law Dictionary* 1160 (10th ed. 2014). The government agency responsible for the relevant controls must own the crops and be the sole distributor of the marijuana. In allowing the National Center to maintain possession of the marijuana and ship it to DEA-approved researchers, the NIDA contract does not create the required government monopoly over the lawful marijuana trade.[10]

[10] The government monopoly need not extend to "medicinal" marijuana. Single Convention art. 23(e). But that exception is not available under current federal law. As noted above, the federal government has not recognized any accepted medical use for marijuana. *See Oakland Cannabis Buyers' Co-op*., 532 U.S. at 491. As a result, "there is currently no such thing in the United States as 'medicinal cannabis'" for purposes of the Single Convention. Lyle E. Craker, 74 Fed. Reg. at 2116. Moreover, anyone who wished to produce medicinal marijuana or marijuana preparations would still be required to pur-

For the reasons discussed above, the National Center does not play the role of the government monopolist. *See supra* Part II.A.2.b. Indeed, that conclusion is buttressed here by a constitutional concern. If the National Center were viewed as exercising significant authority in establishing a federal government monopoly over the lawful distribution of marijuana, in conformity with the international obligations of the United States, its officials might be viewed as officers of the United States, who would need to be appointed consistent with the Appointments Clause. *See Ass'n of Am. Railroads*, 575 U.S. at 55–56; *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 87–93, 100–110, 121 (2007). If any National Center officials were officers of the United States, they would have to be appointed either by the President with the advice and consent of the Senate, or, pursuant to statutory authority, by a court of law, a department head, or the President alone. *See* U.S. Const. art. II, § 2, cl. 2. We are not aware that any National Center officials are so appointed, but because, as discussed above, we do not believe that the National Center is exercising the sovereign authority of the United States, such concerns do not arise.

B.

Even if the current framework departs from Article 23, it would still comply with the Convention if it satisfied Article 39, which provides that, "[n]otwithstanding anything contained in this Convention, a Party shall not be, or be deemed to be, precluded from adopting measures of control more strict or severe than those provided by this Convention." We therefore must consider whether the NIDA contract system may be viewed as resulting in a "more strict or severe" system of controls than one where the government physically possesses the marijuana crops and monopolizes their distribution. *See* State Mem. at 4–6.

Article 39 permits a party to the Single Convention to impose substitute measures that result in tighter controls than those otherwise required. *See Commentary* at 449. But as the *Commentary* explains, such "substitute measures should *clearly* be 'more strict or severe' to prevent any . . . doubts" about their validity. *Id.* (emphasis added). As examples of "[p]ermissible substitute controls," the *Commentary* identifies "the prohibition

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chase cannabis stocks from the national cannabis agency that purchases and takes physical possession of the marijuana crop grown by licensees. *See Commentary* at 284.

of manufacture of and trade in certain drugs instead of subjecting them to a system of licensing, or the imposition of the death penalty in place of 'imprisonment or other penalties of deprivation of liberty.'" *Id*. at 449–50.

The close regulation of the National Center is not clearly more strict or severe than the controls in Articles 23 and 28. The Office of the Legal Adviser points out that the NIDA contract, unlike the controls required by Article 23(2), addresses the risk of diversion during the cultivation process in addition to diversion that may occur after the crops are harvested. *See* State Mem. at 5; State Supp. Mem. at 1.[11] For example, the National Center must maintain its registration for working with scheduled drugs, 2015 NIDA Contract at 13, which requires certain security measures for manufacturing activities, *see, e.g.*, 21 C.F.R. § 1301.73(b) ("Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area.").

As effective as those contractually imposed diversion controls may be during marijuana *cultivation*, however, we cannot say that they clearly compensate for the absence of the required controls governing the *trade* in the crops, which the treaty drafters evidently believed posed greater risks of diversion. The controls required by Article 23 of the Single Convention reflect the specific concern that "experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels." *Commentary* at 278. The treaty drafters thus concluded that "the acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries." *Id*. The *Commentary* then explains that pursuant to Article 23 "[f]armers should be required to deliver the opium as soon as the Agency requests it, that is, is in a position to take physical possession of the crops of the cultivator concerned. . . . The Convention not only requires that the Agency should take physical possession of the

[11] The Office of the Legal Adviser suggests that DEA's framework is also stricter than required by the Single Convention because DEA establishes annual quotas for the National Center's marijuana production. *See* State Mem. at 1, 5. But those quotas not only indirectly implement the requirements in Article 23(2) for the national cannabis agency to designate the land on which cultivation is permitted, *see Commentary* at 281, but also directly implement Article 21 of the Convention, which requires parties to limit the annual quantity of drugs lawfully manufactured and imported. DEA's quotas are therefore not more strict or severe than the Single Convention otherwise requires.

opium, but also that it should 'purchase' it as soon as possible." *Id*. at 283. In other words, allowing the National Center, rather than the federal government, to distribute marijuana replicates in critical respects a system that the drafters rejected as inadequate, not one that they would have seen as "clearly more strict."

We also believe that reliance upon Article 39 here would be hard to reconcile with other provisions in the Single Convention that expressly provide parties with discretion to impose appropriate controls. For example, Article 28(3) gives parties discretion "to adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant."[12] *See also* Single Convention art. 2(8) (requiring parties to "use their best endeavours to apply . . . such measures of supervision as may be practicable" to substances that "may be used in the illicit manufacture of drugs"); *id*. art. 30(2)(b)(ii) (stating that parties should require that prescriptions for Schedule I drugs be written on official forms "[i]f the Parties deem these measures necessary or desirable"); *id*. art. 30(4) (stating that parties should require certain drug wrappings if the parties "consider[] such measure necessary or desirable"). Article 23 and the remaining provisions of Article 28, however, require a party to adopt very specific controls over the cultivation of marijuana (aside from the leaves of the plant) and do not give discretion to choose alternative means, simply because the party believes in good faith that the controls will accomplish the same purpose. Article 39 thus permits parties to depart from the specific controls mandated only where the alternatives are plainly more "strict or severe." The existing licensing scheme falls short of that standard.

C.

In considering the appropriate interpretation of the Single Convention, we have reviewed the statements and practice of the International Narcotics Control Board ("INCB"), the international body established by the Single Convention to monitor treaty compliance, which we understand has not objected to the United States' licensing scheme. While the interpretation of a body charged with monitoring treaty implementation may

[12] As noted above, the Single Convention's definition of cannabis does not include the leaves when unaccompanied by the top of the plant. Single Convention art. 1(1)(b). The CSA's definition of marijuana, by contrast, includes the leaves. 21 U.S.C. § 802(16).

sometimes help in resolving ambiguities in the treaty's text, such views are not authoritative interpretations of the treaty or legally binding on the United States or other parties.[13]

Here, the INCB's failure to object reveals little. The INCB's mandate does not require it to note every instance of noncompliance. Rather, the INCB is charged with identifying situations in which the Convention's aims "are being seriously endangered by reason of the failure of any Party, country or territory to carry out [its] provisions." Single Convention art. 14(1)(a). In fulfilling this mandate, the INCB has, for example, objected to "the legalization of the production, sale and distribution of cannabis for non-medical and non-scientific purposes in the states of Alaska, Colorado, Oregon and Washington." 2014 INCB Report at 25. But the fact that the INCB has not objected to the federal licensing scheme does not mean that the INCB views that framework as complying with the Single Convention.

Indeed, the INCB's interpretation of the Single Convention appears entirely consistent with ours. For instance, the INCB's 2014 annual report advises that "States wishing to establish programmes for the use of cannabis for medical purposes that are consistent with the requirements of the Single Convention must establish a national cannabis agency to control, supervise and license the cultivation of cannabis crops." *Id*. at 35. The national cannabis agency must "purchase and tak[e] physical possession of crops" and maintain "the exclusive right of wholesale trading and maintaining stocks." *Id*. While the INCB has not expressly objected to the United States' licensing scheme, it has "note[d] that the control measures in place under many existing programmes in different countries fall short of the requirements set out above." *Id*. at 36. We do not infer from the INCB's silence any affirmative approval of the existing licensing scheme or the licensing schemes of other countries.

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[13] *See INS v. Aguirre-Aguirre*, 526 U.S. 415, 427–28 (1999) (guidance issued by the Office of the UN High Commissioner for Refugees regarding the interpretation of the Refugee Convention "may be a useful interpretative aid, but it is not binding on the Attorney General, the [Board of Immigration Appeals], or United States courts"); Observations of the United States of America on the Human Rights Committee's Draft General Comment 35: Article 9, *2014 Digest of United States Practice in International Law* ch. 6, § A(2)(b), at 179 ("The United States believes the views of the Committee should be carefully considered by the States Parties. Nevertheless, they are neither primary nor authoritative sources of law.").

D.

We have also reviewed information about executive branch practice and the practice of other state parties to the Single Convention. As we have observed, the Executive Branch has long licensed the National Center to grow marijuana without having a single government agency purchase and take physical possession of the cannabis crops after harvest. A number of other state parties to the Single Convention apparently follow the U.S. practice. *See* State Mem. at 6–7; State Supp. Mem. at 3.

The practice of the Executive Branch and other state parties is relevant in treaty interpretation. Courts "find particularly persuasive a consistent pattern of Executive Branch interpretation, reflected in the application of the treaty by the Executive and the course of conduct of the parties in implementing the agreement." *Relevance of Senate Ratification History to Treaty Interpretation*, 11 Op. O.L.C. 28, 36 (1987) (citing *O'Connor v. United States*, 479 U.S. 27, 32–33 (1986)); *see also* Vienna Convention art. 31(3)(b) (noting that, "together with the context," treaty interpretation should take into account "[a]ny subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation"). The practices of a treaty's parties can also be useful evidence of the parties' "understanding of the agreement they signed." *United States v. Stuart*, 489 U.S. 353, 369 (1989); *see Medellín*, 552 U.S. at 507.

But as the Supreme Court has explained, "where the text [of a treaty] is clear . . . we have no power to insert an amendment." *Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122, 134 (1989) (holding that the text of the Warsaw Convention controlled where it could not "be dismissed as an obvious drafting error").[14] Here, Articles 23 and 28 clearly require that the United

[14] *See Water Splash*, 137 S. Ct. at 1511 ("[W]hen a treaty provision is ambiguous, the Court may look beyond the written words to the history of the treaty, the negotiations, and the practical construction adopted by the parties." (internal quotation marks omitted)); *Eastern Airlines, Inc. v. Floyd*, 499 U.S. 530, 534–35 (1991) (explaining that treaty interpretation begins "with the text of the treaty and the context in which the written words are used," while "[o]ther general rules of construction may be brought to bear on difficult or ambiguous passages" (internal quotation marks omitted)); *United States v. Jeong*, 624 F.3d 706, 711 (5th Cir. 2010) ("Only if the language of a treaty, when read in the context of its structure and purpose, is ambiguous may we resort to extraneous information like the history of the treaty, the content of negotiations concerning the treaty, and the practical construction adopted by the contracting parties." (internal quotation

States have a single government agency "purchase and take physical possession of" lawfully grown cannabis crops "as soon as possible, but not later than four months after the end of the harvest," Single Convention art. 23(2)(d), and that this agency thereafter "have the exclusive right of importing, exporting, wholesale trading and maintaining stocks" of marijuana, *id*. art. 23(2)(e).

In addition to the fact that the Single Convention is unambiguous, state practice does not appear to reflect a conclusive or consistent interpretation of the controls required. *See* Memorandum for Edwin Meese, III, Attorney General, from Charles J. Cooper, Assistant Attorney General, Office of Legal Counsel, *Re: Intent and Constitutionality of Legislation Prohibiting the Maintenance of an Office of the Palestine Liberation Organization in the United States* at 4 n.5 (Feb. 13, 1988) (declining to depart from the text of an international agreement based on inconclusive post-ratification practice). The Office of the Legal Adviser identifies Australia, Canada, Israel, and the United Kingdom as countries with similar licensing practices as the United States, in which the government agency does not purchase or take physical possession of the marijuana, but allows private growers to distribute it. State Supp. Mem. at 3. But the practices of a handful of the 186 parties to the treaty are entitled to comparatively little weight in illuminating the meaning of the treaty, and certainly do not supply the kind of subsequent practice that "establishes the agreement of the parties regarding its interpretation." Vienna Convention art. 31(3)(b).

In fact, the practice of parties regarding lawful marijuana cultivation is hardly unambiguous. In the Czech Republic, for example, the applicable legal regime requires licensed cannabis growers to "transfer cannabis grown and harvested . . . exclusively to the State Institute for Drug Control," which is instructed to "buy cannabis harvested within 4 months of its harvesting." On Dependency Producing Substances and on Amending Certain Other Acts, Act No. 167/1998 Coll. sec. 24b(1) (as amended). And a 2017 report on cannabis legislation in Europe states that in Italy, "[f]rom November 2015, the [Ministry of Health] can issue permits for

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marks omitted)); *Avero Belgium Ins. v. American Airlines, Inc*., 423 F.3d 73, 86 (2d Cir. 2005) (holding that secondary evidence of the parties' intent "may be useful where the intentions of the party States cannot be deduced by the treaty's plain language, but we need not rely upon such evidence here as the text of Montreal Protocol No. 4 is clear and, consequently, controlling" (internal citation omitted)).

cultivation" of cannabis and that "[l]icensed farmers deliver the cannabis to the ministry, which then allocates it for production." European Monitoring Centre for Drugs and Drug Addiction, *Cannabis Legislation in Europe: An Overview* 8 (2017).[15] Currently, it appears that the only authorized grower in Italy is the Italian Army, *see* Anna Momigliano, *In Italy, the Army Provides Medical Marijuana. And Some Say That's a Problem*, Wash. Post, Dec. 1, 2017, which would suggest that a single Italian government agency has physical possession of the crop and a monopoly on trade in cannabis, as the text of Articles 23 and 28 requires. There is also evidence that other parties to the Single Convention have established a single government agency to administer the controls required by Articles 23 and 28. *See, e.g.*, *Narcotic Drugs Act 1967*, Act No. 53/1967 (Cth) ch 2 pt 2 (as amended) (Austl.) (establishing marijuana licensing framework operated by the Department of Health); Report of the International Narcotics Control Board for 2005, at 16 (Mar. 1, 2006) (noting that "since the last report of the Board was published, the Government of the United Kingdom has established a national cannabis agency"); David Mansfield, *An Analysis of Licit Opium Poppy Cultivation: India and Turkey* 10–17 (Apr. 2001) (describing the regulation of opium in Turkey under the Grain Marketing Board and in India under the Central Bureau for Narcotics).

We find relevant as well the practice of countries that license private growers to cultivate the opium poppy and the coca leaf—both of which are subject to the same Article 23 regime as the cannabis plant.[16] The practice among countries that permit lawful production of those plants is consistent with the text of Article 23. In India, Turkey, and Peru, for

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[15] The report also describes the Netherlands' regime for medicinal cannabis, which provides that cannabis producers may be "licenced by the Dutch government and must sell all produce to the [Office of Medicinal Cannabis], which then distributes it to pharmacies." *Cannabis Legislation in Europe: An Overview* at 7. Although this regime appears to comply with the text of the Single Convention, the Netherlands has a separate regime for non-medical cannabis, pursuant to which it licenses coffee shops to sell small quantities of cannabis. The INCB has objected to this practice and noted that it "is in contravention of the provisions of the [Single] Convention." Report of the International Narcotics Control Board for 2001, at 35 (Feb. 27, 2002).

[16] Article 26 provides that Article 23 applies to licit cultivation of the coca leaf except that the government agency is not required to take physical possession of the crops within four months, but only "as soon as possible after the end of the harvest." Single Convention art. 26(1).

example, a government agency purchases and takes physical possession of those crops following the harvest.[17]

The Office of the Legal Adviser suggests that state practice with regard to opium may not be instructive as to marijuana because "[t]he vulnerabilities of the two plants" to diversion "are significantly different" owing to their different properties. State Mem. at 6. But the Single Convention's drafters recognized that "the conditions under which the cannabis plant is cultivated for the production of drugs are very different from those under which the opium poppy is grown for opium," and nonetheless "provide[d] the same regime for both, namely that of article 23." *Commentary* at 313.[18]

While state practice is therefore inconclusive, the Single Convention's drafting history would strongly support our interpretation of the text of Articles 23 and 28 even if the treaty were ambiguous. *See Water Splash*, 137 S. Ct. at 1511. An earlier draft of the Single Convention would have provided a less-stringent regime for cannabis than applicable to the coca leaf, under which a closely regulated private entity could grow marijuana. Under that draft, a "'licensed scientific institute'" would have been permitted to "'produce, manufacture, possess and export under close State supervision to the government of another Party small amounts of cannabis . . . for the purpose of scientific research.'" Memorandum for Malcolm R. Wilkey, Assistant Attorney General, Criminal Division, from Robert Kramer, Assistant Attorney General, Office of Legal Counsel, *Re: Constitutionality of Legislation to Carry Out Certain Provisions of Draft Single Convention on Narcotic Drugs* at 2–3 n.2 (Jan. 20, 1960) (quoting Article 39 of draft Single Convention). With regard to the coca leaf, however, the draft would have provided for the Article 23 system of controls. *See id.*

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[17] *See* Central Bureau of Narcotics, Licit Cultivation, http://www.cbn.nic.in/html/operationscbn.htm (last visited June 6, 2018) (explaining that licensed opium cultivators in India "are required to tender their entire produce to the Government"); Mansfield, *An Analysis of Licit Opium Poppy Cultivation* at 10–12 (describing the licensing and control measures for opium cultivation in Turkey, overseen by the Grain Marketing Board, which takes physical possession of crops); United Nations Office on Drugs and Crime, *Peru Coca Cultivation Survey* 8 (June 2005) (explaining that the National Coca Enterprise ("ENACO") "has a monopoly on the commercialization and industrialization of the coca leaves," such that "the selling of coca leaves to any party other than ENACO is considered illicit by national law").

[18] Indeed, the *Commentary* suggests that the regime for opium could, "in practice," prove to be inadequate to control cannabis production. *Commentary* at 313 n.9.

at 1–2 n.1 (quoting Article 36 of draft Single Convention). In other words, the Single Convention's drafters considered, but rejected, allowing licensed private institutions to produce, store, and ship marijuana under close government supervision, and instead adopted a requirement that the government take physical possession of the crop and conduct trade in the drug. That history also shows that the drafters of the Single Convention considered applying less-stringent controls to marijuana, but declined to do so and instead applied the same stringent controls to marijuana, opium, and the coca leaf.

III.

For similar reasons, DEA's 2016 policy statement also fails to establish a framework that would fully comply with Articles 23 and 28 of the Single Convention.

Under that policy, DEA would allow a licensee "to operate independently" of NIDA, "provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA." Applications To Manufacture Marijuana, 81 Fed. Reg. at 53,848. Such a licensee would also "be subject to all applicable requirements of the CSA and DEA regulations, including those relating to quotas, record keeping, order forms, security, and diversion control." *Id*. DEA suggests that these requirements would be consistent with the purposes of Articles 23 and 28 of the Single Convention because these requirements "will succeed in avoiding one of the scenarios the treaty is designed to prevent: Private parties trading in marijuana outside the supervision or direction of the federal government." *Id*.

While DEA focuses on its view of the broader purposes of the treaty's requirements, the Single Convention requires the United States to adopt specific, listed controls if it licenses cannabis cultivation. A single government agency must purchase and take physical possession of harvested cannabis, and generally monopolize the wholesale trade in that plant. The United States cannot satisfy those requirements simply by employing alternatives that the government believes may prevent unlawful diversion. As we have explained, Articles 23 and 28 certainly could have given the parties the discretion to determine the particular controls necessary. Rather than take that route, the parties to the treaty agreed to certain specific controls, and Congress has required the Attorney General to apply those strictures when granting licenses under the CSA. Accord-

ingly, DEA's licensing procedures must comply with those choices. DEA's announced policy, however, would not comply with Articles 23 and 28 of the Single Convention.

IV.

We conclude that DEA must alter the marijuana licensing framework to comply with the Single Convention. DEA has discretion to develop a regulatory framework that meets the requirements of Articles 23 and 28. In doing so, DEA need not rule out a regime in which DEA purchases or takes legal title to the marijuana plants prior to their cultivation; adopts a system of regulation and day-to-day supervision that would create an agency relationship; or relies upon NIDA's expertise to assist the agency in its functions. At a minimum, however, this licensing framework must provide for a system in which DEA or its legal agent has physical possession and ownership over the cultivated marijuana and assumes control of the distribution of marijuana no later than four months after harvesting.

In justifying the current licensing framework, DEA had concluded that the division of labor with NIDA was "a result of the existing statutes, regulations, and Congressional appropriations," and declined to opine on whether, absent legislation, DEA could carry out all the functions required by the Single Convention. Lyle E. Craker, PhD, 76 Fed. Reg. at 51,409–10. Having examined DEA's and NIDA's authorities, we do not believe that further legislation is required for DEA to perform those functions. DEA has statutory authority to do so pursuant to 21 U.S.C. § 823(a), which obliges DEA (by delegation from the Attorney General) to ensure that registrations for the manufacture of marijuana comply with the Single Convention. That language authorizes DEA to take steps reasonably necessary to ensure that the registration scheme complies with the Single Convention, which as we have said clearly contemplates that a single government agency will purchase and take physical possession of marijuana crops from registrants. The statute thus authorizes DEA to perform the control functions contemplated by the Single Convention, including the functions of purchasing (or otherwise securing title over) and taking physical possession of marijuana crops. Reading the statute otherwise would preclude DEA from registering any marijuana manufacturer because no registration could be in compliance with the Single Convention, contrary to Congress's evident intent that DEA administer the registration system. Congress has also established a fund for DEA's

diversion control program, which includes DEA activities "related to the *registration* and control of the manufacture, distribution, [and] dispensing . . . of controlled substances." 21 U.S.C. § 886a(2)(B) (emphasis added). Because Congress has made compliance with the Single Convention a necessary condition of registration, *id*. § 823(a), that fund may be used in purchasing, storing, and monopolizing the wholesale trade in marijuana. And although HHS has statutory authority to "determine the qualifications and competency" of the *researchers* who seek to purchase marijuana from licensed growers to conduct research, *id*. § 823(f), that provision would not bar DEA from establishing a government monopoly from which those researchers could purchase marijuana.

The NIDA contract is a longstanding feature of the marijuana licensing scheme, and the current version of that contract is annually renewable through March 2020. 2015 NIDA Contract at 27. Although DEA must discharge the obligations required by Article 23(2), NIDA may still play a significant role. The relevant statutes require that "[r]egistration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary [of Health and Human Services], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol." 21 U.S.C. § 823(f). The Single Convention does not require that a single government agency be charged with all responsibilities related to marijuana, and the congressional decision to delegate those responsibilities to HHS is consistent with the Single Convention. Aside from carrying out its role under section 823(f), NIDA may continue to exercise some supervision over certain aspects of the marijuana cultivation, and DEA may consult NIDA in the process. We see no reason why the NIDA contract framework might not remain in place under a system in which DEA assumes clear title to the marijuana, either at inception or by purchase after harvest, and then takes physical possession after harvest. For instance, DEA could station one or more employees at the National Center after cultivation as a way of ensuring physical possession of the marijuana and exclusive control over its distribution.

We would be pleased to advise on these or any other matters concerning implementation of a new licensing framework.

HENRY C. WHITAKER
Deputy Assistant Attorney General
Office of Legal Counsel

85 FR 16292-01, 2020 WL 1324198(F.R.)
PROPOSED RULES
DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Parts 1301 and 1318
[Docket No. DEA-506]
RIN 1117-AB54

Controls To Enhance the Cultivation of Marihuana for Research in the United States

Monday, March 23, 2020

AGENCY: Drug Enforcement Administration, Department of Justice.

***16292** ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing to amend its regulations to comply with the requirements of the Controlled Substances Act, including consistency with treaty obligations, in order to facilitate the cultivation of marihuana for research purposes and other licit purposes. Specifically, this proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and add provisions related to the purchase and sale of this marihuana by DEA.

DATES: Comments must be submitted electronically or postmarked on or before May 22, 2020.

ADDRESSES: To ensure proper handling of comments, please reference "[RIN 1117-AB54/Docket No. DEA-506]" on all electronic and written correspondence, including any attachments.

• Electronic Comments: DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the ***16293** online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• Paper Comments: Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152-2639.

• Paperwork Reduction Act Comments: All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB54/Docket No. DEA-506.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152-2639; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at http://www.regulations.gov. Such information includes personal identifying information (such as your name, address, etc.) that you voluntarily submit. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to http://www.regulations.gov may include any personal identifying information (such as your name, address, etc.) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at http://www.regulations.gov for ease of reference.

Background and Purpose of This Proposed Rule

Under the Controlled Substances Act (CSA), all persons who seek to manufacture a controlled substance must apply for and obtain a DEA registration.[FN1] 21 U.S.C. 822(a)(1). The CSA defines "manufacture" to include the "production" of a controlled substance, which includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. 21 U.S.C. 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marihuana [FN2] to supply researchers or for other uses permissible under the CSA (such as product development) must obtain a DEA manufacturing registration. Because marihuana is a schedule I controlled substance, applications by persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. 823(a). See generally 76 FR 51403 (2011); 74 FR 2101 (2009), pet. for rev. denied, Craker v. DEA, 714 F.3d 17 (1st Cir. 2013). Under section 823(a), for DEA to grant a registration, the DEA Administrator must determine that two conditions are satisfied: (1) The registration is consistent with the public interest (based on the enumerated criteria in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 ("Single Convention" or "Treaty"), 18 U.S.T. 1407.[FN3]

In 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marihuana for research purposes. See Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the provisions requiring consistency with obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed. The pertinent Treaty provisions are found in articles 23 and 28 of the Single Convention, which are summarized below. Additionally, DEA believes that these changes will enhance and improve research with marihuana and facilitate research that could result in the development of marihuana-based medicines approved by the Food and Drug Administration (FDA).

This proposed rule is being issued pursuant to the Administrator's authority under the CSA "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA]," 21 U.S.C. 871(b).

A. Relevant Provisions of the Single Convention

Because the terminology used in the Single Convention is somewhat different from that in the CSA, a brief explanation is warranted. The Single Convention uses the terms "cannabis," "cannabis plant," and "cannabis ***16294** resin"—all of which are generally encompassed by the CSA definition of "marihuana" in 21 U.S.C. 802(16)).[FN4] The Single Convention defines "cannabis plant" as "any plant of the genus Cannabis." Single Convention art. 1(1)(c). The Single Convention defines "cannabis" as the "flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted." Id. art. 1(1)(b). The Single Convention defines "cannabis resin" as the "separated resin, whether crude or purified, obtained from the cannabis plant." Id. art. 1(1)(d).

Article 28 of the Single Convention states in paragraph 1: "If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy." Paragraph 2 of that article excludes from the Convention the cultivation of cannabis for industrial or horticultural purposes. Because the United States permits the cultivation of marihuana for the production of cannabis and cannabis resin currently only for research purposes, it is obligated under the Treaty to apply to the marihuana plant cultivated for these purposes the "system of controls" provided in article 23 respecting the control of the opium poppy.

The Commentary to the Single Convention contains the following explanation of articles 23 and 28 within the overall framework of the Treaty:

The system of control over all stages of the drug economy which the Single Convention provides has two basic features: Limitation of narcotic supplies of each country . . . to the quantities that it needs for medical and scientific purposes, and authorization of each form of participation in the drug economy, that is, licensing of producers, manufacturers and traders . . . . In the case of the production of opium, coca leaves, cannabis and cannabis resin, this r´Egime is supplemented by the requirement of maintaining government monopolies for the wholesale and international trade in these drugs in countries which produce them . . . .

Secretary-General of the United Nations, Commentary on the Single Convention on Narcotic Drugs, 1961, 263 (1973) (emphasis added) (footnotes omitted).[FN5]

Article 23(2) of the Single Convention, made applicable to marijuana cultivation by Article 28, contains five requirements for the supervision, licensing, and distribution of marijuana.[FN6]

(a) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis or cannabis resin shall be permitted.

(b) Ensure that only cultivators licensed by the agency shall be authorized to engage in such cultivation.

(c) Ensure that each license shall specify the extent of the land on which the cultivation is permitted.

(d) Require all cultivators of the cannabis plant to deliver their total crops of cannabis and cannabis resin to the agency and ensure that the agency purchases and takes physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.

(e) Have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin, except that this exclusive right need not extend to medicinal cannabis, cannabis preparations, or the stocks of cannabis and cannabis resin held by manufacturers of such medicinal cannabis and cannabis preparations.[FN7]

DEA already directly performs functions (a), (b), and (c) by virtue of the CSA registration system as applied to manufacturers of marihuana. In order to ensure that DEA complies with the CSA and grants registrations that are consistent with relevant treaty provisions, namely articles 23 and 28 of the Single Convention, DEA proposes to directly perform functions (d) and (e) as well. This proposed rule would amend DEA's regulations so that DEA directly carries out these remaining two functions.

DEA also recognizes that the Department of Health and Human Services (HHS) has, for nearly 50 years, maintained an essential program aimed at ensuring that marihuana is available to meet the research and scientific needs of the United States. The regulations proposed here, if finalized, will require some changes to this program, but DEA is committed to ensuring that the National Institute on Drug Abuse (NIDA) program continues with minimal disruption and there is no impact on the availability of marihuana through the NIDA Drug Supply Program (DSP).

After the publication of the 2016 policy statement, DOJ advised DEA that it must adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single Convention. Therefore, the regulations being proposed herein, if finalized, would ensure that DEA regulations comply with applicable law. Within that framework, DEA is proposing changes to support using marihuana (including extracts and substances derived therefrom) cultivated in the United States to perform research which, among other things, may lead to the approval of FDA-approved medicines. Thus, the proposed rule, if adopted, would supersede the 2016 policy statement.

To address the foregoing considerations, the proposed rule would add regulations stating:

(1) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to DEA. DEA shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. DEA may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against diversion. In such cases, DEA shall designate a secure storage mechanism at the registered location in which DEA may maintain possession of the cannabis, and DEA will control access to the stored cannabis. If DEA determines that no suitable location exists at the registered location of the registered manufacturer authorized to cultivate cannabis, then DEA shall designate a location for the ***16295** authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in 21 CFR part 1301.

(2) DEA shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. DEA may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. DEA will require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with 21 CFR part 1312, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of DEA.

(3) A registered manufacturer authorized to grow cannabis shall notify DEA in writing of its proposed date of harvest at least fifteen days before the commencement of the harvest.

It should be noted that the timing of when DEA would take physical possession of the crops, if delayed, would not only increase the risk of diversion, but would also adversely impact the quality of the crop. Whereas DEA is proposing to take physical possession not later than four months from the time of harvest, it is DEA's intent to take physical possession as soon as possible and to distribute marihuana as soon as is practical to those who are authorized to receive it.

The exceptions made for "medicinal cannabis or cannabis preparations" also warrant explanation. In view of the text of the Single Convention, and taking into account the current wording of Federal law,[FN8] the regulations being proposed would define these terms as follows:

• Medicinal cannabis means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the Federal Food, Drug, and Cosmetic Act. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana.

• Cannabis preparation means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana.

Thus, under the proposed rule, DEA would have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana other than those held by DEA-registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Further, this exclusive right would not apply to medicinal cannabis or cannabis preparations.

To summarize those provisions of the proposed rule that are intended to ensure that registrations are granted in compliance with the CSA as the number of registered manufacturers increases, all marihuana grown by DEA-registered manufacturers in the United States would be delivered by such registrants to DEA no later than four months after the end of the harvest. Thereafter, DEA would authorize exportation, distribution, and maintenance of stocks of such marihuana with two important exceptions:

(1) DEA-registered manufacturers of (a) an FDA-approved marihuana-derived drug (i.e., "medicinal cannabis"), and (b) "cannabis preparations" would be permitted to maintain stocks of cannabis materials obtained from DEA for the purpose of producing such drugs or preparations; [FN9] and

(2) Once marihuana material that was previously purchased by DEA is subsequently converted by a DEA-registered manufacturer into (a) an FDA-approved drug ("medicinal cannabis") or (b) a "cannabis preparation," the material no longer would be subject to the foregoing exclusive right and could be further distributed or dispensed by a DEA registrant in any manner authorized under the CSA. DEA is committed to ensuring this new requirement is implemented in a manner that supports the policy goal of facilitating research involving marijuana and its chemical constituents.

B. Activities Performed by Bulk Manufacturers of Marihuana and the Application of These Proposed Regulations on Those Activities

Based on approximately 35 pending applications resulting from publication of its 2016 policy statement, DEA anticipates that those bulk manufacturers who would obtain a registration from DEA to grow marihuana would be one (or more) of three different types. In this section, DEA describes each type and how the proposed regulations, if finalized as proposed, would impact those registrants with regard to functions (1) and (2) described in the previous section.

(1) A Bulk Manufacturer Who Grows Marihuana for Its Own Research or Drug Development Purposes

A number of applicants seek to grow marihuana for their own research endeavors, including some who wish to develop an FDA-approved medicine from extracts or derivatives of the marihuana plant. Based on the accompanying information supplied by the applicant to DEA in connection with their application, these applicants would list themselves as a "purchaser," meaning that once their crop was harvested, they would seek to use the marihuana for their internal research purposes. Applicants must obtain a separate schedule I research registration from DEA to perform research with marihuana in accordance with 21 CFR 1301.13 and 1301.32. However, bulk marihuana growers may manufacture marihuana for use by other researchers under a manufacturing registration (and pursuant to a quota granted to them by DEA for that purpose under 21 CFR 1303.21(a)).

For applicants within this category, within four months of harvest, DEA would travel to the DEA-registered location, purchase, and take title to the crop by issuing the grower a DEA Form 222.[FN10] Once DEA has taken title to the ***16296** crop, it would then distribute a quantity of marihuana that does not exceed the company's DEA-issued procurement quota back to that same manufacturer. In this way, DEA would take physical possession of the crop and control its distribution. Additionally, the material owned by the government will be maintained at the DEA-registered manufacturer's location and DEA would maintain its ability to access the storage location at which such crops are located as it deemed necessary.

(2) A Bulk manufacturer Who Supplies Marihuana to Other DEA Registrants, Including National Institutes of Health Funded and Non-National Institutes of Health Funded Researchers

Some applicants are seeking to grow marihuana for use by other DEA registrants including "non-bulk" manufacturers and schedule I researchers, including National Institutes of Health (NIH) funded and non-NIH funded researchers. This sub-set of bulk manufacturers would be required to obtain from each customer a bona fide supply agreement, listing the name and address of the end user, the end user's DEA registration number, the quantity of marihuana to be supplied, and the price that the end user and grower have mutually agreed upon. DEA will consider this information, along with additional information, when establishing an individual manufacturing quota for the grower.

For applicants that fall within this sub-set, within four months of harvest, DEA would travel to the DEA-registered location, purchase, and take title to the crop by issuing the grower a DEA Form 222.[FN11] For this reason, each grower must provide written notice to DEA of its proposed date of harvest at least fifteen days prior to the commencement of the harvest. Once DEA has purchased and taken title to the crop, the material would be maintained, under seal, in DEA's possession in the manufacturer's schedule I vault until such time that a distribution is necessary. In this scenario, DEA may distribute (or export) the marihuana directly or may choose to authorize the grower to distribute marihuana on the government's behalf. Again, marihuana owned by the government is maintained at the DEA-registered manufacturer's site where DEA would maintain its ability to access the storage location at which such crops are located as it deemed necessary.

(3) A Bulk Manufacturer Who Supplies Marihuana To Support NIDA's Drug Supply Program

Over the last several decades, NIDA has administered a contract to produce high quality marihuana for use by researchers who have obtained federal funding (grants) for such research.[FN12] This contract has been awarded to the National Center for Natural Products Research at the University of Mississippi (National Center). In accordance with that contract and DEA regulations, NIDA assesses the quantity of marihuana that is necessary to be grown for research purposes in a given year and communicates that information to both the National Center and DEA. The National Center applies for, and must first obtain, a manufacturing quota from DEA and is then authorized to grow marihuana up to the limit established by their DEA-issued quota. At the time of harvest, a portion of that material is held in inventory at the National Center while other portions are distributed to another DEA registrant, Research Triangle Institute (RTI). Currently, at the direction of NIDA, both RTI and the National Center may prepare marihuana in a manner which is suitable for research studies and ship it to researchers. In these instances, marihuana held in inventory at the National Center and RTI are the property of NIDA. The regulations proposed in this notice of proposed rulemaking (NPRM) are intended to enhance and improve upon existing DEA regulations that supported the NIDA DSP and will facilitate research that may lead to the development of FDA-approved medicines.

This regulation, if finalized, would require changes to the current scheme described above. Although NIDA can, and would, continue to administer the contract in support of its DSP and the National Center (or other NIDA contract holder) could continue to grow and produce marihuana in support of research pursuant to that contract (for as long as that contract is renewed), within four months of harvest, DEA would travel to the National Center at the time of harvest and take title and possession to the crop by issuing the National Center a DEA Form 222.[FN13] Once DEA has taken title and possession of the crop, the material would be maintained, under seal, in DEA's possession in the National Center's schedule I vault until such time that a distribution to another DEA registrant is authorized. In this scenario, DEA may distribute (or export) the marijuana directly or may choose to authorize the National Center to distribute marihuana on the government's behalf. In both situations, DEA's distributions would be in accordance with NIDA's recommendation. And, as such, DEA does not envision a scenario in which it would deny

or delay a distribution to a duly registered schedule I researcher authorized to handle marihuana. Marihuana owned by DEA would be maintained at the National Center, where DEA would maintain its ability to access the storage location at which its crops are located.

C. Application of the Public Interest Factors

As indicated, in addition to the foregoing treaty considerations, DEA may grant a registration to manufacture a schedule I or II controlled substance only where the Administrator determines that the registration is consistent with the public interest, based on the criteria listed in 21 U.S.C. 823(a). The first of those criteria, set forth in subsection 823(a)(1), provides that, for the purpose of maintaining effective controls against diversion, the number of registered bulk manufacturers of a given schedule I or II controlled substance should be limited to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions.[FN14]

The proposed rule would explain how DEA will evaluate whether a particular application is consistent with the public interest factors of 21 U.S.C. 823(a), including factor 823(a)(1). As discussed above, a bona fide supply agreement between a grower and a duly registered schedule I researcher or manufacturer provides evidence that an applicant's registration is necessary to produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions. An applicant proposing to grow marihuana to supply its own research may also be deemed to have satisfied the public interest factor of 823(a)(1) upon the presentation of evidence that it possesses a registration to conduct research with marihuana under 21 CFR 1301.32. Such a researcher will only be granted quota to ***16297** the extent authorized by its approved research protocol.

The proposed rule further provides that the Administrator's determination of which applicants to select will be consistent with the public interest factors in section 823(a), with particular emphasis on the criteria discussed in the preceding paragraph as well as the following:

(1) The applicant's ability to consistently produce and supply marihuana of a high quality and defined chemical composition; and

(2) Whether the applicant has demonstrated prior compliance with the CSA and DEA regulations.

The preceding criteria are designed to result in registration of those manufacturers of marihuana that can most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality.[FN15] These criteria are further aimed at selecting applicants that can be entrusted with the responsibility of a DEA registration and complying with the corresponding obligations under the CSA and DEA regulations.

As indicated above, following the publication of the 2016 policy statement, DEA received numerous applications by persons seeking to become registered as bulk manufacturers of marihuana. There are approximately 35 such applications currently pending. As explained above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. In consultation with HHS, DEA wishes to avoid a situation in which the agency is in the midst of evaluating these applications and has to begin an evaluation anew each time it accepts a new marihuana grower application for filing. Thus, the proposed rule provides that, with a limited exception, applications accepted for filing after the date the final rule becomes effective will not be considered pending until all applications accepted for filing on or before the date the final rule becomes effective have been granted or denied by the Administrator.

D. Consideration of the Amendments to the CSA Made by the Hemp Provisions of the Agriculture Improvement Act of 2018

The Agriculture Improvement Act of 2018 (AIA), Public Law 115-334, which became effective December 20, 2018, contained various provisions regarding the cultivation of hemp. The AIA definitions hemp as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

7 U.S.C. 1639*o*(1). The AIA amended the CSA definition of marihuana to exclude hemp. Thus, anything that falls within the foregoing definition of hemp is no longer a controlled substance, and the CSA's requirements no longer apply to such substances. Accordingly, this proposed rule would apply only to persons seeking authorization under the CSA (i.e., seeking a DEA registration) to manufacture marihuana that involves the planting, cultivation, growing, or harvesting of marihuana as that term is currently defined in the CSA (21 U.S.C. 802(16)).[FN16]

E. Factors Affecting Prices for the Purchase and Sale of Marihuana by DEA

As stated above, under articles 23 and 28 of the Single Convention, the government agency must—in addition to taking physical possession—purchase all lawfully grown cannabis crops within four months of harvest. Thus, under the proposed rule, DEA will purchase marihuana grown by DEA-registered manufacturers and subsequently sell the marihuana to DEA registrants who seek to acquire it for research, product development, or other lawful purposes under the CSA.

In purchasing such marihuana, DEA intends to use the Diversion Control Fee Account, as established in 21 U.S.C. 886a. Thus, DEA would, under the proposed rule, need to take into account its obligation under 21 U.S.C. 886a(1)(C) to charge fees under its diversion control program "at a level that ensures the recovery of the full costs of operating the various aspects of that program." There are two potential categories of fees that could be used to recover the costs of carrying out the proposed new aspects of the diversion control program relating to cannabis: (1) Fees charged to persons who apply for, and seek to renew, a DEA registration to manufacture marihuana, and (2) fees charged for the sale of marihuana by DEA.

DEA believes that economic forces will not only drive the types, varieties and strains of marihuana materials that will be produced by growers, but that such forces will also drive the fees that DEA-registrants will be willing to pay for marihuana used for research purposes. Accordingly, DEA proposes to allow market forces to direct prices for marihuana grown by the manufacturer and purchased by DEA. As we have stated elsewhere in this proposal, DEA will establish limits on individual production based on bona fide supply agreements between the grower and the end user (a DEA registered manufacturer or a schedule I researcher). Accordingly, DEA will use these terms as the basis for purchasing marijuana from the grower and additionally, for the basis by which it will sell that same marihuana to an end user.

In addition to that negotiated fee, DEA is proposing to add a variable administrative cost (per kilogram (kg)) which it intends to add onto the sales price of the marihuana it sells to end users. The purpose of this administrative fee is to ensure the full recovery by DEA of the costs of administering the program as required by 21 U.S.C. 886a(1)(C). DEA will calculate this variable cost annually by taking the preceding fiscal year's cost to operate the program and dividing it by the quantity in kg of the manufacturing quota for marihuana issued during the current quota year. For example, based on the economic analysis provided below, DEA would calculate an administrative fee of $304 per kg for marihuana distributed to end users. The calculation below is illustrative:

Variable Administrative Fee = $607,644/2,000 kg = $304 per kg [FN17]

DEA proposes to establish this fee no less than annually and proposes to publish this rate on its website by December 15th of the year preceding the year in which the administrative fee will be collected.

***16298 Regulatory Analyses**

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles,

structures, and definitions governing regulatory review established in Executive Order 12866. Section 3(f) of Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

DEA has determined that, although this proposed rule is not economically significant, it is a significant regulatory action under section 3(f) of Executive Order 12866, thus subjecting it to review by OMB.

I. Need for the Rule

This rule is needed to ensure that DEA complies with the CSA and grants registrations that are consistent with relevant treaty provisions as DEA seeks to increase the number of registered growers of marihuana. Specifically, this proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and add provisions related to the purchase and sale of this marihuana by DEA. These amendments will ensure that DEA carries out all five functions under Article 23 and Article 28 of the Single Convention pertaining to marihuana, thus facilitating the planning and coordinated management of marihuana production necessary as the number of registered marihuana manufacturers increases.

II. Alternative Approaches

This proposed rule would amend DEA regulations only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana. In areas where DEA has discretion, such as in setting a fee structure to recover the cost of this proposed rule, alternative approaches would be discussed. However, because DEA does not have sufficient information at this time to discuss alternatives for either the future registration fees or the fees for the sale of marihuana, the alternative approaches for such provisions are not included in this proposed rule. Consistent with past agency practice, any proposed changes to registration fees will be the subject of a separate rulemaking proceeding, including a discussion of alternative approaches.

III. Analysis of Benefits and Costs

There are two key benefits associated with this proposed rule. First, DEA believes it is possible that the approval of new growers may increase the variety (quality, potency, etc.) of bulk marihuana for research, leading to more effective research and potentially resulting in the development of FDA-approved drug products. Second, this rule would ensure that DEA's regulations comply with the requirements of the CSA by granting registrations that are consistent with the Single Convention relating to marihuana. DEA is unable to quantify these benefits at this time.

DEA analyzed the costs of this proposed rule and estimates an annual cost of $607,644. The details of the analysis are below.

This proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and add provisions related to the purchase and sale of this marihuana by DEA. If this proposed rule is promulgated, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes would mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights would not extend to medicinal cannabis or cannabis preparations. The changes described above would affect three primary groups of entities: Growers and prospective

growers, the authorizing agencies,[FN18] and purchasers (generally medical and scientific researchers). To examine the impact of the proposed rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

Current System

Under current regulations, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.[FN19] The National Center has designated a secure plot of land or indoor grow facility where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[FN20] NIDA obligated approximately $1.5 million in Fiscal Year 2015 under this contract.[FN21] This amount included costs unrelated to growing and cultivating marihuana, such as extracting chemical components and producing marihuana cigarettes and other marihuana-related material. However, based on recent discussion with NIDA,[FN22] DEA estimates NIDA's expenses under the contract with the National Center (and any related ***16299** subcontracts) for the bulk marihuana for 2019 are approximately $2.9 million.[FN23] The $2.9 million includes compensation for the cultivating and the 2019 manufacturing quota (MQ) of 2,000 kgs for NIDA (National Center) as well as all other duties required in the contract.[FN24]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is currently available at no cost to research investigators supported by a NIH grant. Marihuana is also available to research investigators who are funded through non-federal sources. Although NIDA considered charging for marihuana on a "cost-reimbursement basis," [FN25] the current policy is to provide the marihuana at no charge.[FN26]

Changes to Growers

If this proposed rule is implemented, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. As explained earlier in this document, the CSA imposes limitations on the number of registrations that DEA may issue to bulk manufacturers of a given schedule I or II controlled substance. In addition, in deciding whether to grant an application for any such registration, the CSA requires DEA to consider the other public interest factors of 21 U.S.C. 823(a), which must be evaluated on an applicant-by-applicant basis. Further, DEA cannot accurately predict in advance which particular applications will be granted, or how many. Accordingly, DEA is unable to accurately estimate the number of registered bulk marihuana growers. As a result, to allow for this analysis, DEA will estimate the economic impact of this proposed rule under two different hypothetical scenarios, the first in which the number of growers expands to three growers, and the second in which the number of growers expands to 15 growers. It should be understood that this range of potential registrants is not necessarily reflective of the actual number of applications that DEA will grant.

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[FN27] Since the publication of the 2016 policy statement, DEA has received approximately 35 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of 3 to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The Aggregate Production Quota (APQ), which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[FN28] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and the reimbursement of production cost through sales) is transferred from the single incumbent grower to new growers. This means that there is only

a transfer of economic activity rather than any new cost. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[FN29]

Transitioning from one large grower to multiple growers may introduce inefficiencies, driving up production or facility costs. Some growers may introduce more costly growing techniques to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down costs. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. In particular, one of the goals of this new rule is to enhance marijuana availability for product development, which may have the effect of increasing the MQ. However, DEA does not have a basis to estimate the impact of these possibilities. Therefore, for the purposes of this analysis, DEA estimates that an increase in the number of approved growers does not impact the MQ. In summary, there is no new cost to growers.

Changes to Authorizing Agencies—Cost to DEA

DEA anticipates that there will be a transfer of economic activity from NIDA to DEA as well as several new costs as a result of this rule. This analysis should in no way be construed as a proposal to modify agency funding or funding sources.

As discussed above, assuming a constant MQ for bulk marihuana of 2,000 kgs, DEA estimates the cost of all the activities the National Center performs under its contract with NIDA and the purchase of the entire aggregate crop, regardless of the number of growers, is $2.9 million. This $2.9 million is not a new cost; it is a transfer. Rather than NIDA paying the current single grower, DEA would pay the multiple new growers. In practice, DEA anticipates crops from multiple growers will be purchased at different times of the year, allowing funds from sales of earlier purchases to pay for subsequent purchases. Therefore, to purchase and distribute $2.9 million in bulk marihuana, a working capital of a lesser amount is likely needed. However, due to many unknowns and to be conservative, for the purposes of this analysis, the estimated transfer and working capital requirement is $2.9 million.

DEA anticipates incurring new costs associated with the following activities: Taking title to the crops and employing personnel to administer the program. The growers, purchasers, and DEA would already understand prior to growing and harvesting, the quantities of marihuana to be distributed and to whom the distribution would be made because the bona fide supply agreements presented during the registration application process would provide such information. In most instances, DEA is expected to purchase and take title to the crop, then sell and distribute the crop to the purchaser on the same day at the grower's registered location. For the purposes of this analysis, DEA assumes the following process:

1. After marihuana is harvested and prepared for delivery to DEA, the registered manufacturer will contact ***16300** DEA to inform it that the marihuana is ready for collection.

2. Within a reasonable timeframe, but in no event later than four months after the harvest, DEA will purchase and take title to the marihuana. Two DEA Special Agents (or Deputized Task Force Officers) from the nearest local DEA field office will drive an estimated 100 miles (200 miles roundtrip) to the registered manufacturer to take title. Any marihuana that is not immediately distributed is stored in a designated secure storage mechanism at the grower's registered location for later distribution. The number of trips by the two DEA Special Agents equals the number of harvests.

3. For marihuana distributed from storage at the grower's registered location, the grower distributes marihuana on DEA's behalf. If DEA deems it necessary to be present at such distribution, the distribution is scheduled to coincide with DEA's visit to take title to the next crop, requiring no additional trips by DEA to the grower.

4. Each grower has three harvests, requiring DEA to collect three times per year per grower.

For each collection, DEA estimates $2,071 of labor cost [FN30] and $116 of vehicle cost [FN31] for a total of $2,187 per collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA

believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of $2,187 per collection, DEA estimates a transport cost of $19,683 and $98,415 for scenarios with three and 15 growers, respectively.

Additionally, DEA anticipates it would need additional personnel resources to operate this program. There are many unknowns and no decisions have been made on hiring. However, for the purposes of this analysis, DEA estimates three full-time-equivalent (FTE) professional staff in the Diversion Control Division would be needed, consisting of one FTE diversion investigator (DI), and two FTE professional/administrative (PA) resources.

Applying the fully loaded annual cost of $211,981 per DI and $168,307 per PA, the estimated total cost of the three FTE employees is $548,595. For the purposes of this analysis, this cost does not vary with the number of growers. Table 1 below summarizes the costs associated with increased staffing.

Table 1—Cost of Personnel Resources

Position	Job category	Modular cost/unit cost ($)	Number of FTEs	Cost ($)
Staff Coordinator	DI	211,981	1	211,981
Program Analyst	PA	168,307	2	336,614
Total	N/A	N/A	3	548,595

In summary the estimated cost to DEA is:

• $19,683 or $98,415 per year to purchase and take title to the bulk marihuana for scenarios with 3 or 15 authorized growers, respectively;

• $548,595 per year for three DEA FTE employees;

• The estimated total annual cost is $568,278 with three growers and $647,010 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is $607,644. Table 2 summarizes the costs.

Table 2—DEA Cost Summary

	Low ($)	High ($)		Average ($)
Transport Cost	19,683	98,415	N/A	
Personnel Cost	548,596	548,595	N/A	
Total Cost	568,278	647,010		607,644

Changes Affecting Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that some researchers would acquire the bulk marihuana from DEA, rather than from NIDA. As discussed earlier, the only new cost associated with this proposed regulation is the cost to DEA of $607,644, an average of high and low scenarios, which would be recovered by adding an administrative fee of $304 per kg. As discussed earlier, the administrative fee would be adjusted annually.

While the purchaser would purchase marihuana from DEA, this rule does not in any way affect the purchaser's source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase. In particular, NIH has long served as a third-party funder for research through grants, including grants to researchers studying marihuana. Nothing in this rule prohibits NIH from continuing to fund such research by continuing to cover the cost of marihuana materials ***16301** used in research, via grants to researchers.

Cost Summary

DEA estimates the cost of producing the 2019 MQ for bulk marihuana of 2,000 kgs and operating NIDA's marihuana DSP is $2.9 million per year. Under the proposed rule, DEA anticipates more bulk marihuana producers would be approved. DEA estimates the $2.9 million in economic activity would be transferred across multiple growers, without introducing new costs.

DEA's purchase of bulk marihuana is not a new cost (to the economy); it is a transfer from NIDA to DEA. However, $568,278 to $647,010 in operating costs would be incurred by DEA. DEA will recover the costs of carrying out the proposed new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis.

The net present values (NPVs) of the low cost estimate of $568,278 per year over 10 years are $4.8 million and $4.0 million at a three percent discount rate and 7 percent discount rate, respectively. The NPVs of the high cost estimate of $647,010 over 10 years are $5.5 million and $4.5 million at a three percent discount rate and seven percent discount rate, respectively. The average of the estimated low and high costs is $607,644. The NPVs of the average of $607,644 over 10 years are $5.2 million and $4.3 million at three percent and seven percent discount rates, respectively. Table 3 summarizes the estimated annual effect and NPVs calculation for each of the transfers and the three scenarios.

Table 3—Summary of Annual Effect and NPVs

	Annual effect ($)	NPVs at 3% ($M)	NPVs at 7% ($M)
Cost (Low)	568,278	4.8	4.0
Cost (Average)	607,644	5.2	4.3
Cost (High)	647,010	5.5	4.5

***Executive Order 13771** (Reducing Regulation and Controlling Regulatory Costs)*

This proposed rule is expected to be a deregulatory action for the purposes of Executive Order 13771. The rule is an enabling rule which, coincidentally with other provisions, expands the number of authorized bulk marihuana growers.

Executive Order 12988 (Civil Justice Reform)

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens on regulated parties and the court system.

Executive Order 13132 (Federalism)

This proposed rule does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless the agency can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and a discussion of its findings is below.

As discussed in the section of this proposed rulemaking relating to Executive Orders 12866, 13565, and 13771, this proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, and add provisions related to the purchase and sale of this marihuana by DEA. If this proposed rule is promulgated, the following key changes are anticipated: More persons will be authorized to grow marihuana; DEA will purchase and take physical possession of crops; and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes, as explained above, would mean that authorized purchasers of bulk marihuana may only purchase from DEA, except that DEA's exclusive right would not extend to medicinal cannabis or cannabis preparations as these terms are defined in paragraphs (b) and (c), respectively, of proposed § 1318.02 of this proposed rule.

The changes described above would affect three primary groups of entities: Growers and prospective growers, the authorizing agencies (including NIDA and DEA), and purchasers (generally researchers). Because any economic impact on federal agencies is outside the scope of the RFA, the transfer of economic activity between the agencies is excluded from this discussion. To examine the impact of the proposed rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the two affected non-federal groups: Growers (bulk manufacturers of marihuana) and researchers.

Current System

Under current regulations, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for ***16302** use in research studies.[FN32] The National Center designates a secure plot of land where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[FN33] As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 are approximately $2.9 million.[FN34] The $2.9 million includes compensation for the cultivating and the 2019 MQ of 2,000 kgs for NIDA as well as all other duties required in the contract.[FN35]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marihuana is also available to research investigators who are funded through non-federal sources. Although NIDA considered charging for marihuana on a "cost-reimbursement basis," [FN36] the current policy is to provide the marihuana at no charge.[FN37]

Impact on Growers

If this proposed rule is implemented, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[FN38] Since the publication of the 2016 policy statement, there are approximately 35 pending applications for registration as bulk manufacturer of marihuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacture and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this proposed rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[FN39] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and reimbursement of their production cost through sales) is transferred from the incumbent grower to new growers. This means that there is no new cost; instead, there is only a transfer of economic activity. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[FN40]

Transitioning from one large grower to multiple smaller growers may reduce production efficiency, driving up cost. Some growers may introduce more costly growing techniques in order to produce certain traits. Alternatively, some growers may introduce more efficient growing methods, driving down cost. Additionally, having more growers may spur more demand in bulk marihuana for research, pushing up the MQ. However, DEA does not have a basis to estimate the impact of these possibilities.

Impact on Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that the researcher would acquire the bulk marihuana from DEA, rather than from NIDA or the National Center. As discussed earlier, the only new cost associated with this proposed regulation is the cost to DEA of $607,644, which would be recovered by adding an administrative fee of $304 per kg. As discussed earlier, the administrative fee would be adjusted annually. While purchasers would purchase marihuana from DEA, this rule does not in any way affect the purchasers' source of funds to purchase from DEA. If marihuana for research is funded by a third party, the researcher may not experience any cost increase.

Affected Number of Small Entities

This proposed rule affects the current and prospective bulk manufacturers of marihuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this proposed rule. Additionally, based on a discussion with NIDA,[FN41] DEA estimates 40 researchers are affected by this proposed rule. The 40 researchers represent the approximate number of researchers that receive marihuana from NIDA's marihuana DSP.

Based on a review of representative North American Industry Classification System (NAICS) codes for bulk manufacturers and researchers, the following number of firms may be affected: [FN42]

• 421 firms related to 'Medicinal and Botanical Manufacturing' (325411) [FN43]

• 9,634 firms related to 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) [FN44]

The United States Small Business Administration (SBA) sets size standards that determine how large an entity can be and still qualify as a small business for federal government programs. For the most part, size standards are based on the average annual receipts or the average number of employees of a firm. The SBA size standard for both industries identified by the NAICS codes above is 1,000 employees.[FN45]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates ***16303** the following number of small entities and percent of firms that are small entities by industry:

• 392 (93.1 percent of total) firms in the area of 'Medicinal and Botanical Manufacturing' (325411)

• 9,090 (94.4 percent of total) firms in the area of 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712)

Table 4 details the calculation for the number of small entities by industry.

Table 4—Number of Small Entities by Industry

NAICS description	Firm size by average employees	Firms	SBA size standard	Small entities	% Small entities
325411—Medicinal and Botanical Manufacturing	<500	384	1,000	384	100
	500-749	3		3	100
	750-999	5		5	100
	1,000-1,499	6		.....	0
	1,500-1,999	2		.....	0
	2,000-2,499	1		.....	0
	2,500-4,999	7		.....	0
	5,000+	13		.....	0

Total		421		392	93.1
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	<500	8,972	1,000	8,972	100
	500-749	68		68	100
	750-999	50		50	100
	1,000-1,499	70			0
	1,500-1,999	40			0
	2,000-2,499	35			0
	2,500-4,999	132			0
	5,000+	267			0
Total		9,634		9,090	94.4

Applying the calculated respective percentage for small entities to the number of affected bulk manufacturers and researchers, DEA estimates 14 (15 x 93.1 percent) bulk manufacturers and 38 (40 x 94.4 percent) researchers, for a total of 52 small entities, will be affected by this proposed rule. The 14 affected small entity bulk manufacturers represent four percent of the estimated 392 small entities in the 'Medicinal and Botanical Manufacturing' (325412) industry, and the 38 affected small entity researchers represent 0.4 percent of the estimated 9,090 small entities in the 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) industry. Table 5 summarizes the calculations for the percentage of small entities that are affected by the proposed rule.

Table 5—Percent of Small Entities Affected by Industry

NAICS description	Number of firms	SBA size standard	Estimated number of small entities	Estimated number of affected small entities	Percentage of small entities affected
325411—Medicinal and Botanical Manufacturing	421	1,000	392	14	4
541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)	9,634	1,000	9,090	38	0.4
Total	10,055	N/A	9,482	52	N/A

DEA generally uses a threshold of 30 percent as a "substantial" number of affected small entities. Thus, the above analysis reveals that a non-substantial amount of small bulk manufacturer entities (4 percent) and of small researcher entities (0.4 percent) will be affected by this proposed rule.

DEA generally considers impacts that are greater than three percent of annual revenue to be a "significant economic impact" on an entity. As discussed earlier, DEA estimates that there will be a new cost to DEA of $568,278 to $647,010 per year, or the average of the high and low estimates of $607,644 per year. DEA will recover the costs of carrying out the proposed new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis. Based on the average of the high and low estimates of $607,644 and MQ of 2,000 kgs, the administrative fee is $304 per kg, adjusted annually.

Furthermore, NIH-funded or other third-party funded researchers are likely to request and receive enough funding ***16304** for the full price of marihuana, including the administrative fee. There would be no impact to these researchers. However, DEA does not have sufficient information to estimate the number of small entity researchers that would fall under this category. Although DEA is unable to quantify the economic impact for the estimated 14 small entity bulk manufacturers and 38 small entity researchers, the number of affected small entity manufacturers and researchers is not a substantial number of small entities in their respective industries.

Based on the analysis above, and because of these facts, DEA believes this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., DEA has determined that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." See 2 U.S.C. 1532(a). Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., DEA has identified the following collections of information related to this proposed rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at https://www.reginfo.gov/.

A. Collections of Information Associated With the Proposed Rule

Title: Application for Registration (DEA Form 225); Renewal Application for Registration (DEA Form 225A); Affidavit for Chain Renewal (DEA Form 225B).

OMB control number: 1117-0012.

Form numbers: DEA-225, DEA-225A, DEA-225B.

Type of information collection: Revision of a currently approved collection.

Applicable component of the department sponsoring the collection: Department of Justice/Drug Enforcement Administration, Diversion Control Division.

Affected public who will be asked or required to respond: Business or other for-profit.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, or conduct research and laboratory analysis with controlled substances to register with DEA. 21 U.S.C. 822; 21 CFR 1301.11,

1301.13. Registration is a necessary control measure that helps to detect and prevent diversion by ensuring that the closed system of distribution of controlled substances can be monitored by DEA, and that the businesses and individuals handling controlled substances are accountable.

If adopted, this proposed rule would amend the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and add provisions related to the purchase and sale of this marihuana by DEA. Persons seeking to become registered with DEA to grow marihuana as bulk manufacturers would still apply for registration using the same DEA Form 225 as other bulk manufacturers, but DEA would use a new supplemental questionnaire unique to marihuana manufacturers in order to gather additional information about applicants. There would also be new questionnaires used for importer applicants and non-marihuana bulk manufacturer applicants. Forms 225, 225A, and 225B would all receive minor revisions to improve clarity and usability for registrants.

DEA estimates the following number of respondents and burden associated with this collection of information:

• Number of respondents: 15,919.

• Frequency of response: 1 per respondent per year.

• Number of responses: 15,919.

• Burden per response: 0.1304 hours.

• Total annual burden in hours: 2,076.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the Federal Register with the notice of proposed rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), DEA solicits comment on the following issues:

• Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information shall have practical utility.

• The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

• Recommendations to enhance the quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB54/Docket No. DEA-506. All comments must be submitted to OMB on or before May 22, 2020. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152-2639; Telephone: (571) 362-3261.

List of Subjects

21 CFR Part 1301
Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1318
Administrative practice and procedure, Drug traffic control.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR chapter II as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.
21 CFR § 1301.33

2. In § 1301.33, revise paragraph (c) and add paragraph (d) to read as follows:
21 CFR § 1301.33

§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

* * * * *

***16305** (c) Except as provided in paragraph (d) of this section, this section shall not apply to the manufacture of basic classes of controlled substances listed in Schedule I or II as an incident to research or chemical analysis as authorized in § 1301.13(e)(1).

(d) An application for registration to manufacture marihuana that involves the planting, cultivating, growing, or harvesting of marihuana shall be subject to the requirements of this section and the additional requirements set forth in part 1318 of this chapter.

3. Add part 1318 to read as follows:

PART 1318—CONTROLS TO SATISFY THE REQUIREMENTS OF THE ACT APPLICABLE TO THE MANUFACTURING OF MARIHUANA

Sec.

Authority: 21 U.S.C. 801(7), 821, 822(a)(1), (b), 823(a), 871(b), 886a.
21 CFR § 1318.01

§ 1318.01 Scope of this part.
Procedures governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana are set forth by this part.
21 CFR § 1318.02

§ 1318.02 Definitions.
(a) Except as provided in paragraph (e) of this section, the term cannabis means any plant of the genus Cannabis.

(b) Except as provided in paragraph (e) of this section, the term medicinal cannabis means a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act.

(c) Except as provided in paragraph (e) of this section, the term cannabis preparation means cannabis that was delivered to the Administration and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis.

(d) Except as provided in paragraph (e) of this section, the term cannabis resin means the separated resin, whether crude or purified, obtained from the cannabis plant.

(e) As used in this part, the terms cannabis, medicinal cannabis, and cannabis preparation do not include any material, compound, mixture, or preparation that falls outside the definition of marihuana in section 102(16) of the Controlled Substances Act (the Act) (21 U.S.C. 802(16)).

(f) The term Single Convention means the Single Convention on Narcotic Drugs, 1961 (18 U.S.T. 1407).

(g) The term bona fide supply agreement means a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act.

(h) The term registered researcher or manufacturer means a person registered under the Act to perform research or manufacture of marihuana in Schedule I.
21 CFR § 1318.03

§ 1318.03 Implementation of statutory requirements.
(a) As provided in section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator may grant an application for a registration to manufacture marihuana, including the cultivation of cannabis, only if he determines that such registration is consistent with the public interest and with United States obligations under the Single Convention.

(b) In accordance with section 303(a) of the Act and § 1301.44(a) of this chapter, the burden shall be on the applicant to demonstrate that the requirements for such registration have been satisfied.
21 CFR § 1318.04

§ 1318.04 Specific control measures applicable to the bulk manufacture of marihuana.
For a registration to manufacture marihuana that involves the cultivation of cannabis, the following provisions must be satisfied:

(a) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to the Administration. The Administration shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. The Administration may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against

diversion. In such cases, the Administration shall designate a secure storage mechanism at the registered location in which the Administration may maintain possession of the cannabis, and the Administration will control access to the stored cannabis. If the Administration determines that no suitable location exists at the registered location of the registered manufacturer authorized to cultivate cannabis, then the Administration shall designate a location for the authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in part 1301 of this chapter.

(b) The Administration shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. The Administration may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. The Administration shall require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with part 1312 of this chapter, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of the Administration.

(c) A registered manufacturer authorized to grow cannabis shall notify in writing the Administration of its proposed date of harvest at least 15 days before the commencement of the harvest.

21 CFR § 1318.05

§ 1318.05 Application of the public interest factors.

(a) In accordance with section 303(a) of the Act (21 U.S.C. 823(a)), the Administrator shall consider the public interest factors set forth in paragraphs (a)(1) through (6) of this section:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately ***16306** competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(b) The Administrator's determination of which applicants to select will be consistent with the public interest factors set forth in section 303(a), with particular emphasis on the following criteria:

(1) Whether the applicant has demonstrated prior compliance with the Act and this chapter;

(2) The applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition; and

(3)(i) In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall place particular emphasis on the extent to which any applicant is able to supply cannabis or its derivatives in quantities and varieties that will satisfy the anticipated demand of researchers and other registrants in the United States who wish to obtain cannabis to conduct activities permissible under the Act, as demonstrated through a bona fide supply agreement with a registered researcher or manufacturer as defined in this subpart.

(ii) If an applicant seeks registration to grow cannabis for its own research or product development, the applicant must possess registration as a schedule I researcher with respect to marihuana under § 1301.32 of this chapter. As specified in § 1301.13 of this chapter, chemical analysis and preclinical research (including quality control analysis) are not coincident activities of a manufacturing registration for schedule I substances, including cannabis. In determining under section 303(a)(1) of the Act (21 U.S.C. 823(a)(1)) the number of qualified applicants necessary to produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions, the Administrator shall consider the holding of an approved marihuana research protocol by a registered schedule I researcher seeking to grow cannabis for its own research or product development as evidence of the necessity of the applicant's registration under this factor.

(c) Applications accepted for filing after [EFFECTIVE DATE OF FINAL RULE] will not be considered pending for purposes of paragraph (a) of this section until all applications accepted for filing on or before [EFFECTIVE DATE OF FINAL RULE] have been granted or denied by the Administrator. Where an application is subject to section 303(i) of the Act (21 U.S.C. 823(i)), that section shall apply in lieu of this paragraph (c).

(d) In determining the legitimate demand for cannabis and its derivatives in the United States, the Administrator shall consult with the U.S. Department of Health and Human Services, including its components.

21 CFR § 1318.06

§ 1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.

(a) In accordance with section 111(b)(3) of Public Law 102-395 (21 U.S.C. 886a(1)(C)), seeking to recover the full costs of operating the aspects of the diversion control program that are related to issuing registrations that comply with the Controlled Substances Act (CSA), the Administration shall assess an administrative fee. To set the administrative fee, the Administration shall annually determine the preceding fiscal year's cost of operating the program to cultivate cannabis and shall divide the prior fiscal year's cost by the number of kgs of cannabis authorized to be manufactured in the current year's quota to arrive at the administrative fee per kg. The administrative fee per kg shall be added to the sale price of cannabis purchased from the Administration. The administrative fee shall be paid to the Diversion Control Fee Account.

(b) As set forth in § 1318.04, the Administration shall have the exclusive right of, among other things, wholesale trading in cannabis that it purchases from registered manufacturers. The Administration will, therefore, buy from such manufacturer, sell cannabis to registered researchers and manufacturers, and establish prices for such purchase and sale. The Administration will set such prices in the following manner:

(1) Bulk growers of cannabis shall negotiate directly with registered researchers and manufacturers authorized to handle cannabis to determine a sale price for their cannabis. Upon entering into a contract for the provision of bulk cannabis and prior to the exchange of cannabis, the parties shall pay to the Administration an administrative fee assessed based on the number of kgs to be supplied. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(2) The Administration shall sell the cannabis to the buyer at the negotiated sale price plus the administrative fee assessed on a per kg basis. Prior to the purchase of the cannabis by the Administration, the buyer shall pay the negotiated purchase price and administrative fee to the Administration. The Administration shall hold funds equal to the purchase price in escrow until the delivery of the cannabis by the grower to the Administration. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

(3) After receiving the purchase price and administrative fee from the buyer, the Administration shall purchase the cannabis from the grower, on behalf of the buyer, at the negotiated sale price. The Administration shall retain the administrative fee. In the event the buyer fails to pay the purchase price and the administrative fee, the Administration shall have no obligation to purchase the crop and may order the grower to destroy the crop if the grower cannot find an alternative buyer within four months of harvest.

(4) In instances where the grower of the cannabis is the same entity as the buyer of the cannabis, or a related or subsidiary entity, the entity may establish a nominal price for the purchase of the cannabis. The Administration shall then purchase the entity's cannabis at that price and sell the cannabis back to the entity, or a related or subsidiary entity, at the same price with the addition of the administrative fee.

(c) Administrative fees set in accordance with this part will be made available, on an updated basis, on the Administration's website, no later than December 15th of the year preceding the year in which the administrative fee will be collected.

(d) Nothing in this section shall prohibit the U.S. Department of Health and Human Services from continuing to fund the acquisition of cannabis for use in research by paying, directly or indirectly, the purchase cost and administrative fee to the Administration.

21 CFR § 1318.07

§ 1318.07 Non-liability of Drug Enforcement Administration.

***16307** The Administration shall have no liability with respect to the performance of any contractual terms agreed to by a grower and buyer of bulk cannabis, including but not limited to the quality of any cannabis delivered to a buyer. In the event that a buyer deems the delivered cannabis to be defective, the buyer's sole remedy for damages shall be against the grower and not the Administration.

Dated: March 16, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020-05796 Filed 3-20-20; 8:45 am]

BILLING CODE 4410-09-P

Footnotes

1 All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

2 This document uses both the CSA spelling “marihuana” and the modern spelling “marijuana” interchangeably.

3 Section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be “consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.” The Single Convention entered into force for the United States on June 24, 1967. See Single Convention, 18 U.S.T. 1407.

4 As discussed below, the Agriculture Improvement Act of 2018, Public Law 115-334, removed hemp from the CSA definition of marihuana. This proposed rule applies only to cannabis that is included in the CSA definition of marihuana.

5 The United Nations' Economic and Social Council requested that the Secretary-General prepare the Commentary "in the light of the relevant conference proceedings and other material" in order to aid governments in applying the Single Convention. The Commentary (1973) is not binding on Parties to the Convention. Economic and Social Council Resolution 1962/914(XXXIV) D (Aug. 3, 1962).

6 The Single Convention provides that the five functions of article 23, paragraph 2 "shall be discharged by a single government agency if the constitution of the Party concerned permits it." Single Convention art. 23(3). Nothing in the Constitution would preclude the United States from discharging all of those controls through one government agency. The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed on constitutional grounds, administrative arrangements should be made to ensure the required coordination.

7 The meanings of the terms "medicinal cannabis" and "cannabis preparations" are addressed later in this document. Article 23, paragraph 2(e) also refers to "opium alkaloids." However, due to distinctions between the opiates derived from the opium poppy and the cannabinoids derived from the cannabis plant, the notion of "cannabis alkaloids" is inapplicable.

8 Among other things, these definitions take into account the current CSA definition of marihuana (21 U.S.C. 802(16)), which was amended in 2018 to exclude "hemp" as defined in section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639*o*(1)).

9 As indicated above, the requirement that registered growers deliver all cannabis to DEA no later than four months after the end of the harvest applies in all situations—even where the cannabis will later be distributed by DEA back to the grower for further use. Thus, the above exception that allows DEA-registered manufacturers of medicinal cannabis and cannabis preparations to maintain stocks of cannabis materials for the purpose of producing such drugs or preparations only applies where the raw cannabis material was previously delivered to DEA.

10 DEA would take title to an amount up to the applicant's manufacturing quota. Growing marihuana in excess of a manufacturing quota is a violation of federal law. 21 U.S.C. 842(b). Thus, any marihuana grown in excess of a manufacturing quota would be subject to seizure and destruction. See id. 881(g).

11 As in the first scenario, DEA only would take title to an amount up to the applicant's manufacturing quota. Any marihuana grown in excess of a manufacturing quota would be subject to seizure and destruction. See 21 U.S.C. 842(b), 881(g).

12 The Department of Health and Human Services maintains procedures for providing this same marihuana to non-NIH funded researchers as well.

13 As above, DEA only would take title to an amount up to the National Center's manufacturing quota, with amount grown in excess of the manufacturing quota subject to seizure and destruction. See 21 U.S.C. 842(b), 881(g).

14 For a detailed explanation of subsection 823(a) (1), see 74 FR at 2127-33.

15 The proposed rule provides that, in determining the legitimate demand for marihuana and its derivatives in the United States, the Administrator shall consult with the Department of Health and Human Services, including its components.

16 The United States Department of Agriculture has issued regulations and guidance to implement a program for the commercial production of industrial hemp in the United States under the framework of the AIA. See Establishment of a Domestic Hemp Production Program, 84 FR 58522 (Oct. 31, 2019).

17 Rounded to nearest whole dollar. The cost of $607,644 is explained below.

18 The "authorizing agency" refers to federal government agencies, including NIDA and DEA.

19 Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.

20 NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.

21 Information on Marijuana Farm Contract, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research/information-marijuana-farm-contract.

22 Conference call between DEA Regulatory Drafting and Policy Support section and members of NIDA's Marijuana Drug Supply Program, July 30, 2019.

23 Anticipated spending for the marihuana DSP for 2019 is $3.3 million to $3.4 million, of which 10%-15% meet the definition of "hemp" under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million for marihuana, excluding hemp. The figures are based on a general discussion, and actual figures may differ.

24 The 2019 Aggregate Production Quota for all marihuana is 2,450 kgs. 2,000 of the 2,450 kgs are for the NIDA (National Center) cultivating and manufacturing quota of bulk marihuana. See 83 FR 67348.

25 Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.

26 See note 22.

27 Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). This proposed rule, if adopted, would supersede the 2016 policy statement.

28 21 CFR 1303.11(a).

29 The phrase "multiple growers" includes the possibility that the current grower is one of "multiple growers."

30 DEA's loaded hourly rate of a Special Agent is $103.54. Assuming 10 hours each (full work-day) for two agents, the total labor cost associated with collection from a registered manufacturer is $2,071. "Loaded hourly rate" includes wages, benefits, and "loading" of "non-productive" hours, i.e., leave, training, travel, etc.

31 $116 is based on IRS standard mileage rates for 2019 of $0.58 per mile multiplied by the estimated 200 miles driven, roundtrip.

32 Production, Analysis, and Distribution of Cannabis and Related Materials, Federal Business Opportunities (Apr. 12, 2015), https://www.fbo.gov/spg/HHS/NIH/NIDA-01/N01DA-15-7793/listing.html.

33 NIDA's Role in Providing Marijuana for Research, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research.

34 Anticipated spending for the marihuana DSP for 2019 is $3.3 million to $3.4 million, of which 10 percent to 15 percent meet the definition of "hemp" under the provisions of the AIA. Using the midpoint of these ranges, the estimated spending is $2.9 million. The figures are based on a general discussion, and actual figures may differ.

35 The 2019 APQ for all manufacturers of marihuana is 2,450 kgs. 2,000 kgs are for cultivating and manufacturing of bulk marihuana. See 83 FR 67348.

36 Marijuana Plant Material Available from the NIDA Drug Supply Program, National Institute on Drug Abuse, https://www.drugabuse.gov/research/research-data-measures-resources/nida-drug-supply-program/marijuana-plant-material-available-nida-drug-supply-program.

37 See note 22.

38 Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (2016). This proposed rule, if adopted, would superseded the 2016 policy statement.

39 21 U.S.C. 826(a).

40 The phrase "multiple growers" includes the possibility that the current grower is one of the "multiple growers."

41 See note 22.

42 For the purposes of this analysis, the term "firms" is synonymous with "entities."

43 2015 SUSB Annual Datasets by Establishment Industry, U.S. & States, NAICS, Detailed Employment Sizes (U.S., 6-digit and States, NAICS Sectors), United States Census Bureau, https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html.

44 Ibid.

45 Table of Small Business Size Standards Matched to North American Industry Classification System Codes, United States Small Business Association (Oct. 1, 2017). The NAICS code was updated for 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' from 541712 to 541715. The 2015 SUSB data uses 541712 and the 2017 SBA size standard uses 541715 for the same industry.

End of Document

SINGLE CONVENTION

ON

NARCOTIC DRUGS, 1961

As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961,

UNITED NATIONS

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AS AMENDED BY THE 1972 PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

PREAMBLE

The Parties,

Concerned with the health and welfare of mankind,

Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,

Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,

Conscious of their duty to prevent and combat this evil,

Considering that effective measures against abuse of narcotic drugs require co-ordinated and universal action,

Understanding that such universal action calls for international co-operation guided by the same principles and aimed at common objectives,

Acknowledging the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,

Desiring to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international co-operation and control for the achievement of such aims and objectives,

Hereby agree as follows:[1]

Article 1

DEFINITIONS

1. Except where otherwise expressly indicated or where the context otherwise requires, the following definitions shall apply throughout the Convention:

a) "Board" means the International Narcotics Control Board,
b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
c) "Cannabis plant" means any plant of the genus Cannabis,
d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.
e) "Coca bush" means the plant of any species of the genus Erythroxylon.
f) "Coca leaf" means the leaf of the coca bush except a leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed.
g) "Commission" means the Commission on Narcotic Drugs of the Council.
h) "Council" means the Economic and Social Council of the United Nations.
i) "Cultivation" means the cultivation of the opium poppy, coca bush or cannabis plant.
j) "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.
k) "General Assembly" means the General Assembly of the United Nations.

[1] *Note by the Secretariat*: The Preamble to the Protocol amending the Single Convention on Narcotic Drugs, 1961, reads as follows:
"*The Parties to the Present Protocol,*
"*Considering* the provisions of the Single Convention on Narcotic Drugs, 1961, done at New York on 30 March 1961 (hereinafter called the Single Convention),
"*Desiring* to amend the Single Convention
"*Have agreed* as follows:"

l) "Illicit traffic" means cultivation or trafficking in drugs contrary to the provisions of this Convention.
m) "Import" and "export" mean in their respective connotations the physical transfer of drugs from one State to another State, or from one territory to another territory of the same State.
n) "Manufacture" means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.
o) "Medicinal opium" means opium which has undergone the processes necessary to adapt it for medicinal use.
p) "Opium" means the coagulated juice of the opium poppy.
q) "Opium poppy" means the plant of the species *Papaver somniferum L*.
r) "Poppy straw" means all parts (except the seeds) of the opium poppy, after mowing.
s) "Preparation" means a mixture, solid or liquid, containing a drug.
t) "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained.
u) "Schedule I", "Schedule II", "Schedule III" and "Schedule IV" mean the correspondingly numbered list of drugs or preparations annexed to this Convention, as amended from time to time in accordance with article 3.
v) "Secretary-General" means the Secretary-General of the United Nations.
w) "Special stocks" means the amounts of drugs held in a country or territory by the Government of such country or territory for special government purposes and to meet exceptional circumstances; and the expression "special purposes" shall be construed accordingly.
x) "Stocks" means the amounts of drugs held in a country or territory and intended for:

i) Consumption in the country or territory for medical and scientific purposes,
ii) Utilization in the country or territory for the manufacture of drugs and other substances, or
iii) Export;

but does not include the amounts of drugs held in the country or territory,

iv) By retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions, or
v) As "special stocks".

y) Territory" means any part of a State which is treated as a separate entity for the application of the system of import certificates and export authorizations provided for in article 31. This definition shall not apply to the term "territory" as used in articles 42 and 46.

2. For the purposes of this Convention a drug shall be regarded as "consumed" when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research; and "consumption" shall be construed accordingly.

Article 2

SUBSTANCES UNDER CONTROL

1. Except as to measures of control which are limited to specified drugs, the drugs in Schedule I are subject to all measures of control applicable to drugs under this Convention and in particular to those prescribed in article 4 *c)*, 19, 20, 21, 29, 30, 31, 32, 33, 34 and 37.

2. The drugs in Schedule II are subject to the same measures of control as drugs in Schedule I with the exception of the measures prescribed in article 30, paragraphs 2 and 5, in respect of the retail trade.

3. Preparations other than those in Schedule III are subject to the same measures of control as the drugs which they contain, but estimates (article 19) and statistics (article 20) distinct from those dealing with these drugs shall not be required in the case of such preparations, and article 29, paragraph 2 *c)* and article 30, paragraph 1 *b)* ii) need not apply.

4. Preparations in Schedule III are subject to the same measures of control as preparations containing drugs in Schedule II except that article 31, paragraphs 1 *b)* and 3 to 15 and, as regards their acquisition and retail distribution, article 34, paragraph *b)*, need not apply, and that for the purpose of estimates (article 19) and statistics (article 20) the information required shall be restricted to the quantities of drugs used in the manufacture of such preparations.

Article 21

LIMITATION OF MANUFACTURE AND IMPORTATION

1. The total of the quantities of each drug manufactured and imported by any country or territory in any one year shall not exceed the sum of the following:

a) The quantity consumed, within the limit of the relevant estimate, for medical and scientific purposes;
b) The quantity used, within the limit of the relevant estimate, for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention;
c) The quantity exported;
d) The quantity added to the stock for the purpose of bringing that stock up to the level specified in the relevant estimate; and
e) The quantity acquired within the limit of the relevant estimate for special purposes.

2. From the sum of the quantities specified in paragraph 1 there shall be deducted any quantity that has been seized and released for licit use, as well as any quantity taken from special stocks for the requirements of the civilian population.

3. If the Board finds that the quantity manufactured and imported in any one year exceeds the sum of the quantities specified in paragraph l, less any deductions required under paragraph 2 of this article, any excess so established and remaining at the end of the year shall, in the following year, be deducted from the quantity to be manufactured or imported and from the total of the estimates as defined in paragraph 2 of article 19.

4. a) If it appears from the statistical returns on imports or exports (article 20) that the quantity exported to any country or territory exceeds the total of the estimates for that country or territory, as defined in paragraph 2 of article 19, with the addition of the amounts shown to have been exported, and after deduction of any excess as established in paragraph 3 of this article, the Board may notify this fact to States which, in the opinion of the Board, should be so informed;
b) On receipt of such a notification, Parties shall not during the year in question authorize any further exports of the drug concerned to that country or territory, except:

i) In the event of a supplementary estimate being furnished for that country or territory in respect both of any quantity over imported and of the additional quantity required, or
ii) In exceptional cases where the export, in the opinion of the Government of the exporting country, is essential for the treatment of the sick.

Article 21 bis

LIMITATION OF PRODUCTION OF OPIUM

1. The production of opium by any country or territory shall be organized and controlled in such manner as to ensure that, as far as possible, the quantity produced in any one year shall not exceed the estimate of opium to be produced as established under paragraph 1 *f)* of article 19.

2. If the Board finds on the basis of information at its disposal in accordance with the provisions of this Convention that a Party which has submitted an estimate under paragraph l *f)* of article 19 has not limited opium produced within its borders to licit purposes in accordance with relevant estimates and that a significant amount of opium produced, whether licitly or illicitly, within the borders of such a Party, has been introduced into the illicit traffic, it may, after studying the explanations of the Party concerned, which shall be submitted to it within one month after notification of the finding in question, decide to deduct all, or a portion, of such an amount from the quantity to be produced and from the total of the estimates as defined in paragraph 2 *b)* of article 19 for the next year in which such a deduction can be technically accomplished, taking into account the season of the year and contractual commitments to export opium. This decision shall take effect ninety days after the Party concerned is notified thereof.

3. After notifying the Party concerned of the decision it has taken under paragraph 2 above with regard to a deduction, the Board shall consult with that Party in order to resolve the situation satisfactorily.

4. If the situation is not satisfactorily resolved, the Board may utilize the provisions of article 14 where appropriate.

5. In taking its decision with regard to a deduction under paragraph 2 above, the Board shall take into account not only all relevant circumstances including those giving rise to the illicit traffic problem referred to in paragraph 2 above, but also any relevant new control measures which may have been adopted by the Party.

Article 22

SPECIAL PROVISION APPLICABLE TO CULTIVATION

1. Whenever the prevailing conditions in the country or a territory of a Party render the prohibition of the cultivation of the opium poppy, the coca bush or the cannabis plant the most suitable measure, in its opinion, for protecting the public health and welfare and preventing the diversion of drugs into the illicit traffic, the Party concerned shall prohibit cultivation.

2. A Party prohibiting cultivation of the opium poppy or the cannabis plant shall take appropriate measures to seize any plants illicitly cultivated and to destroy them, except for small quantities required by the Party for scientific or research purposes.

Article 23

NATIONAL OPIUM AGENCIES

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.

2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:

a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
c) Each licence shall specify the extent of the land on which the cultivation is permitted.
d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

Article 24

LIMITATION ON PRODUCTION OF OPIUM FOR INTERNATIONAL TRADE

1. a) If any Party intends to initiate the production of opium or to increase existing production, it shall take account of the prevailing world need for opium in accordance with the estimates thereof published by the Board so that the production of opium by such Party does not result in overproduction of opium in the world.
b) A Party shall not permit the production of opium or increase the existing production thereof if in its opinion such production or increased production in its territory may result in illicit traffic in opium.

2. a) Subject to paragraph 1, where a Party which as of 1 January 1961 was not producing opium for export desires to export opium which it produces, in amounts not exceeding five tons annually, it shall notify the Board, furnishing with such notification information regarding:

i) The controls in force as required by this Convention respecting the opium to be produced and exported; and
ii) The name of the country or countries to which it expects to export such opium;

and the Board may either approve such notification or may recommend to the Party that it not engage in the production of opium for export.

b) Where a Party other than a party referred to in paragraph 3 desires to produce opium, for export in amounts exceeding five tons annually, it shall notify the Council, furnishing with such notification relevant information including:

i) The estimated amounts to be produced for export;
ii) The controls existing or proposed respecting the opium to be produced;
iii) The name of the country or countries to which it expects to export such opium;

and the Council shall either approve the notification or may recommend to the Party that it not engage in the production of opium for export.

3. Notwithstanding the provisions of subparagraphs *a)* and *b)* of paragraph 2, a Party that during ten years immediately prior to l January 1961 exported opium which such country produced may continue to export opium which it produces.

4. a) A Party shall not import opium from any country or territory except opium produced. in the territory of:

i) A Party referred to in paragraph 3;
ii) A Party that has notified the Board as provided in subparagraph a) of paragraph 2; or
iii) A Party that has received the approval of the Council as provided in subparagraph b) of paragraph 2.

b) Notwithstanding subparagraph *a)* of this paragraph, a Party may import opium produced by any country which produced and exported opium during the ten years prior to 1 January 1961 if such country has established and maintains a national control organ or agency for the purposes set out in article 23 and has in force an effective means of ensuring that the opium it produces is not diverted into the illicit traffic.

5. The provisions of this article do not prevent a Party:

a) From producing opium sufficient for its own requirements; or
b) From exporting opium seized in the illicit traffic, to another Party in accordance with the requirements of this Convention.

Article 25

CONTROL OF POPPY STRAW

1. A Party that permits the cultivation of the opium poppy for purposes other than the production of opium shall take all measures necessary to ensure:

a) That opium is not produced from such opium poppies; and
b) That the manufacture of drugs from poppy straw is adequately controlled.

2. The Parties shall apply to poppy straw the system of import certificates and export authorizations as provided in article 31, paragraphs 4 to 15.

3. The Parties shall furnish statistical information on the import and export of poppy straw as required for drugs under article 20, paragraphs 1 *d)* and 2 *b)*.

Article 26

THE COCA BUSH AND COCA LEAVES

1. If a Party permits the cultivation of the coca bush, it shall apply thereto and to coca leaves the system of controls as provided in article 23 respecting the control of the opium poppy, but as regards paragraph 2 *d)* of that article, the requirements imposed on the Agency therein referred to shall be only to take physical possession of the crops as soon as possible after the end of the harvest.

2. The Parties shall so far as possible enforce the uprooting of all coca bushes which grow wild. They shall destroy the coca bushes if illegally cultivated.

Article 27

ADDITIONAL PROVISIONS RELATING TO COCA LEAVES

1. The Parties may permit the use of coca leaves for the preparation of a flavouring agent, which shall not contain any alkaloids, and, to the extent necessary for such use, may permit the production, import, export, trade in and possession of such leaves.

2. The Parties shall furnish separately estimates (article 19) and statistical information (article 20) in respect of coca leaves for preparation of the flavouring agent, except to the extent that the same coca leaves are used for the extraction of alkaloids and the flavouring agent, and so explained in the estimates and statistical information.

Article 28

CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.

2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

Article 29

MANUFACTURE

1. The Parties shall require that the manufacture of drugs be under licence except where such manufacture is carried out by a State enterprise or State enterprises.

2. The Parties shall:

a) Control all persons and enterprises carrying on or engaged in the manufacture of drugs;
b) Control under licence the establishments and premises in which such manufacture may take place; and
c) Require that licensed manufacturers of drugs obtain periodical permits specifying the kinds and amounts of drugs which they shall be entitled to manufacture. A periodical permit, however, need not be required for preparations.

3. The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions.

14. The provisions of paragraphs 11 to 13 relating to the passage of drugs through the territory of a Party do not apply where the consignment in question is transported by aircraft which does not land in the country or territory of transit. If the aircraft lands in any such country or territory, those provisions shall be applied so far as circumstances require.

15. The provisions of this article are without prejudice to the provisions of any international agreements which limit the control which may be exercised by any of the Parties over drugs in transit.

16. Nothing in this article other than paragraphs 1 *a)* and 2 need apply in the case of preparations in Schedule III.

Article 32

SPECIAL PROVISIONS CONCERNING THE CARRIAGE OF DRUGS IN FIRST-AID KITS OF SHIPS OR AIRCRAFT ENGAGED IN INTERNATIONAL TRAFFIC

1. The international carriage by ships or aircraft of such limited amounts of drugs as may be needed during their journey or voyage for first-aid purposes or emergency cases shall not be considered to be import, export or passage through a country within the meaning of this Convention.

2. Appropriate safeguards shall be taken by the country of registry to prevent the improper use of the drugs referred to in paragraph 1 or their diversion for illicit purposes. The Commission, in consultation with the appropriate international organizations, shall recommend such safeguards.

3. Drugs carried by ships or aircraft in accordance with paragraph 1 shall be subject to the laws, regulations, permits and licences of the country of registry, without prejudice to any rights of the competent local authorities to carry out checks, inspections and other control measures on board ships or aircraft. The administration of such drugs in the case of emergency shall not be considered a violation of the requirements of article 30, paragraph 2 *b)*.

Article 33

POSSESSION OF DRUGS

The Parties shall not permit the possession of drugs except under legal authority.

Article 34

MEASURES OF SUPERVISION AND INSPECTION

The Parties shall require:

a) That all persons who obtain licences as provided in accordance with this Convention, or who have managerial or supervisory positions in a State enterprise established in accordance with this Convention, shall have adequate qualifications for the effective and faithful execution of the provisions of such laws and regulations as are enacted in pursuance thereof; and

b) That governmental authorities, manufacturers, traders, scientists, scientific institutions and hospitals keep such records as will show the quantities of each drug manufactured and of each individual acquisition and disposal of drugs. Such records shall respectively be preserved for a period of not less than two years. Where counterfoil books (article 30, paragraph 2 b)) of official prescriptions are used, such books including the counterfoils shall also be kept for a period of not less than two years.

Article 35

ACTION AGAINST THE ILLICIT TRAFFIC

Having due regard to their constitutional, legal and administrative systems, the Parties shall:

a) Make arrangements at the national level for co-ordination of preventive and repressive action against the illicit traffic; to this end they may usefully designate an appropriate agency responsible for such co-ordination;
b) Assist each other in the campaign against the illicit traffic in narcotic drugs;
c) Co-operate closely with each other and with the competent international organizations of which they are members with a view to maintaining a co-ordinated campaign against the illicit traffic;
d) Ensure that international co-operation between the appropriate agencies be conducted in an expeditious manner; and
e) Ensure that where legal papers are transmitted internationally for the purposes of a prosecution, the transmittal be effected in an expeditious manner to the bodies designated by the Parties; this requirement shall be without prejudice to the right of a Party to require that legal papers be sent to it through the diplomatic channel;
f) Furnish, if they deem it appropriate, to the Board and the Commission through the Secretary-General, in addition to information required by article 18, information relating to illicit drug activity within their borders, including information on illicit cultivation, production, manufacture and use of, and on illicit trafficking in, drugs; and
g) Furnish the information referred to in the preceding paragraph as far as possible in such manner, and by such dates as the Board may request; if requested by a Party, the Board may offer its advice to it in furnishing the information and in endeavouring to reduce the illicit drug activity within the borders of that Party.

Article 36

PENAL PROVISIONS

1. a) Subject to its constitutional limitations, each Party shall adopt such measures as will ensure that cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs contrary to the provisions of this Convention, and any other action which in the opinion of such Party may be contrary to the provisions of this Convention, shall be punishable offences when committed intentionally, and that serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of liberty.
b) Notwithstanding the preceding subparagraph, when abusers of drugs have committed such offences, the Parties may provide, either as an alternative to conviction or punishment or in addition to conviction or punishment, that such abusers shall undergo measures of treatment, education, after-care, rehabilitation and social reintegration in conformity with paragraph 1 of article 38.

2. Subject to the constitutional limitations of a Party, its legal system and domestic law,

a) i) Each of the offences enumerated in paragraph 1, if committed in different countries, shall be considered as a distinct offence;
ii) Intentional participation in, conspiracy to commit and attempts to commit, any of such offences, and preparatory acts and financial operations in connexion with the offences referred to in this article, shall be punishable offences as provided in paragraph 1;
iii) Foreign convictions for such offences shall be taken into account for the purpose of establishing recidivism; and
iv) Serious offences heretofore referred to committed either by nationals or by foreigners shall be prosecuted by the Party in whose territory the offence was committed, or by the Party in whose territory the offender is found if extradition is not acceptable in conformity with the law of the Party to which application is made, and if such offender has not already been prosecuted and judgement given.

b) i) Each of the offences enumerated in paragraphs 1 and 2 *a)* ii) of this article shall be deemed to be included as an extraditable offence in any extradition treaty existing between Parties. Parties undertake to include such offences as extraditable offences in every extradition treaty to be concluded between them.

ii) If a Party which makes extradition conditional on the existence of a treaty receives a request for extradition from another Party with which it has no extradition treaty, it may at its option consider this Convention as the legal basis for extradition in respect of the offences enumerated in paragraphs 1 and 2 a) ii) of this article. Extradition shall be subject to the other conditions provided by the law of the requested Party.

iii) Parties which do not make extradition conditional on the existence of a treaty shall recognize the offences enumerated in paragraphs 1 and 2 a) ii) of this article as extraditable offences between themselves, subject to the conditions provided by the law of the requested Party.

iv) Extradition shall be granted in conformity with the law of the Party to which application is made, and, notwithstanding subparagraphs b) i), ii) and iii) of this paragraph, the Party, shall have the right to refuse to grant the extradition in cases where the competent authorities consider that the offence is not sufficiently serious.

3. The provisions of this article shall be subject to the provisions of the criminal law of the Party concerned on questions of jurisdiction.

4. Nothing contained in this article shall affect the principle that the offences to which it refers shall be defined, prosecuted and punished in conformity with the domestic law of a Party.

Article 37

SEIZURE AND CONFISCATION

Any drugs, substances and equipment used in or intended for the commission of any of the offences, referred to in article 36, shall be liable to seizure and confiscation.

Article 38

MEASURES AGAINST THE ABUSE OF DRUGS

1. The Parties shall give special attention to and take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved and shall co-ordinate their efforts to these ends.

2. The Parties shall as far as possible promote the training of personnel in the treatment, after-care, rehabilitation and social reintegration of abusers of drugs.

3. The Parties shall take all practicable measures to assist persons whose work so requires to gain an understanding of the problems of abuse of drugs and of its prevention, and shall also promote such understanding among the general public if there is a risk that abuse of drugs will become widespread.

Article 38 bis

AGREEMENTS ON REGIONAL CENTRES

If a Party considers it desirable as part of its action against the illicit traffic in drugs, having due regard to its constitutional, legal and administrative systems, and, if it so desires, with the technical advice of the Board or the specialized agencies, it shall promote the establishment, in consultation, with other interested Parties in the region, of agreements which contemplate the development of regional centres for scientific research and education to combat the problems resulting from the illicit use of and traffic in drugs.

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COMMENTARY

on the

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

(Prepared by the Secretary-General in accordance with paragraph 1 of Economic and Social Council resolution 914 D (XXXIV) of 3 August 1962)

UNITED NATIONS

Article 1

DEFINITIONS

Paragraph 1, introductory subparagraph and subparagraph **(a)**

1. Except where otherwise expressly indicated or where the context otherwise requires, the following definitions shall apply throughout the Convention:

(*a*) "Board" means the International Narcotics Control Board.

Commentary

This abbreviation of the name of the International Narcotics Control Board is employed throughout the Single Convention except in article 5 where the full name is used. In article 45 qualifying words supplement the abbreviation to make clear that reference is made to that organ and not to the past Permanent Central Board which is also mentioned in that article. Article 45 refers to the International Narcotics Board by the following phrases: "the Board provided for in article 9" (of the Single Convention), "the new Board referred to in article 9" and "that Board". The Permanent Central Board had been constituted under the terms of chapter VI of the 1925 Convention and functioned from 15 January 1929 to 1 March 1968. [1] As from 2 March 1968 it was replaced by the International Narcotics Control Board by resolution 1106 (XL) of the Economic and Social Council of the United Nations adopted pursuant to article 45, paragraph 2 of the Single Convention. The name "Permanent Central Board" was that given by the 1925 Convention to the earlier organ which called itself first Permanent Central Opium Board and later (since 1965) Permanent Central Narcotics Board [2] in order to indicate in its name the nature of its work.

See below, comments on article 45.

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[1] The 1925 Convention entered into force on 25 September 1928; the members of the first Permanent Central Board were elected on 14 December 1928 (*Official Journal of the League of Nations, 10th Year, No. 1* (January 1929), pp. 52-53); the Board held its first meeting on 15 January 1929 (League of Nations document C.C.P./1st session/P.V.1).

[2] The Permanent Central Board adopted this new name at its 86th session (26 May to 4 June 1965). (Document E/OB/W.1925; see also document E/OB/21.)

Convention to furnish estimates under article 19, paragraph 1, subparagraph (*b*) of the quantities of drugs to be utilized for the manufacture of salts, although salts are "other drugs" within the meaning of this phrase, nor does it request the Government to supply under article 20, paragraph 1, subparagraph (*b*) statistical information on the utilization of drugs for such manufacture.

11. "The isomers, unless specifically excepted, of the drugs" in Schedule I "whenever the existence of such isomers is possible within the specific chemical designation", "the esters and ethers, unless appearing in another Schedule, of the drugs in this Schedule whenever the existence of such esters or ethers is possible", and "the isomers, unless specifically excepted, of the drugs" in Schedule II "whenever the existence of such isomers is possible within the specific chemical designation", are included in Schedules I and II respectively. [42] They are therefore "drugs" within the meaning of this term in the Single Convention. [43] The manufacture of such isomers, esters and ethers is thus "manufacture" of drugs in the sense of article 1, paragraph 1, subparagraph (*n*) and therefore subject to the provisions of the Single Convention governing the manufacture of drugs.

12. The manufacture of preparations of drugs is, however, not "manufacture" of drugs in the sense of article 1, paragraph 1, subparagraph (*n*). [44] The Single Convention provides that preparations should be subjected to the same measures of control as the drugs which they contain. There are a few exceptions. [45] The making of preparations is therefore subject to those control provisions which apply to the manufacture of drugs. Manufacturers of preparations need not obtain the periodical permits which manufacturers of drugs must have, and which indicate the kind and amounts of drugs which the latter are entitled to make. [46]

[42] Third and second para. from the bottom of Schedule I and penultimate para. of Schedule II as adopted by the Plenipotentiary Conference.

[43] Article 1, para. 1, subpara. (*j*).

[44] The term "manufacture" is however applied to the making of preparations in Schedule III in article 2, para. 4, article 19, para. 1, subpara. (*b*), article 20, para. 1, subpara (*b*) and article 21, para. 1, subpara. (*b*). The term "manufacturers" is used in article 23, para. 2, subpara. (*e*) for makers of opium preparations; see also above foot-note 15.

[45] Article 2, para. 3.

[46] Article 2, para. 3 and article 29, para. 2, subpara. (*c*).

Paragraph 1, subparagraph (o)

(*o*) "Medicinal opium" means opium which has undergone the processes necessary to adapt it for medicinal use.

Commentary

1. The Single Convention follows earlier narcotics treaties [1] in defining "medicinal opium" as a special form of opium in which that drug is used in

[1] Chapter III, introductory paragraph of the 1912 Convention; article 1 of the 1925 Convention; and article 1 of the 1931 Convention. The term is also used, but not defined in the 1948 Protocol (article 4) and the 1953 Protocol (article 1) (in the definition of opium) and article 7, para. 5.

medical treatment. The early treaties [2] defined three forms of opium i.e. "raw opium", "prepared opium", and "medicinal opium", because they provided different régimes for each of them. The 1953 Protocol abolished these differences, subjecting all three forms to the same control measures. The Protocol made this clear by expressly stating in its definition of opium that it meant "the coagulated juice of the poppy in whatever form including raw opium, medicinal opium and prepared opium". [3] The Single Convention subjects opium in all its forms to the same régime, opium being listed in Schedule I and consequently falling under the same régime as other drugs in the Schedule. [4] It uses the term "medicinal opium" in a single provision, article 23, paragraph 2, subparagraph (*e*). This subparagraph requires a Party to the Single Convention which permits the cultivation of the opium poppy for the production [5] of opium, to limit the right of maintaining (wholesale) stocks of opium [6] to its "National Opium Agency". [7] It authorizes the Party to except from this exclusive right of the Agency opium stocks "held by manufacturers of opium alkaloids, medicinal opium [8] or opium preparations".

2. Lactose is generally added to the opium to reduce its morphine content to the standard of about 10 percent prescribed for "medicinal opium". When containing lactose or other admixtures such as burnt sugar or powdered cocoa husk, medicinal opium is in fact a "preparation" [9] of opium. In any event, whether it is an opium preparation or only manipulated opium, it is subject to the provisions of the Single Convention controlling opium. [10]

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[2] The 1912 introductory paras. of Chapters I, II and III and the 1925 (article 1). Conventions.

[3] Article 1.

[4] Article 2, para. 1.

[5] For a definition of production see below article 1, para. 1, subpara. (*t*); see also above the comments on article 1, para. 1, subpara. (*n*).

[6] For a definition of "stocks" see below article 1, para. 1, subpara. (*x*); the definition excludes stocks held by retail outlets.

[7] The "national opium agency" is the "one or more government agencies" which a Party permitting the cultivation of the opium poppy for the production of opium must charge with carrying out the functions described in article 23, para. 2.

[8] The fifth edition of the *Pharmacopœa Helvetica* (1949), p. 765, defines "medicinal opium" as opium powder reduced to a content of 9.2 to 10.2 per cent of anhydrous morphine by the addition of lactose. This pharmacopœas calls "medicinal opium" also "powdered opium". The term "medicinal opium" has been abandoned in several new pharmacopœas, e.g. the *British Pharmacopœa* of 1968, p. 686, which uses the term "Powdered Opium"; and *Pharmacopœa Internationalis*, first edition, vol. I, p. 164 which uses the term "Standardized Powdered Opium"; the same name is used in its second edition (1967), p. 403.

[9] Article 1, para. 1, subpara. (*s*).

[10] Article 2, paras. 1 and 3.

Article 24

LIMITATION ON PRODUCTION OF OPIUM FOR INTERNATIONAL TRADE

General comments

1. Four basic provisions of the Single Convention are intended to ensure the limitation of opium production [1] to medical and scientific needs: (i) article 4, subparagraph (*c*), establishing this general aim of the treaty; [2] (ii) article 22, providing under certain conditions for the prohibition of the cultivation of the opium poppy in order to prevent diversion of opium into illicit channels; (iii) article 23, requiring that opium-producing countries establish adequate machinery for the control of opium production and that they make the international and wholesale trade in opium a government monopoly, and finally (iv) article 24, which as a general principle obligates Parties not to contribute to overproduction of opium, and more specifically establishes rules by which the number of countries producing opium for exports should be reduced in order to contribute to the achievement of this aim. Only countries which in the recent past before the adoption of the Single Convention have exported opium which they produced, or which obtain the authorization of the Economic and Social Council to engage in such export, are free to export opium which they produce. Other countries may, however, annually export a maximum of five tons of opium of their own production, provided they comply with the procedure provided in article 24. [3] The provision of article 6, paragraph 2, subparagraph (*a*) of the 1953 Protocol, limiting the international trade in opium to that produced in expressly named countries, [4] was not taken over by the Single Convention.

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[1] Article 1, para. 1, subpara. (*t*).

[2] See, however, article 49.

[3] Para. 2, subpara. (*a*) and para. 4, subpara. (*a*), clause (ii).

[4] I.e. Bulgaria, Greece, India, Iran, Turkey, Union of Soviet Socialist Republics and Yugoslavia.

Paragraph 1, subparagraph **(a)**

1. (*a*) If any Party intends to initiate the production of opium or to increase existing production, it shall take account of the prevailing world need for opium in accordance with the estimates thereof published by the Board so that the production of opium by such Party does not result in over-production of opium in the world.

Commentary

1. A Party which permits the cultivation of the poppy for the production of opium can carry out its treaty obligations relating thereto only if it deter-

3. Paragraph 2, subparagraph (*a*) thus applies in fact only to those Parties which during ten years prior to 1 January 1961 did not export opium which they produced—as does its subparagraph (*b*). Both subparagraphs, however, do not apply to non-Parties, nor to opium produced in those non-metropolitan territories of Parties to which the Single Convention does not apply. [5]

4. The question arises whether the subparagraph under consideration imposes upon the Parties to which it applies a legal obligation not to export opium of their own harvest, even in quantities not exceeding five tons annually, without the notification to the Board for which the subparagraph provides, or whether failure of a Party to make such a notification only obligates the other Parties not to import opium produced in the territory of such a Party under paragraph 4, subparagraph (*a*), clause (ii). In the latter case the Party which has neglected to make the notification would be in a position to export its opium to a non-Party. While the wording of paragraph 4 imposes only on importing Parties an obligation not to engage in the international transactions concerned, the text of paragraph 3 and paragraph 5, subparagraph (*b*) justifies the conclusion that exporting Parties are also bound to abide by the prohibitions of article 24, [6] as accords with the object and purpose of this article.

5. In view of article 2, paragraph 3, the subparagraph under consideration, like the other restrictions imposed by article 24 on the international trade in opium, applies not only to opium as base drug, but also to preparations of opium, including medicinal opium, but not to other drugs made from opium, e.g. morphine or codeine. The application of article 24 to opium preparations and medicinal opium may, however, cause considerable difficulties in practice. [7]

6. The notification under paragraph 2, subparagraph (*a*), need not be repeated for each year in which a Party desires to export up to five tons of opium which it produces. Once made, it enables the Parties to import continuously such opium pursuant to paragraph 4, subparagraph (*a*), clause (ii). [8]

7. The "controls in force" on which the notifying Party must furnish information to the Board are in any event those required by the provision of article 23 and article 31, paragraphs 4-15. This information has to be given to the Board even if it duplicates information already sent to the Secretary-General under article 18, and in particular under paragraph 1, subparagraphs (*a*) and (*b*) of that article.

8. When considering whether to approve the notification or to recommend to the notifying Party not to engage in the production of opium for export, the Board should take into account not only whether the Party has enacted satisfactory laws and regulations for the control of opium production and of the domestic and international trade in opium as required by the Single Convention, but also, *inter alia*, whether the Party under its particular condi-

[5] Articles 42 and 46; see on the other hand article 24, para. 4, subpara. (*b*).

[6] See also article 6, para. 2, subpara. (*a*) of the 1953 Protocol.

[7] See below, comments on para. 4; as regards the calculation of the amount of opium in preparations, see form C/S (4th edition, November 1969) of the Board, instruction 4 and form A/S (5th edition, November 1969), instruction 4.

[8] *Records*, vol. II, p. 162.

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 823

§ 823. Registration requirements

Effective: October 24, 2018
Currentness

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

United States Court of Appeals
For the First Circuit

No. 21-1055

DR. LYLE E. CRAKER,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, D. CHRISTOPHER EVANS, in his official capacity as Acting Administrator of Drug Enforcement Administration,

Respondents.

No. 21-1323

SCOTTSDALE RESEARCH INSTITUTE,

Petitioner,

v.

US DRUG ENFORCEMENT ADMINISTRATION; D. CHRISTOPHER EVANS, Administrator of Drug Enforcement Administration; MERRICK B. GARLAND, Attorney General,

Respondents.

RESPONDENT'S BRIEFING NOTICE

Issued: July 16, 2021

Respondent's brief must be filed by **August 16, 2021**.

The deadline for filing petitioner's reply brief will run from service of respondent's brief in accordance with Fed. R. App. P. 31 and 1st Cir. R. 31.0. Parties are advised that extensions of time are not normally allowed without timely motion for good cause shown.

Presently, it appears that this case may be ready for argument or submission at the coming **November, 2021** session.

The First Circuit Rulebook, which contains the Federal Rules of Appellate Procedure, First Circuit Local Rules and First Circuit Internal Operating Procedures, is available on the court's website at www.ca1.uscourts.gov. Please note that the court's website also contains tips on filing briefs, including a checklist of what your brief must contain.

Failure to file a brief in compliance with the federal and local rules will result in the issuance of an order directing the party to file a conforming brief and could result in the respondent not being heard at oral argument. See 1st Cir. R. 3.0 and 45.0.

Maria R. Hamilton, Clerk

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