UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 17-70162

HEMP INDUSTRIES ASSOCIATION, ET AL.

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.

PETITION FOR REVIEW OF RULES
OF DRUG ENFORCEMENT ADMINISTRATION

PETITIONERS' EXCERPTS OF RECORD

Patrick D. Goggin, SBN # 182218
Hoban Law Group
870 Market Street, Suite 1148
San Francisco, CA 94102
Telephone: (415) 981-9290

Of counsel:
Robert Hoban (Admitted)
Garrett Graff (Admitted)
Hoban Law Group
730 17th St, Ste 420
Denver, CO 80202

Attorneys for Petitioners

Dated: April 3, 2017

INDEX TO EXCERPTS OF RECORD

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. _____

Hemp Industries Association; Centuria Natural Foods, Inc.; and R.M.H. Holdings, Inc.	)
Petitioners	)
v.	)
Drug Enforcement Administration; Charles Rosenberg, as Acting Administrator, Drug Enforcement Administration	)
Respondents	)

AMENDED PETITION FOR REVIEW

Pursuant to 21 U.S.C. §877 (section 507 of the Controlled Substances Act ("CSA")); 5 U.S.C. § 702 (the Administrative Procedures Act ("APA")); and Rule 15 of the Federal Rules of Appellate Procedure, Hemp Industries Association ("HIA"), R.M.H. Holdings, Inc. ("R.M.H."), and Centuria Natural Foods, Inc. ("Centuria") (collectively, "Petitioners") hereby petition the Court for review of the "Final Rule—Establishment of a New Drug Code for Marihuana Extract," issued by the Drug Enforcement Administration on December 14, 2016, 81 Fed. Reg. 90,194-

96 (Dec. 14, 2016) (the "Final Rule"). A copy of the Final Rule is attached hereto as Exhibit 1. A copy of Proposed Rule—Establishment of a New Drug Code for Marihuana Extract, 76 Fed. Reg. 39,039-41 (July 5, 2011), published more than **five (5) years** before the Final Rule, is also attached hereto as Exhibit 2.

The principal place of business of Petitioner HIA is in the State of California, within this Circuit. The principal place of business of Petitioner Centuria is in the State of Nevada, within this Circuit. The principal place of business of Petitioner R.M.H., a Wyoming corporation, is in the State of Colorado, not within this Circuit; but pursuant to Fed.R.App.P. 15(a)(1), R.M.H.'s interests make joinder to this petition practicable.

Petitioners seek judicial review of the Final Rule pursuant to 21 U.S.C. § 877 on the basis that the Final Rule creates a new drug code without the DEA having followed the procedures or made the findings required by the CSA in order to add new substances to the schedules of the CSA, 21 U.S.C. §811(a). Additionally, the Final Rule creates this new drug code, indicative of being a controlled substance, for substances which are in fact not controlled pursuant to the CSA. Specifically, the Final Rule dictates that the mere presence of "cannabinoids," which are not controlled substances, is the determinative factor of whether a compound is a "marihuana extract." Further, the Final Rule overbroadly defines "marihuana extract," without reflecting that certain portions and varieties of the genus *Cannabis*

sativa L. are Congressionally exempted from the CSA and/or are exempted from being treated as controlled substances altogether pursuant to the relevant laws, as enacted by Congress. *See e.g.* 21 U.S.C. § 802(16); 7 U.S.C. § 5940(b)(2) (part of the Agricultural Act of 2014 (the "Farm Bill")). Moreover, the Final Rule may also run afoul of other federal law including, but not limited to, the Data Quality Act, Regulatory Flexibility Act, and Congressional Review Act.

In addition to 21 U.S.C. § 877, Petitioners seek judicial review of the Final Rule pursuant to 5 U.S.C. §§ 702, 706 on the grounds that the Final Rule is (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, *e.g.* the CSA, the Farm Bill, and the DEA's regulations; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations; and, (4) without observance of procedure required by law.

Respectfully submitted,

s/Patrick D. Goggin

Patrick D. Goggin, SBN 182218
Hoban Law Group
870 Market Street, Suite 1148
San Francisco, CA 94102
Telephone: (415) 981-9290

Of counsel:
Robert Hoban
Garrett Graff
Hoban Law Group
730 17th St, Ste 420
Denver, CO 80202

Dated: January 27, 2017

CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 26.1, FEDERAL RULES OF APPELLATE PROCEDURE

Non-governmental corporate Petitioners include the Hemp Industries Association; Centuria Natural Foods, Inc.; and R.M.H. Holdings, Inc. Hemp Industries Association is a trade association. R.M.H. Holdings, Inc. and Centuria Natural Foods, Inc. are privately held corporations and none of them has any parent companies, subsidiaries, or affiliates that have issued shares to the public.

CERTIFICATE OF SERVICE

I certify that on January 27, 2017, I served a true and correct copy of the foregoing *Amended Petition for Review*:

Via PACER, e-filed upon:

Brian Stretch
United States Attorney
Office of the United States Attorney
450 Golden Gate Ave, 11th Floor
San Francisco, CA 94102

John J. Martin
Special Agent in Charge
Drug Enforcement Administration
450 Golden Gate Ave, 14th Floor
San Francisco, CA 94102

The Honorable Loretta Lynch
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania, NW
Washington, DC 20530

The Honorable Chuck Rosenberg
Drug Enforcement Administration
7000 Army-Navy Dr
Arlington, VA 22202

Wendy H. Goggin
Chief Counsel
Office of General Counsel
Drug Enforcement Administration
8701 Morrissette Dr
Springfield, VA 22152

s/Patrick D. Goggin
Patrick D. Goggin

Dated: January 27, 2017

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Hemp Industries Association, *et al.*,	)	No. 17-70162
Petitioners,	)	Drug Enforcement Administration
Drug Enforcement Administration, *et al.*,	)	
Respondents.	)	

CERTIFIED LIST OF DOCUMENTS
COMPRISING THE ADMINISTRATIVE RECORD

In accordance with Rule 17 of the Federal Rules of Appellate Procedure, the undersigned, Bettie E. Goldman, Deputy Chief Counsel for Litigation and Policy, Office of the Chief Counsel, United States Department of Justice, Drug Enforcement Administration (DEA), certifies the following as a list of all available documents and other materials comprising the administrative record in the matter under review in this case:

1. July 5, 2011, Notice of Proposed Rulemaking, "Establishment of a New Drug Code for Marihuana Extract," 76 Fed. Reg. 39039.

2. July 8, 2011, comment on proposed rule on behalf of Pacific Coast Wellness & Evolution Center.

3. July 8, 2011, comment on proposed rule by Benjamin Kerensa.

4. July 11, 2011, comment on proposed rule on behalf of HempRock.

5. August 22, 2011, comment on proposed rule by Sherrie Berry.

6. September 5, 2011, comment on proposed rule on behalf of GW Pharmaceuticals Ltd.

7. September 7, 2011, comment on proposed rule on behalf of GW Pharmaceuticals Ltd.

8. December 14, 2016, Final Rule, "Establishment of a New Drug Code for Marihuana Extract," 81 Fed. Reg. 90194.

FEB 2 1 2017

Bettie E. Goldman
Deputy Chief Counsel for
Litigation and Policy
Office of the Chief Counsel
Drug Enforcement Administration

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system as to participants in the case who are registered CM/ECF users.

A copy of the foregoing has been served today by United States mail, postage prepaid, upon the following individual:

Robert Thomas Hoban
Hoban Law Group
730 17th Street
Suite 420
Denver, CO 80202

s/ Sarah Carroll
Sarah Carroll

keep them operationally current. It, therefore, (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in subtitle VII, part, A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would establish Class E airspace at Keller Brothers Airport, Lebanon, PA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA E5 Lebanon, PA [New]

Keller Brothers Airport
(Lat. 40°917'30" N., long. 76°19'43" W.)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of the Keller Brothers Airport.

Issued in College Park, Georgia, on June 23, 2011.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–16660 Filed 7–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–342P]

RIN 1117–AB33

Establishment of a New Drug Code for Marihuana Extract

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to create a new Administration Controlled Substances Code Number ("Code Number" or "drug code") under 21 CFR 1308.11 for "Marihuana Extract." This Code Number will allow DEA and DEA-registered entities to track quantities of this material separately from quantities of marihuana. This in turn will aid in complying with relevant treaty provisions.

Under international drug control treaties (administered by the United Nations), some differences exist between the regulatory controls pertaining to marihuana extract versus those for marihuana and tetrahydrocannabinols. DEA has established separate Code Numbers for marihuana and for tetrahydrocannabinols, but not for marihuana extract. To better track these materials and better comply with treaty provisions, DEA is proposing to create a separate Code Number for marihuana extract under 21 CFR 1308.11(d)(36): "Marihuana Extract meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinols and cannabidiols." Such extracts of marihuana would continue to be treated as schedule I controlled substances.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before September 6, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–342" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, *etc.*) voluntarily submitted by the commenter.

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 posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket 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

posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

Background

As provided in 21 CFR 1308.03, each controlled substance or basic class thereof is assigned a four digit Code Number that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, DEA uses these Code Numbers in establishing aggregate production quotas for basic classes of controlled substances listed in schedules I and II as required by 21 U.S.C. 826.

Consistent with the Controlled Substances Act (CSA), the schedules contained in the DEA regulations include marihuana (drug code 7360) in schedule I. 21 CFR 1308.11(d)(23). This listing includes (unless specifically excepted or unless listed in another schedule) any material, compound, mixture, or preparation, which contains any quantity of the substance, or which contains any of its salts, isomers, and salts of isomers that are possible within the specific chemical designation. Because the definition of marihuana in 21 U.S.C. 802(16) includes both derivatives and preparations of marihuana, DEA until now has used drug code 7360 for extracts of marihuana as well. In this proposed rule, DEA is proposing that the new drug code 7350 be used for extracts of marihuana.

Why a New Code Number Is Needed

The United Nations Conventions on international drug control treat extracts from the cannabis plant differently than marihuana or tetrahydrocannabinols. The creation of a new drug code in DEA regulations for marihuana extracts will allow for more appropriate accounting of such materials consistent with treaty provisions.

The Single Convention on Narcotic Drugs, 1961 ("Single Convention") and the 1971 Convention on Psychotropic Substances ("Psychotropic Convention") provide for the international control of marihuana constituents. Many of the CSA's provisions were drafted to comply with these Conventions. The CSA includes schemes of drug scheduling and procedures for adding, removing, and transferring drugs among the schedules that are similar, in some ways, to those in the Single Convention. With respect to those drugs that are subject to control under the Single Convention, the CSA mandates that DEA control such drugs at least as strictly as required by the Single Convention. 21 U.S.C. 811(d).

Somewhat similar to the CSA, the Single Convention controls substances through four schedules. However, under the Single Convention, the drugs that are subject to the most stringent controls are in schedule IV. Another difference between the CSA and the Single Convention is that, under the latter, a drug can be listed in more than one schedule. Cannabis and cannabis resin are listed in both schedule IV and schedule I of the Single Convention. Schedule I controls under the Single Convention include requirements for import and export authorization, licensing of manufacturers/distributors, recordkeeping requirements, requirement for prescriptions for medical use, annual estimate of needs, quotas, annual statistical reporting, and a requirement that use be limited to medical and scientific purposes. Schedule II of the Single Convention is similar in controls to schedule I with a few exceptions, and schedule III is less restrictive. All substances listed in schedule IV are also listed in schedule I. The placing of a drug into both schedule I and schedule IV therefore imposes the most stringent controls under the Single Convention. Although cannabis and cannabis resin are listed in Schedules I and IV of the Single Convention, cannabis extracts are listed only in Schedule I.

Proposed Actions

DEA therefore proposes to update 21 CFR 1308.11(d) to include new subparagraph (36) which would create a new Code Number in schedule I as follows:

"(36) Marihuana Extract 7350

Meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinols and cannabidiols."

The creation of a new drug code in DEA regulations for marihuana extracts would allow for more appropriate accounting of such materials consistent with treaty provisions. Such marihuana extracts remain in schedule I. Firms registered to handle marihuana (under drug code 7360) that also handle marihuana extracts, will need to apply to add the new drug code 7350 to their existing DEA registrations and procure quotas specifically for drug code 7350 each year.

Regulatory Compliance Analyses

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This rule proposes the establishment of a new drug code for marihuana extracts. DEA already registers persons handling marihuana extracts, but within another already-established drug code. Thus, persons who handle these marihuana extracts have already met DEA's registration, security, and other statutory and regulatory requirements. The only direct effect to registrants who handle marihuana extracts would be the requirement to add the new drug code to their registration once the code is established.

Executive Orders 12866 and 13563

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders 12866 and 13563. Although this rule is not a "significant regulatory action" under Executive Order 12866 Section 3(f), it was submitted to the Office of Management and Budget (OMB) and subsequently approved.

Executive Order 12988

This proposed regulation 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 burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism

implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act of 1995

This action does not impose a collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Executive Order 13175

This rule is not a policy that has Tribal implications under Executive Order 13175. It will 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.

List of Subjects in 21 CFR Part 1308

Drug traffic control, Controlled substances.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Section 1308.11 is amended by adding new paragraph (d)(36) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(36) Marihuana Extract 7350

Meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinols and cannabidiols.

* * * * *

Dated: June 14, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–16800 Filed 7–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218–AC46

Infectious Diseases

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of stakeholder meetings.

SUMMARY: OSHA invites interested parties to participate in informal stakeholder meetings concerning occupational exposure to infectious diseases. OSHA plans to use the information gathered at these meetings to explore the possible development of a proposed rule to protect workers from occupational exposure to infectious agents in settings, either where workers provide direct patient care or where workers perform tasks other than direct patient care that also have occupational exposure. These other work tasks include: Providing patient support services (*e.g.*, housekeeping, facility maintenance); handling, transporting, receiving or processing infectious items or wastes (*e.g.*, transporting medical specimens, disposing of medical waste); conducting autopsies or performing mortuary services; and performing tasks in laboratories.

DATES: Dates and locations for the stakeholder meetings are:

July 29, 2011, 9 a.m.–noon in Washington, DC.

July 29, 2011, 1:30 p.m.–4:30 p.m. in Washington, DC.

The deadline for confirmed registration at the meeting is: July 22, 2011. However, if space remains after this deadline, OSHA may accept additional participants until the meetings are full. Those who submit their registration after July 22, 2011 may not receive confirmation of their attendance from OSHA.

ADDRESSES:

Registration: Submit your notice of intent to participate in a stakeholder meeting through one of the methods below. Specify which meeting (morning or afternoon) you would like to attend.

Electronic: Register at: *https://www2.ergweb.com/projects/conferences/osha/register-osha-stakeholder.htm* (follow the instructions online).

Facsimile: Fax your request to: (781) 674–7200, and label it "*Attention:* OSHA Infectious Diseases Stakeholder Meeting Registration."

Regular mail, express delivery, hand (courier) delivery, and messenger service: Send your request to: OSHA Infectious Diseases Stakeholder Meeting Registration, *Attention:* Thomas Nerad, OSHA, Room N–3718, 200 Constitution Avenue, NW., Washington, DC 20210.

Meetings: The July 29, 2011 meetings will be held in the Francis Perkins Building, Room N–4437 at 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Frank Meilinger, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; *telephone:* (202) 693–1999.

General and technical information: Contact Andrew Levinson, Director, Office of Biological Hazards, OSHA Directorate of Standards and Guidance, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; *telephone:* (202) 693–2048.

Copies of this ***Federal Register*** *notice:* Electronic copies are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available on the OSHA Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 6, 2010, OSHA published a Request for Information, entitled "Infectious Diseases" (Docket Number: OSHA–2010–0003). The Agency was interested in more accurately characterizing the nature and extent of occupationally-acquired infectious diseases and the strategies that are currently being used to mitigate the risk of occupational exposure to infectious agents. More than 200 comments were received in response to the RFI. Based upon these responses and an ongoing review of current literature on this subject, OSHA is considering what action, if any, the Agency should take to limit the spread of occupationally-acquired infectious diseases.

One action the Agency is considering is the development of a program standard to control workers' exposure to infectious agents in settings, either where workers provide direct patient care or where workers perform tasks other than direct patient care which also have occupational exposure. These other tasks might include such tasks as: Providing patient support services (*e.g.*, housekeeping, food delivery, facility maintenance); handling, transporting, receiving or processing infectious items

FDA performs to monitor third-party certification bodies that are accredited by a recognized accreditation body under § 1.662.

§ 1.710 How will FDA notify the public about the fee schedule?

FDA will notify the public of the fee schedule annually. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

§ 1.715 When must a user fee required by this subpart be submitted?

(a) Accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

§ 1.720 Are user fees under this subpart refundable?

User fees accompanying completed applications and annual fees under this subpart are not refundable.

§ 1.725 What are the consequences of not paying a user fee under this subpart on time?

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of § 1.631(a) until the date that FDA receives the application fee. An application for direct accreditation or for renewal of direct accreditation will not be considered complete for the purposes of § 1.671(a) until FDA receives the application fee.

(b) A recognized accreditation body that fails to submit its annual user fee within 30 days of the due date will have its recognition suspended.

(1) FDA will notify the accreditation body electronically that its recognition is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While an accreditation body's recognition is suspended, the accreditation body will not be able to accredit additional third-party certification bodies. The accreditation of third-party certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications issued by such third-party certification bodies, would remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will revoke the accreditation body's recognition under § 1.634(a)(4)(iii), and provide notice of such revocation in accordance with § 1.634.

(c) An accredited third-party certification body that fails to submit its annual fee within 30 days of the due date will have its accreditation suspended.

(1) FDA will notify the third-party certification body that its accreditation is suspended, electronically and in English. FDA will notify a recognized accreditation body, electronically and in English, if the accreditation of one if its third-party certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While a third-party certification body's accreditation is suspended, the third-party certification body will not be able to issue food or facility certifications. A food or facility certification issued by a third-party certification body prior to the suspension of the auditor/certification body accreditation will remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will withdraw the third-party certification body's accreditation under § 1.664(a)(4), and provide notice of such withdrawal in accordance with § 1.664.

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30033 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–342]

RIN 1117–AB33

Establishment of a New Drug Code for Marihuana Extract

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is creating a new Administration Controlled Substances Code Number for "Marihuana Extract." This code number will allow DEA and DEA-registered entities to track quantities of this material separately from quantities of marihuana. This, in turn, will aid in complying with relevant treaty provisions.

Under international drug control treaties administered by the United Nations, some differences exist between the regulatory controls pertaining to marihuana extract versus those for marihuana and tetrahydrocannabinols. The DEA has previously established separate code numbers for marihuana and for tetrahydrocannabinols, but not for marihuana extract. To better track these materials and comply with treaty provisions, DEA is creating a separate code number for marihuana extract with the following definition: "Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." Extracts of marihuana will continue to be treated as Schedule I controlled substances.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

As provided in 21 CFR 1308.03, each controlled substance or basic class thereof is assigned a four digit Administration Controlled Substance Code Number ("Code number" or "drug code") that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, the DEA uses these code numbers in establishing aggregate production quotas for basic classes of controlled substances listed in Schedules I and II as required by 21 U.S.C. 826.

Consistent with the Controlled Substances Act (CSA), the schedules contained in DEA regulations include marihuana (drug code 7360) in Schedule I. 21 CFR 1308.11(d)(23). This listing includes (unless specifically excepted or unless listed in another schedule) any material, compound, mixture, or preparation, which contains any quantity of the substance, or which contains any of its salts, isomers, and salts of isomers that are possible within the specific chemical designation. Because the definition of marihuana in 21 U.S.C. 802(16) includes both derivatives and preparations of marihuana, the DEA until now has used drug code 7360 for extracts of marihuana. This final rule finalizes a

July 5, 2011, Notice of Proposed Rulemaking (76 FR 39039) in which the DEA proposed that a new drug code 7350 be used for extracts of marihuana.

Why a New Code Number Is Needed

The United Nations Conventions on international drug control treats extracts from the cannabis plant somewhat differently than marihuana or tetrahydrocannabinols. The creation of a new drug code in the DEA regulations for marihuana extracts will allow for more appropriate accounting of such materials consistent with treaty provisions.

The Single Convention on Narcotic Drugs, 1961 ("Single Convention") and the 1971 Convention on Psychotropic Substances ("Psychotropic Convention") provide for the international control of marihuana constituents. Many of the CSA's provisions were drafted to comply with these Conventions. The CSA includes schemes of drug scheduling and procedures for adding, removing, and transferring drugs among the schedules that are similar, in some ways, to those in the Single Convention. With respect to those drugs that are subject to control under the Single Convention, the CSA mandates that DEA control such drugs in a manner that will ensure the United States meets its obligations under the Single Convention. 21 U.S.C. 811(d)(1).

Somewhat similar to the CSA, the Single Convention lists substances in four schedules. However, under the Single Convention, the drugs that are subject to the most stringent controls are in Schedule IV. Another difference between the CSA and the Single Convention is that, under the latter, a drug can be listed in more than one schedule. Cannabis and cannabis resin are listed in both Schedule IV and Schedule I of the Single Convention. Schedule I controls under the Single Convention include: Requirements for import and export authorization, licensing of manufacturers/distributors, recordkeeping requirements, a requirement for prescriptions for medical use, annual estimate of needs, quotas, annual statistical reporting, and a requirement that use be limited to medical and scientific purposes. Schedule II of the Single Convention is similar in controls to Schedule I with a few exceptions, and Schedule III is less restrictive. All substances listed in Schedule IV are also listed in Schedule I under the Single Convention in order to encompass the requirements mentioned above. In addition, as indicated, the Single Convention imposes certain heightened measures of control with respect to Schedule IV drugs. The placing of a drug into both Schedule I and Schedule IV, therefore imposes the most stringent controls under the Single Convention. Although cannabis and cannabis resin are listed in Schedules I and IV of the Single Convention, cannabis extracts are listed only in Schedule I.

Comments

In response to the July 5, 2011, Notice of Proposed Rulemaking (76 FR 39039), the DEA received six submissions from five commenters. Three of the comments raised issues relating to the medical use or legality of marihuana/cannabis; these comments were not germane to the issues addressed by this rulemaking. A fourth comment was merely a clarification of a comment previously submitted.

One comment requested clarification of whether the new drug code will be applicable to cannabidiol (CBD), if it is not combined with cannabinols.

DEA response: For practical purposes, all extracts that contain CBD will also contain at least small amounts of other cannabinoids.[1] However, if it were possible to produce from the cannabis plant an extract that contained only CBD and no other cannabinoids, such an extract would fall within the new drug code 7350. In view of this comment, the regulatory text accompanying new drug code 7350 has been modified slightly to make clear that it includes cannabis extracts that contain only one cannabinoid.

Another comment from a pharmaceutical firm currently involved in cannabinoid research and product development praised DEA's efforts to establish a new drug code for marihuana extracts as a means to more accurately reflect the activities of scientific research and provide more consistent adherence to the requirements of the Single Convention. However, the comment expressed concerns that the proposed definition for the new drug code (*i.e.* "meaning extracts that have been derived from any plant of the genus Cannabis and which contain cannabinols and cannabidiols") is too narrow. The comment suggested that the broader term "cannabinoids" be substituted for "cannabinols and cannabidiols." The comment pointed out that other constituents of the marihuana plant may have therapeutic potential. The comment further clarified that the broader term "cannabinoid" includes both cannabinol-type compounds and cannabidiol-type compounds, as well as cannabichromene-type compounds, cannabigerol-type compounds, and other categories of compounds.

DEA response: DEA agrees with the commenter that the term "cannabinoid" would provide for a broader definition of marihuana extract; however, use of the term "cannabinoid" necessitates that the DEA clarify that the new marihuana extract category (drug code 7350) is not intended to include "cannabis resin" as defined in the U.N. Single Convention.

As discussed in the NPRM, a new drug code is necessary in order to better account for these materials in accordance with treaty obligations. The Single Convention placed "cannabis" and "cannabis resin" under both Schedule I and IV of the Convention, the most stringent level of control under the Convention. While "cannabis resin" is extracted from "cannabis," the Single Convention specifically controls "extracts" separately. Extracts of cannabis are controlled only under Schedule I of the Convention, which is a lower level of control than "cannabis resin."

Accordingly, it is the DEA's intent to define the term "marihuana extract" so as to exclude material referenced as "cannabis resin" under the Single Convention on Narcotics. "Cannabis resin" (regulated under the CSA as a resin of marihuana) contains a variety of "cannabinoids" and will continue to be regulated as marihuana under drug code 7360. The new drug code for marihuana extracts under 21 CFR 1308.11(d)(58) will exclude the resin. Cannabis resin and marihuana resin remain captured under the drug code for marihuana (drug code 7360), thus differentiating this material from marihuana extracts (new drug code 7350). This will maintain compliance with the Single Convention.

Final Action

After careful consideration of all comments, the DEA is hereby amending 21 CFR 1308.11(d) to include a new subparagraph (58) which creates a new code number in Schedule I as follows:

"(58) Marihuana Extract—7350

"Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant."

The creation of this new drug code in the DEA regulations for marihuana extracts allows for more appropriate accounting of such materials consistent with treaty provisions. Such marihuana

[1] Although it might be theoretically possible to produce a CBD extract that contains absolutely no amounts of other cannabinoids, the DEA is not aware of any industrially-utilized methods that have achieved this result.

extracts remain in Schedule I. Entities registered to handle marihuana (under drug code 7360) that also handle marihuana extracts, will need to apply to modify their registrations to add the new drug code 7350 to their existing DEA registrations and procure quotas specifically for drug code 7350 each year.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders 12866 and 13563. This rule is not a significant regulatory action under Executive Order 12866.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking 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 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

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This rule establishes a new drug code for marihuana extracts. DEA already registers persons handling marihuana extracts but within another already-established drug code. Thus, persons who handle these marihuana extracts have already met DEA's registration, security, and other statutory and regulatory requirements. The only direct effect to registrants who handle marihuana extracts will be the requirement to add the new drug code to their registration. Therefore, DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, 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 for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Drug traffic control, Controlled substances.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding paragraph (d)(58) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(58) Marihuana Extract—(7350)

Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.

* * * * *

Dated: December 7, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–29941 Filed 12–13–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1988

[Docket Number: OSHA–2015–0021]

RIN 1218–AC88

Procedures for Handling Retaliation Complaints Under Section 31307 of the Moving Ahead for Progress in the 21st Century Act (MAP–21)

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: On March 16, 2016, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor (Department) issued an interim final rule (IFR) that provided procedures for the Department's processing of complaints under the employee protection (retaliation or whistleblower) provisions of Section 31307 of the Moving Ahead for Progress in the 21st Century Act (MAP–21). The IFR established procedures and time frames for the

Michele M. Leonhart, Administrator
Drug Enforcement Administration (DEA)
8701 Morrissette Drive
Springfield, Virginia 22152

September 5, 2011

RE: Docket No. DEA-342
Establishment of a New Drug Code for Marihuana extract

Dear Administrator Leonhart:

GW Pharmaceuticals, Ltd. (GWP) would like to thank the Drug Enforcement Administration (DEA) for the opportunity to share our perspectives concerning DEA's Notice of Proposed Rulemaking (NPRM) establishing a new Administration Controlled Substances Code Number (drug code) for Marihuana Extract, as 7350. GWP supports this rulemaking; however, we are concerned about the proposed definition of Marihuana Extract and have explained our concerns below.

GWP was founded in the United Kingdom (U.K.) in 1998 and is fully licensed by the U.K. Home Office to work with a range of controlled drugs for medical research purposes. GWP is listed on AIM, a market of the London Stock Exchange and employs more than 150 individuals with extensive experience in developing cannabinoid medicines and plant-based prescription pharmaceutical products. GWP is a world leader in the cannabinoid product development process, including botanical research, extraction technology, formulation into delivery technologies, clinical trials and regulatory affairs. GWP holds Good Manufacturing Practice (GMP) manufacturing licenses in the U.K. for the manufacture of pharmaceutical products for both clinical trials and commercial purposes; and its research, which initially focused on multiple sclerosis, cancer pain and neuropathic pain now extends to oncology, diabetes, epilepsy and psychiatric illness.

GWP's lead product, Sativex®, is produced from extracts of two proprietary chemotypes of the cannabis plant, a high-tetrahydrocannabinol (THC) producing plant and a high-cannabidiol (CBD) producing plant. Each extract contains other cannabinoid and non-cannabinoid ingredients naturally found in the respective chemotype of the cannabis plant, and the two extracts are formulated together with inert excipients (e.g., ethanol and propylene glycol) to produce a pharmaceutical drug product for administration to the sub-lingual and oral mucosa. Each plant chemotype yields a reproducible and standardized extract without chemical manipulation, other than decarboxylation and extraction using liquid carbon dioxide under pressure. Neither THC nor CBD are isolated, synthesized, or altered in any way. Sativex® is administered in a metered dose oromucosal spray, in order to facilitate absorption by the lining of the oral cavity. Each 100µL spray contains 2.7 mg THC and 2.5 mg CBD, together with other plant components Sativex® has received marketing authorization in the U.K., Canada, New Zealand, Germany, Denmark, the Czech Republic, Sweden and Spain as a prescription medicine for symptom

improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Additional European approvals are expected over the next year. Sativex® is also in clinical development in the United States for the treatment of persistent cancer pain that is not adequately relieved by opioids.

In 2007, GWP entered into a strategic alliance with Otsuka Pharmaceutical Company, Ltd. (Otsuka) which comprised two separate agreements: a Sativex® United States (U.S.) license agreement and a global cannabinoid research collaboration. Under our agreement with Otsuka, GWP has granted Otsuka an exclusive license to develop and market Sativex® in the U.S. GWP will be responsible for the manufacture and supply of Sativex® to Otsuka. GWP and Otsuka jointly oversee all clinical development and regulatory activities. For clinical trials in the U.S., Sativex® will be exported from GWP (only in completely labeled and finished dosage unit form) to a DEA-registered importer for distribution to state-licensed and DEA-registered clinical sites.

GW Pharmaceuticals, Ltd. fully supports DEA's efforts in this NPRM to track quantities of marihuana extract separately from quantities of marihuana. By establishing a separate drug code for marihuana extracts, DEA and those who handle these extracts, including the pharmaceutical industry, will be able to differentiate between marihuana and marihuana extracts on certain registrants' DEA certificates of registration, on certain DEA-issued order forms, and on DEA applications for import (DEA Form 357), export (DEA Form 161 or 161R), as well as on the resulting DEA permits, and on manufacturing (DEA Form 189) and procurement (DEA Form 250) quota applications and issuance letters and certificates. DEA and the pharmaceutical industry will be able to more accurately identify the substance, and thus the purpose, requested in procurement quota applications and for individual manufacturing quotas. Additionally, the separate identification and tracking of marihuana and marihuana extracts will allow DEA to more accurately delineate national aggregate production quotas and annual estimates of legitimate medical and scientific need for these two substances or basic classes of substances.

GWP believes this NPRM takes a significant step toward clarifying the documentation required for importation and exportation of these substances and allows the United States and other governments to better fulfill their obligations as a Parties to the Single Convention of Narcotic Drugs 1961 and its amending Protocol of 1972. As noted by DEA, the Single Convention places cannabis and cannabis resin in both Schedule IV and Schedule I of the convention and thus invokes the strictest controls over these substances. By contrast, cannabis extracts are listed separately as a drug and only in Schedule I of the Single Convention of 1961. The controls for Schedule I permit greater movement than Schedule IV and thus broader conditions for legitimate research, medical and scientific development.

However, even under these broader conditions of control, when cannabis extracts must be identified as cannabis or marihuana because of limited drug codes or categories, the result is a misleading and less accurate record of the actual transactions. Requiring separate identification of marihuana and marihuana extract transactions will more accurately reflect the ongoing activities of scientific research, pharmaceutical companies, governments, and the international controlled substance community. International trade documents will be more accurate with this clarification, and required government

reporting to the International Narcotics Control Board will more clearly depict actual international trade and consequent government adherence to the requirements of the Single Convention of 1961. GWP further believes that while marihuana extracts remain in Schedule I under the United States (U.S.) Controlled Substances Act of 1970, the importation of marihuana extracts would be feasible for the legitimate manufacture of a product following approval of a New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) and subsequent rescheduling by DEA. Furthermore, GWP believes that a specific FDA-and DEA-approved formulation derived from marihuana extracts could be placed in the appropriate DEA drug schedule based on its potential for abuse, its physical and psychological dependence liability, and its currently accepted medical use in treatment in the U.S.

GWP also agrees with the DEA that establishment of this new hallucinogenic Administration Controlled Substance Code Number for Marihuana Extract (9350) under Title 21, Code of Federal Regulations (CFR), Section 1308.11 (d) (36) can be effected as an agency rulemaking action and is also not a scheduling action.

GWP believes that this rulemaking will create a new basic class of controlled substances for Marihuana Extract, drug code 9350. The term "basic class" is not defined in the Controlled Substances Act of 1970; however, it is used throughout Title 21, U.S.C., Section 826 to depict how quotas will be established and quantified for Schedule I and II controlled substances. The term "basic class" is defined in the regulations at 21 CFR 1300.01 (5) and the term is used throughout the Quota Section, 21 CFR 1303, and the Schedules of Controlled Substances Section, 21 CFR 1308. GWP notes the clear application of "basic class" for Marihuana Extract under 21 CFR 1300.01 (5) (iii) wherein it is defined as "each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in 21 CFR 1308.11 (d)".

However, GWP is concerned that the proposed definition of this new basic class (i.e., "meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinols ***and*** *cannabidiols") lacks clarity and may inadvertently be very limiting to the scientific, research and medical communities which are working with marihuana extracts in search of new therapeutic medicines. It is GWP's understanding that the term "cannabinol" (CBN) was used in the early scientific literature (such as the Dispensary of the United States of America, 20th Ed. 1918) to describe what was believed at that time to be the active constituent of the cannabis plant. Subsequently, cannabidiol (CBD) was discovered, but both CBN and CBD were believed to be inactive. (Adams, R., "Marijuana," Bulletin New York Academy of Medicine, vol 18, 1942, pp. 705-73). More recent research has definitively demonstrated that delta-9-tetrahydrocannabinol is the primary* ***psychoactive*** *ingredient of the plant. Furthermore, many of the other unique constituents of the plant also have been shown to have independent pharmacological/physiological activity and may have therapeutic potential. GWP believes that the currently-accepted term in the scientific literature for these unique constituent classes is "cannabinoids." "Cannabinol-type" is now identified as only one among those specific classes or types of cannabinoids; "cannabidiol-type" is another; still others include cannabichromene-type, cannabigerol-type, etc. (Safwat A., Samir R., Slade D., Radwan M., Zulfizar F., and ElSohly M., "Cannabinoid Ester Constituents from High-Potency Cannabis sativa," J. Natural Products 71(6), p. 1119, 2008; Radwan M., ElSohly M., Slade D.,*

Safwat A., Khan I., and Ross S., "Biologically Active Cannabinoids from High-Potency Cannabis sativa," J. Natural Products 72(5), pp. 906-911, 2009). Cannabis chemotypes have been developed which predominantly express THC, CBD, and other cannabinoid classes; and there are therefore cannabis/marihuana extracts currently being studied that are composed of one or more cannabinoid classes.

It is unclear whether all of these marihuana extracts would meet the DEA definition since they may or may not contain ***both*** *a cannabinol* ***and*** *a cannabidiol. Yet these extracts are derivatives of cannabis, meet the basic general definition of an extract and are controlled in Schedule I. GWP believes that it would appear incongruous to report these other extracts under the Marihuana drug code (7360), and more appropriate to include them in the proposed new Marihuana Extract basic class (7350). GWP encourages DEA in its Final Rule to define "Marihuana Extract" as broadly as possible to allow medical and scientific disciplines to research and develop all the possible constituents of marihuana extract. To this end, GWP recommends that DEA adopt the following definition of Marihuana Extract: "meaning extracts that have been derived from any plant of the genus cannabis and which contain one or more cannabinoids." In the alternative, GWP recommends that the phrase "any quantity of" be inserted in the DEA proposed definition, immediately before "cannabinols". These changes will provide more accurate identification and tracking of the handling and movement of these controlled substances and will also assist DEA and FDA by requiring greater specificity in Schedule I research protocols. Since research into these other extracts and active ingredients continues to move rapidly forward, GWP encourages DEA to consider establishing new basic classes for such substances and/or extracts (e.g., "cannabinol" and also for "cannabidiol"). The separate identification of these controlled substances would also provide DEA and the medical, scientific and research communities with better, more accurate tracking and accounting of these materials separately from marihuana, and separately from marihuana extracts, consistent with U.S. obligations as a Party to both the Single Convention of 1961 which controls cannabis, cannabis resin, cannabis extracts and cannabis tinctures and the Psychotropic Convention of 1971 which controls tetrahydrocannabinol and certain isomers and their stereochemical variants*.

GW Pharmaceuticals, Ltd. appreciates the opportunity to comment on DEA's proposal to create a new drug code for Marihuana extract. GWP believes that this DEA action strengthens the "closed system" of distribution created by the Controlled Substances Act of 1970 by facilitating more accurate accounting of all controlled substances and thus reducing the potential for diversion from this closed system. Thank you for consideration of our comments.

Respectfully submitted,

Alice P. Mead
Director, U.S. Professional Relations
GW Pharmaceuticals Ltd.

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Comment on FR Doc # 2011-16800

The is a Comment on the **Drug Enforcement Administration** (DEA) Proposed Rule: **Establishment of a New Drug Code for Marihuana Extract**

For related information, **Open Docket Folder**

Comment

I would like to tell you in this case how wrong you guys are. I need CBD for my pain.I have dealt w/Cancer since i was 17 almost the last 18 yrs of my life.It was never cured until March.I started on a CBD formula and I can tell you it is not a narcotic drug at all.You never feel high or any side effects from this part of the plant.Only relief of pain, you get and oxygen feeling in your body because it replaces it in your cells.You can feel tiny little bubbles in your body, which helped my arthritis greatly, and started helping the cancer and of course THC knocked the cancer all the way out.But you can process all THC out of the medication too.The DEA really needs to talk to the people who can make a formula like this.You are really screwing with my life.I can get sick again just waiting on you guys to get your info correct.I never write in on things, I just let you boys do your job.But in this case you have never been so wrong.You can not flunk a drug test off CBD.it is on of the least harmless things you can put in your body.Heck water is more dangerous than CBD.Really a schedule 1?Please rethink this...My Life demands on it.Blessings.Keep up the good work.

Comment Period Closed
Sep 6 2011, at 11:59 PM ET

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Submitter Information

Submitter Name:
Tonya Myers

Organization Name:
Pacific Coast Welness&Evolution Center

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Comment on FR Doc # 2011-16800

The is a Comment on the **Drug Enforcement Administration** (DEA) Proposed Rule: **Establishment of a New Drug Code for Marihuana Extract**

For related information, **Open Docket Folder**

Comment

Will this new code be applied to Cannabidiol if it is not combined with any other cannabinols?
Specifically, here is the quote that applies to the new code: "Marihuana Extract meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinols and cannabidiols."
This quote clearly states that the new code will apply to combined cannabinols and cannabidiols.
But what about 100% pure Cannabidiol by itself with nothing else? It is currently exempt as a schedule 1 drug and no DEA license is required to purchase it.
Will 100% pure Cannabidiol have this new code?
Thank you,
Sherrie

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Submitter Name:
Sherrie Berry

Organization Name:
None

EXHIBIT A

UNODC
United Nations Office on Drugs and Crime

Response to questions formulated by Ukraine on cannabis, under the international drug control conventions

I. Background

1. This summary note is prepared in response to questions formulated by the State Service of Ukraine on Drugs Control about the requirements of the international drug control conventions on the "processing of cannabis for non-narcotic products". As a background to the questions raised, Ukraine informed UNODC that it is engaged in "developing a legal and normative framework on the envisaged use of medical products made from cannabis plants." It was also indicated that the production and use of narcotics and non-narcotic products obtained from cannabis is currently prohibited in Ukraine (for Ukraine's request, see Annex 1).

2. Ukraine is party to the Single Convention on Narcotic Drugs as amended by the 1972 protocol amending the Single Convention on Narcotic Drugs ('1961 Convention'), the 1971 Convention on Psychotropic Substances ('1971 Convention') and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances ('1988 Convention').

II. Status of cannabis and substances derived therefrom under the 1961 Convention and the 1971 Convention

3. As a general obligation, States parties to the international drug control conventions are required to take such legislative and administrative measures as may be necessary to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of narcotic drugs and psychotropic substances controlled under the 1961 and 1971 Conventions, in accordance with their provisions.[1]

4. Cannabis and cannabis resin and extracts and tinctures of cannabis are subject to international control by virtue of inclusion in Schedule I and, for cannabis and cannabis resin, Schedule IV of the 1961 Convention. Under Article 1 of the 1961 Convention, "cannabis" is defined 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; "cannabis plant" is defined as "any plant of the genus Cannabis; and "cannabis resin" as the "separated resin, whether crude or purified, obtained from the cannabis plant".

5. In view of the scope of the questions formulated by Ukraine, it should be clarified that while cannabis contains several psychoactive compounds, named cannabinoids, the 1961 Convention does not apply to such compounds, once extracted from cannabis. Among these cannabinoids are tetrahydrocannabinol, cannabidiol, cannabiol and cannabichromene. Once extracted from cannabis, tetrahydrocannabinol is under international control, by virtue of its inclusion in Schedule 1 of the 1971 Convention. While cannabidiol, cannabiol and cannabichromene are not, per se, subject to control measures under the international drug control conventions, the cannabis or cannabis resin, from which such cannabinoids may be extracted, would be subject to the control measures foreseen in the 1961 Convention, which

[1] Article 4(c), 1961 Convention.

allows related cultivation and production for medical or scientific purposes. The term "non-narcotic cannabinoids" is not consistent with the terms used in the international drug control conventions.

6. Inclusion in Schedule I of the 1961 Convention means that cannabis would be subject to all measures of control foreseen in that Convention, including licensing requirements applicable to the cultivation, manufacture, wholesale, retail, trade distribution, transportation, possession, purchase, import and export of cannabis, cannabis resin, and extracts and tinctures of cannabis for medical and scientific purposes.[2]

7. Cannabis and cannabis resin are also included in schedule IV of the 1961 Convention. Therefore, a State party may adopt special measures of control for cannabis and cannabis resin or, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit their production, manufacture, export and import of, trade in, possession or use, except for amounts which may be necessary for medical and scientific research only.[3]

8. With regard to the 1971 Convention, States parties are also expected to limit the manufacture, export, import, distribution and trade in, use and possession of controlled substances to medical and scientific purposes.[4] While cannabis is not a controlled psychotropic substance under the 1971 Convention, the cannabinoid tetrahydrocannabinol is included in Schedule I of the 1971 Convention. According to article 7(1) of the 1971 Convention, States parties are required to prohibit all use of substances listed in this Schedule except for scientific and very limited medical purposes by duly authorized persons in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them. States parties are also required to provide for other specific measures described in article 7(1) of the 1971 Convention.

III. Questions formulated by Ukraine

a. Is cannabis processing in order to receive non-narcotic products such as cannabidiol, cannabiol, cannabichromeme prohibited internationally?

9. With the observation made above, that cannabidiol, cannabiol and cannabichromene are cannabinoids, and that the control measures of the 1961 Convention apply to cannabis, from which such substances may be extracted, the answer to the question would depend on the purpose for which the cannabis would be produced. As mentioned above, the 1961 Convention requires that the *production, manufacture, export, import, distribution and trade* of cannabis be exclusively for medical and scientific purposes. Conduct of these activities for other purposes would be considered as not permitted and should be established as punishable offences under domestic legislation.[5]

10. The meaning of "cannabis processing" in the question in not entirely clear. The 1961 Convention refers to the cultivation, manufacture and production of cannabis for which the Convention requires that States parties put in place various measures of control, including

[2] Article 2(1) of the 1961 Convention.
[3] Article 2(5) of the 1961 Convention. See also article 22 of the same convention.
[4] Article 5 of the 1971 Convention.
[5] Article 36(1)(a) of the 1961 Convention and article 3(1)(a) of the 1988 Convention.

licencing, record-keeping, reporting obligations and periodic permit limitations. "Manufacture" is defined as "all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs"[6] and "production" is defined as "the separation of [...] cannabis and cannabis resin from the plants from which they are obtained".[7]

11. With regard to cultivation, a State party may prohibit cultivation of the cannabis plant if, in its opinion, the prevailing conditions in the country render this measure the most suitable for the protection of public health and welfare, and preventing the diversion of drugs into illicit traffic.[8] Where a State party permits the cultivation of cannabis, this should be limited to medical and scientific purposes, in accordance with Article 4(c) of the 1961 Convention. The Convention does not define the terms "medical and scientific purposes." The Secretary General's *Commentary* on article 4(c) of the 1961 Convention[9] indicates that its interpretation should take into consideration the evolution of science and socio-economic circumstances over time. The *Commentary* also notes that *medical purposes* not only refers to "modern" or "western" medicine, but also to "legitimate systems of indigenous medicine" that could exist in various jurisdictions.[10]

12. In addition to the above-mentioned requirement, articles 23 and 28 of the 1961 Convention require that the State party concerned designate a Government agency to license the cultivators of the cannabis plant for the production of cannabis or cannabis resin and to take physical possession of all the crops "as soon as possible after the end of the harvest." If Ukraine or any other Party would wish to engage in the cultivation, production and international trade of cannabis products for medical and scientific purposes, the designated Government agency should also have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis and cannabis resin, among other specific requirements.[11] These requirements do not apply where cultivation of the cannabis plant is exclusively for industrial (such as for its fibre) or horticultural purposes.[12]

13. It should also be clarified that the requirements mentioned above do not apply to narcotic drugs, as defined in the 1961 Convention, which are commonly used in industry for other than medical and scientific purposes, provided that it is ensured by appropriate methods of denaturing or by other means, that the scheduled drugs so used are not liable to be abused or have ill effects and that the harmful substances cannot in practice be recovered.[13] In this case, the relevant Government agency is also required to submit statistical information on cannabis used for industrial purposes to the International Narcotics Control Board.[14]

14. In summary, the cannabinoids mentioned in question (a) are not in themselves subject to control under the international drug control conventions. However, the cannabis plant, cannabis and cannabis resin, from which they may be extracted, are subject to the measures

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[6] Article 1(n) of the 1961 Convention.
[7] Article 1(t) of the 1961 Convention.
[8] Article 22 of the 1961 Convention.
[9] See *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 of 3 August 1962), United Nations publication, Sales No. E.73.XI.1, 1973, p. 111.
[10] *Ibid.*
[11] Article 23(2) of the 1961 Convention (read in conjunction with article 28(1)).
[12] Article 28(2) of the 1961 Convention. See *Commentary on the Single Convention on Narcotic Drugs, 1961, supra*, p. 312-5.
[13] Article 2(9)(a) of the 1961 Convention.
[14] Article 2(9)(b) of the 1961 Convention.

of control stipulated above.[15] In addition, States parties have an obligation to apply to substances which do not fall under international control, but which may be used in the illicit manufacture of narcotic drugs, such measures of supervision as may be practicable.[16]

b. What procedure and level of international control is established for the production of non-narcotic cannabinoids?

15. The measures of control mentioned in the response to question (a) above would apply to the permission of the cultivation of the cannabis plant for the production of cannabis or cannabis resin, aimed at the extraction of certain cannabinoids for medical purposes.

c. Do the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971 apply for the processing of cannabis in order to produce non-narcotic cannabinoids?

16. Some of the above considerations are valid as to the meaning of "non-narcotic cannabinoids" and the "processing of cannabis". It should be emphasized that the measures of control stipulated by the Conventions apply to specifically controlled substances. It is hoped that the responses provided to questions (a) and (b) above provide guidance on the applicability of the 1961 Convention for the cultivation of the cannabis plant for the production of cannabis or cannabis resin, aimed at the manufacture of certain cannabinoids for medical purposes.

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Annex 1. English translation of letter from State Service of Ukraine on Drugs Control

[15] For further information on measures under the 1961 Convention and the use of cannabis for medical purposes, and on related views of the International Narcotics Control Board, please refer to paragraphs 218 to 227 of the INCB Annual Report of 2014 (available at: https://www.incb.org/documents/Publications/AnnualReports/AR2014/English/Special_Topics_AR_2014_E.pdf).
[16] Article 2(8) of the 1961 Convention. See also relevant provisions of the 1988 Convention, on the control of precursors.

CERTIFICATE OF SERVICE

I certify that on April 4, 2017, I served a true and correct copy of the foregoing *Excerpts of Record* and *Statutory Addendum*:

Via PACER, e-filed upon:

Brian Stretch
United States Attorney
Office of the United States Attorney
450 Golden Gate Ave, 11th Floor
San Francisco, CA 94102

John J. Martin
Special Agent in Charge
Drug Enforcement Administration
450 Golden Gate Ave, 14th Floor
San Francisco, CA 94102

The Honorable Loretta Lynch
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania, NW
Washington, DC 20530

The Honorable Chuck Rosenberg
Drug Enforcement Administration
7000 Army-Navy Dr.
Arlington, VA 22202

Wendy H. Goggin
Chief Counsel
Office of General Counsel
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield, VA 22152

/s/ Patrick D. Goggin
Patrick D. Goggin

Dated: April 4, 2017

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 17-70162

HEMP INDUSTRIES ASSOCIATION, ET AL.

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.

PETITION FOR REVIEW OF RULES
OF DRUG ENFORCEMENT ADMINISTRATION

PETITIONERS' STATUTORY ADDENDUM TO OPENING BRIEF

Patrick D. Goggin, SBN # 182218
Hoban Law Group
870 Market Street, Suite 1148
San Francisco, CA 94102
Telephone: (415) 981-9290

Of counsel:
Robert Hoban (Admitted)
Garrett Graff (Admitted)
Hoban Law Group
730 17th St, Ste 420
Denver, CO 80202

Attorneys for Petitioners

Dated: April 3, 2017

STATUTORY ADDENDUM

Table of Contents

REGULATORY FLEXIBILITY ACT

5 U.S.C. §§ 601 - 602

601. Definitions

For purposes of this chapter —

(1) the term "agency" means an agency as defined in section 551(1) of this title;

(2) the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term "rule" does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

(3) the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(4) the term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(5) the term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

(6) the term "small entity" shall have the same meaning as the terms "small business", "small organization" and "small governmental jurisdiction" defined in paragraphs (3), (4) and (5) of this section; and

(7) the term "collection of information"—

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

(B) shall not include a collection of information described under section 3518(c)(1) of title 44, United States Code.

(8) Recordkeeping requirement.—The term "recordkeeping requirement" means a requirement imposed by an agency on persons to maintain specified records.

602. Regulatory agenda

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain—

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking, and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

ADMINISTRATIVE PROCEDURE ACT

5 U.S.C. § 702

702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided,* That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

ADMINISTRATIVE PROCEDURE ACT

5 U.S.C. § 706(2)

706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CONGRESSIONAL REVIEW ACT

5 U.S.C § 801

801. Congressional review

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

(i) a complete copy of the cost-benefit analysis of the rule, if any;

(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).

(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

(3) A major rule relating to a report submitted under paragraph (1) shall take effect on the latest of—

(A) the later of the date occurring 60 days after the date on which—

(i) the Congress receives the report submitted under paragraph (1); or

(ii) the rule is published in the Federal Register, if so published;

(B) if the Congress passes a joint resolution of disapproval described in section 802 relating to the rule, and the President signs a veto of such resolution, the earlier date—

(i) on which either House of Congress votes and fails to override the veto of the President; or

(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President; or

(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by operation of this chapter beyond the date on which either House of Congress votes to reject a joint resolution of disapproval under section 802.

(b)(1) A rule shall not take effect (or continue), if the Congress enacts a joint resolution of disapproval, described under section 802, of the rule.

(2) A rule that does not take effect (or does not continue) under paragraph (1) may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.

(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a rule that would not take effect by reason of subsection (a)(3) may take effect, if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

(2) Paragraph (1) applies to a determination made by the President by Executive order that the rule should take effect because such rule is—

(A) necessary because of an imminent threat to health or safety or other emergency;

(B) necessary for the enforcement of criminal laws;
(C) necessary for national security; or
(D) issued pursuant to any statute implementing an international trade agreement.

(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under section 802 or the effect of a joint resolution of disapproval under this section.

(d)(1) In addition to the opportunity for review otherwise provided under this chapter, in the case of any rule for which a report was submitted in accordance with subsection (a)(1)(A) during the period beginning on the date occurring—
(A) in the case of the Senate, 60 session days, or
(B) in the case of the House of Representatives, 60 legislative days,

before the date the Congress adjourns a session of Congress through the date on which the same or succeeding Congress first convenes its next session, section 802 shall apply to such rule in the succeeding session of Congress.

(2)(A) In applying section 802 for purposes of such additional review, a rule described under paragraph (1) shall be treated as though—
(i) such rule were published in the Federal Register (as a rule that shall take effect) on—
(I) in the case of the Senate, the 15th session day, or
(II) in the case of the House of Representatives, the 15th legislative day,

after the succeeding session of Congress first convenes; and
(ii) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

(B) Nothing in this paragraph shall be construed to affect the requirement under subsection (a)(1) that a report shall be submitted to Congress before a rule can take effect.

(3) A rule described under paragraph (1) shall take effect as otherwise provided by law (including other subsections of this section).

(e)(1) For purposes of this subsection, section 802 shall also apply to any major rule promulgated between March 1, 1996, and the date of the enactment of this chapter.

(2) In applying section 802 for purposes of Congressional review, a rule described under paragraph (1) shall be treated as though—

(A) such rule were published in the Federal Register on the date of enactment of this chapter; and

(B) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

(3) The effectiveness of a rule described under paragraph (1) shall be as otherwise provided by law, unless the rule is made of no force or effect under section 802.

(f) Any rule that takes effect and later is made of no force or effect by enactment of a joint resolution under section 802 shall be treated as though such rule had never taken effect.

(g) If the Congress does not enact a joint resolution of disapproval under section 802 respecting a rule, no court or agency may infer any intent of the Congress from any action or inaction of the Congress with regard to such rule, related statute, or joint resolution of disapproval.

CONGRESSIONAL REVIEW ACT

5 U.S.C. § 804

804. Definitions

For purposes of this chapter—

(1) The term "Federal agency" means any agency as that term is defined in section 551(1).

(2) The term "major rule" means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—

(A) an annual effect on the economy of $100,000,000 or more;

(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act.

(3) The term "rule" has the meaning given such term in section 551, except that such term does not include—

(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing;

(B) any rule relating to agency management or personnel; or

(C) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

AGRICULTURAL ACT OF 2014

7 U.S.C. § 5940

5940. Legitimacy of industrial hemp research

(a) In general

Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug-Free Schools and Communities Act (20 U.S.C. 7101 et seq.), chapter 81 of title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp if—

(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

(2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

(b) Definitions

In this section:

(1) Agricultural pilot program

The term "agricultural pilot program" means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

(A) in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

(B) in a manner that—

(i) ensures that only institutions of higher education and State departments of agriculture are used to grow or cultivate industrial hemp;

(ii) requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and

(iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States in accordance with the purposes of this section.

(2) Industrial hemp

The term "industrial hemp" means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

(3) State department of agriculture

The term "State department of agriculture" means the agency, commission, or department of a State government responsible for agriculture within the State.

SMALL BUSINESS ACT

15 U.S.C. § 632

632. Small-business concern

(a) Criteria

(1) For the purposes of this chapter, a small-business concern, including but not limited to enterprises that are engaged in the business of production of food and fiber, ranching and raising of livestock, agriculture, and all other farming and agricultural related industries, shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation: *Provided*, That notwithstanding any other provision of law, an agricultural enterprise shall be deemed to be a small business concern if it (including its affiliates) has annual receipts not in excess of $750,000.

(2) Establishment of size standards.—

(A) In general.—In addition to the criteria specified in paragraph (1), the Administrator may specify detailed definitions or standards by which a business concern may be determined to be a small business concern for the purposes of this chapter or any other Act.

(B) Additional criteria.—The standards described in paragraph (1) may utilize number of employees, dollar volume of business, net worth, net income, a combination thereof, or other appropriate factors.

(C) Requirements.—Unless specifically authorized by statute, no Federal department or agency may prescribe a size standard for categorizing a business concern as a small business concern, unless such proposed size standard—

(i) is proposed after an opportunity for public notice and comment;

(ii) provides for determining—

(I) the size of a manufacturing concern as measured by the manufacturing concern's average employment based upon employment during each of the manufacturing concern's pay periods for the preceding 12 months;

(II) the size of a business concern providing services on the basis of the annual average gross receipts of the business concern over a period of not less than 3 years;

(III) the size of other business concerns on the basis of data over a period of not less than 3 years; or

(IV) other appropriate factors; and

(iii) is approved by the Administrator.

(3) When establishing or approving any size standard pursuant to paragraph (2), the Administrator shall ensure that the size standard varies from industry to industry to the extent necessary to reflect the differing characteristics of the various industries and consider other factors deemed to be relevant by the Administrator.

(4) Exclusion of certain security expenses from consideration for purpose of small business size standards.—

(A) Determination required.—Not later than 30 days after January 6, 2006, the Administrator shall review the application of size standards established pursuant to paragraph (2) to small business concerns that are performing contracts in qualified areas and determine whether it would be fair and appropriate to exclude from consideration in the average annual gross receipts of such small business concerns any payments made to such small business concerns by Federal agencies to reimburse such small business concerns for the cost of subcontracts entered for the sole purpose of providing security services in a qualified area.

(B) Action required.—Not later than 60 days after January 6, 2006, the Administrator shall either—

(i) initiate an adjustment to the size standards, as described in subparagraph (A), if the Administrator determines that such an adjustment would be fair and appropriate; or

(ii) provide a report to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives explaining in detail the basis for the determination by the Administrator that such an adjustment would not be fair and appropriate.

(C) Qualified areas.—In this paragraph, the term "qualified area" means—

(i) Iraq,

(ii) Afghanistan, and

(iii) any foreign country which included a combat zone, as that term is defined in section 112(c)(2) of title 26, at the time of performance of the relevant Federal contract or subcontract.

(5) Alternative Size Standard.—

(A) In general.—The Administrator shall establish an alternative size standard for applicants for business loans under section 636(a) of this title and applicants for development company loans under title V of the Small Business Investment

Act of 1958 (15 U.S.C. 695 et seq.), that uses maximum tangible net worth and average net income as an alternative to the use of industry standards.

(B) Interim rule.—Until the date on which the alternative size standard established under subparagraph (A) is in effect, an applicant for a business loan under section 636(a) of this title or an applicant for a development company loan under title V of the Small Business Investment Act of 1958 may be eligible for such a loan if—

(i) the maximum tangible net worth of the applicant is not more than $15,000,000; and

(ii) the average net income after Federal income taxes (excluding any carry-over losses) of the applicant for the 2 full fiscal years before the date of the application is not more than $5,000,000.

(b) "Agency" defined

For purposes of this chapter, any reference to an agency or department of the United States, and the term "Federal agency", shall have the meaning given the term "agency" by section 551(1) of title 5, but does not include the United States Postal Service or the Government Accountability Office.

(c) Qualified employee trust; eligibility for loan guarantee; "qualified employee trust" defined; regulations for treatment of trust as qualified employee trust

(1) For purposes of this chapter, a qualified employee trust shall be eligible for any loan guarantee under section 636(a) of this title with respect to a small business concern on the same basis as if such trust were the same legal entity as such concern.

(2) For purposes of this chapter, the term "qualified employee trust" means, with respect to a small business concern, a trust—

(A) which forms part of an employee stock ownership plan (as defined in section 4975(e)(7) of title 26)—

(i) which is maintained by such concern, and

(ii) which provides that each participant in the plan is entitled to direct the plan as to the manner in which voting rights under qualifying employer securities (as defined in section 4975(e)(8) of title 26) which are allocated to the account of such participant are to be exercised with respect to a corporate matter which (by law or charter) must be decided by a majority vote of outstanding common shares voted; and

(B) in the case of any loan guarantee under section 636(a) of this title, the trustee of which enters into an agreement with the Administrator which is binding on the trust and on such small business concern and which provides that—

(i) the loan guaranteed under section 636(a) of this title shall be used solely for the purchase of qualifying employer securities of such concern,

(ii) all funds acquired by the concern in such purchase shall be used by such concern solely for the purposes for which such loan was guaranteed,

(iii) such concern will provide such funds as may be necessary for the timely repayment of such loan, and the property of such concern shall be available as security for repayment of such loan, and

(iv) all qualifying employer securities acquired by such trust in such purchase shall be allocated to the accounts of participants in such plan who are entitled to share in such allocation, and each participant has a nonforfeitable right, not later than the date such loan is repaid, to all such qualifying employer securities which are so allocated to the participant's account.

(3) Under regulations which may be prescribed by the Administrator, a trust may be treated as a qualified employee trust with respect to a small business concern if—

(A) the trust is maintained by an employee organization which represents at least 51 percent of the employees of such concern, and

(B) such concern maintains a plan—

(i) which is an employee benefit plan which is designed to invest primarily in qualifying employer securities (as defined in section 4975(e)(8) of title 26),

(ii) which provides that each participant in the plan is entitled to direct the plan as to the manner in which voting rights under qualifying employer securities which are allocated to the account of such participant are to be exercised with respect to a corporate matter which (by law or charter) must be decided by a majority vote of the outstanding common shares voted,

(iii) which provides that each participant who is entitled to distribution from the plan has a right, in the case of qualifying employer securities which are not readily tradeable on an established market, to require that the concern repurchase such securities under a fair valuation formula, and

(iv) which meets such other requirements (similar to requirements applicable to employee stock ownership plans as defined in section 4975(e)(7) of title 26) as the Administrator may prescribe, and

(C) in the case of a loan guarantee under section 636(a) of this title, such organization enters into an agreement with the Administration which is described in paragraph (2)(B).

(d) "Qualified Indian tribe" defined

For purposes of section 636 of this title, the term "qualified Indian tribe" means an Indian tribe as defined in section 450b(e) of title 25, which owns and controls 100 per centum of a small business concern.

(e) "Public or private organization for the handicapped" defined

For purposes of section 636 of this title, the term "public or private organization for the handicapped" means one—

(1) which is organized under the laws of the United States or of any State, operated in the interest of handicapped individuals, the net income of which does not inure in whole or in part to the benefit of any shareholder or other individuals;

(2) which complies with any applicable occupational health and safety standard prescribed by the Secretary of Labor; and

(3) which, in the production of commodities and in the provision of services during any fiscal year in which it received financial assistance under this subsection, employs handicapped individuals for not less than 75 per centum of the man-hours required for the production or provision of the commodities or services.

(f) "Handicapped individual" defined

For purposes of section 636 of this title, the term "handicapped individual" means an individual—

(1) who has a physical, mental, or emotional impairment, defect, ailment, disease, or disability of a permanent nature which in any way limits the selection of any type of employment for which the person would otherwise be qualified or qualifiable; or

(2) who is a service-disabled veteran.

(g) "Energy measures" defined

For purposes of section 636 of this title, the term "energy measures" includes—

(1) solar thermal energy equipment which is either of the active type based upon mechanically forced energy transfer or of the passive type based on convective, conductive, or radiant energy transfer or some combination of these types;

(2) photovoltaic cells and related equipment;

(3) a product or service the primary purpose of which is conservation of energy through devices or techniques which increase the energy efficiency of existing equipment, methods of operation, or systems which use fossil fuels, and which is on the Energy Conservation Measures list of the Secretary of Energy or which the Administrator determines to be consistent with the intent of this subsection;

(4) equipment the primary purpose of which is production of energy from wood, biological waste, grain, or other biomass source of energy;

(5) equipment the primary purpose of which is industrial cogeneration of energy, district heating, or production of energy from industrial waste;

(6) hydroelectric power equipment;

(7) wind energy conversion equipment; and

(8) engineering, architectural, consulting, or other professional services which are necessary or appropriate to aid citizens in using any of the measures described in paragraph (1) through (7).

(h) "Credit elsewhere" defined

For purposes of this chapter the term "credit elsewhere" means the availability of credit from non-Federal sources on reasonable terms and conditions taking into consideration the prevailing rates and terms in the community in or near where the concern transacts business, or the homeowner resides, for similar purposes and periods of time.

(i) "Homeowners" defined

For purposes of section 636 of this title, the term "homeowners" includes owners and lessees of residential property and also includes personal property.

(j) "Small agricultural cooperative" defined

For the purposes of this chapter, the term "small agricultural cooperative" means an association (corporate or otherwise) acting pursuant to the provisions of the Agricultural Marketing Act (12 U.S.C. 1141j), whose size does not exceed the size standard established by the Administration for other similar agricultural small business concerns. In determining such size, the Administration shall regard the association as a business concern and shall not include the income or employees of any member shareholder of such cooperative.

(k) "Disaster" defined

(1) For the purposes of this chapter, the term "disaster" means a sudden event which causes severe damage including, but not limited to, floods, hurricanes, tornadoes, earthquakes, fires, explosions, volcanoes, windstorms, landslides or mudslides, tidal waves, commercial fishery failures or fishery resource disasters (as determined by the Secretary of Commerce under section 4107(b) of title 16), ocean conditions resulting in the closure of customary fishing waters, riots, civil disorders or other catastrophes, except it does not include economic dislocations.

(2) For purposes of section 636(b)(2) of this title, the term "disaster" includes—

(A) drought;

(B) below average water levels in the Great Lakes, or on any body of water in the United States that supports commerce by small business concerns; and

(C) ice storms and blizzards.

(*l*) "Computer crime" defined

For purposes of this chapter—

(1) [1] the term "computer crime" means—

(A) any crime committed against a small business concern by means of the use of a computer; and

(B) any crime involving the illegal use of, or tampering with, a computer owned or utilized by a small business concern.

(m) "Simplified acquisition threshold" defined

For purposes of this chapter, the term "simplified acquisition threshold" has the meaning given such term in section 134 of title 41.

(n) "Small business concern owned and controlled by women" defined

For the purposes of this chapter, a small business concern is a small business concern owned and controlled by women if—

(1) at least 51 percent of small business concern is owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) the management and daily business operations of the business are controlled by one or more women.

(*o*) Definitions of bundling of contract requirements and related terms

In this chapter:

(1) Bundled contract

The term "bundled contract" means a contract that is entered into to meet requirements that are consolidated in a bundling of contract requirements.

(2) Bundling of contract requirements

The term "bundling of contract requirements" means consolidating 2 or more procurement requirements for goods or services previously provided or performed under separate smaller contracts into a solicitation of offers for a single contract that is likely to be unsuitable for award to a small-business concern due to—

(A) the diversity, size, or specialized nature of the elements of the performance specified;

(B) the aggregate dollar value of the anticipated award;

(C) the geographical dispersion of the contract performance sites; or

(D) any combination of the factors described in subparagraphs (A), (B), and (C).

(3) Separate smaller contract

The term "separate smaller contract", with respect to a bundling of contract requirements, means a contract that has been performed by 1 or more small business concerns or was suitable for award to 1 or more small business concerns.

(p) Definitions relating to HUBZones

In this chapter:

(1) Historically underutilized business zone

The term "historically underutilized business zone" means any area located within 1 or more—

(A) qualified census tracts;

(B) qualified nonmetropolitan counties;

(C) lands within the external boundaries of an Indian reservation;

(D) redesignated areas; or

(E) base closure areas.

(2) HUBZone

The term "HUBZone" means a historically underutilized business zone.

(3) HUBZone small business concern

The term "HUBZone small business concern" means—

(A) a small business concern that is at least 51 percent owned and controlled by United States citizens;

(B) a small business concern that is—

(i) an Alaska Native Corporation owned and controlled by Natives (as determined pursuant to section 1626(e)(1) of title 43); or

(ii) a direct or indirect subsidiary corporation, joint venture, or partnership of an Alaska Native Corporation qualifying pursuant to section 1626(e)(1) of title 43, if that subsidiary, joint venture, or partnership is owned and controlled by Natives (as determined pursuant to section 1626(e)(2) of title 43);

(C) a small business concern—

(i) that is wholly owned by one or more Indian tribal governments, or by a corporation that is wholly owned by one or more Indian tribal governments; or

(ii) that is owned in part by one or more Indian tribal governments, or by a corporation that is wholly owned by one or more Indian tribal governments, if all other owners are either United States citizens or small business concerns;

(D) a small business concern that is—

(i) wholly owned by a community development corporation that has received financial assistance under part 1 of subchapter A of the Community Economic Development Act of 1981 (42 U.S.C. 9805 et seq.); or

(ii) owned in part by one or more community development corporations, if all other owners are either United States citizens or small business concerns; or

(E) a small business concern that is—

(i) a small agricultural cooperative organized or incorporated in the United States;

(ii) wholly owned by 1 or more small agricultural cooperatives organized or incorporated in the United States; or

(iii) owned in part by 1 or more small agricultural cooperatives organized or incorporated in the United States, if all owners are small business concerns or United States citizens.

(4) Qualified areas

(A) Qualified census tract

The term "qualified census tract" has the meaning given that term in section 42(d)(5)(C)(ii) [2] of title 26.

(B) Qualified nonmetropolitan county

The term "qualified nonmetropolitan county" means any county—

(i) that was not located in a metropolitan statistical area (as defined in section 143(k)(2)(B) of title 26) at the time of the most recent census taken for purposes of selecting qualified census tracts under section 42(d)(5)(C)(ii) [2] of title 26; and

(ii) in which—

(I) the median household income is less than 80 percent of the nonmetropolitan State median household income, based on the most recent data available from the Bureau of the Census of the Department of Commerce;

(II) the unemployment rate is not less than 140 percent of the average unemployment rate for the United States or for the State in which such county is located, whichever is less, based on the most recent data available from the Secretary of Labor; or

(III) there is located a difficult development area, as designated by the Secretary of Housing and Urban Development in accordance with section 42(d)(5)(C)(iii) [2] of title 26, within Alaska, Hawaii, or any territory or possession of the United States outside the 48 contiguous States.

(C) Redesignated area

The term "redesignated area" means any census tract that ceases to be qualified under subparagraph (A) and any nonmetropolitan county that ceases to be qualified under subparagraph (B), except that a census tract or a nonmetropolitan county may be a "redesignated area" only until the later of—

(i) the date on which the Census Bureau publicly releases the first results from the 2010 decennial census; or

(ii) 3 years after the date on which the census tract or nonmetropolitan county ceased to be so qualified.

(D) Base closure area

The term "base closure area" means lands within the external boundaries of a military installation that were closed through a privatization process under the authority of—

(i) the Defense Base Closure and Realignment Act of 1990 (part A of title XXIX of division B of Public Law 101–510; 10 U.S.C. 2687 note);

(ii) title II of the Defense Authorization Amendments and Base Closure and Realignment Act (Public Law 100–526; 10 U.S.C. 2687 note);

(iii) section 2687 of title 10; or

(iv) any other provision of law authorizing or directing the Secretary of Defense or the Secretary of a military department to dispose of real property at the military installation for purposes relating to base closures of redevelopment, while retaining the authority to enter into a leaseback of all or a portion of the property for military use.

(5) Qualified HUBZone small business concern

(A) In general

A HUBZone small business concern is "qualified", if—

(i) the small business concern has certified in writing to the Administrator (or the Administrator otherwise determines, based on information submitted to the Administrator by the small business concern, or based on certification procedures, which shall be established by the Administration by regulation) that—

(I) it is a HUBZone small business concern—

(aa) pursuant to subparagraph (A), (B), (C), (D), or (E) of paragraph (3), and that its principal office is located in a HUBZone and not fewer than 35 percent of its employees reside in a HUBZone; or

(bb) pursuant to paragraph (3)(C), and not fewer than 35 percent of its employees engaged in performing a contract awarded to the small business concern on the basis of a preference provided under section 657a(b) of this title reside within any Indian reservation governed by one

or more of the tribal government owners, or reside within any HUBZone adjoining any such Indian reservation;

(II) the small business concern will attempt to maintain the applicable employment percentage under subclause (I) during the performance of any contract awarded to the small business concern on the basis of a preference provided under section 657a(b) of this title; and

(III) with respect to any subcontract entered into by the small business concern pursuant to a contract awarded to the small business concern under section 657a of this title, the small business concern will ensure that—

(aa) in the case of a contract for services (except construction), not less than 50 percent of the cost of contract performance incurred for personnel will be expended for its employees or for employees of other HUBZone small business concerns;

(bb) in the case of a contract for procurement of supplies (other than procurement from a regular dealer in such supplies), not less than 50 percent of the cost of manufacturing the supplies (not including the cost of materials) will be incurred in connection with the performance of the contract in a HUBZone by 1 or more HUBZone small business concerns; and

(cc) in the case of a contract for the procurement by the Secretary of Agriculture of agricultural commodities, none of the commodity being procured will be obtained by the prime contractor through a subcontract for the purchase of the commodity in substantially the final form in which it is to be supplied to the Government; and

(ii) no certification made or information provided by the small business concern under clause (i) has been, in accordance with the procedures established under section 657a(c)(1) of this title—

(I) successfully challenged by an interested party; or

(II) otherwise determined by the Administrator to be materially false.

(B) Change in percentages

The Administrator may utilize a percentage other than the percentage specified in item (aa) or (bb) of subparagraph (A)(i)(III), if the Administrator determines that such action is necessary to reflect conventional industry practices among small business concerns that are below the numerical size standard for businesses in that industry category.

(C) Construction and other contracts

The Administrator shall promulgate final regulations imposing requirements that are similar to those specified in items (aa) and (bb) of subparagraph (A)(i)(III) on contracts for general and specialty construction, and on contracts for any other industry category that would not otherwise be subject to those requirements. The percentage applicable to any such requirement shall be determined in accordance with subparagraph (B).

(D) List of qualified small business concerns

The Administrator shall establish and maintain a list of qualified HUBZone small business concerns, which list shall, to the extent practicable—

(i) once the Administrator has made the certification required by subparagraph (A)(i) regarding a qualified HUBZone small business concern and has determined that subparagraph (A)(ii) does not apply to that concern, include the name, address, and type of business with respect to each such small business concern;

(ii) be updated by the Administrator not less than annually; and

(iii) be provided upon request to any Federal agency or other entity.

(6) Native American small business concerns

(A) Alaska Native Corporation

The term "Alaska Native Corporation" has the same meaning as the term "Native Corporation" in section 1602 of title 43.

(B) Alaska Native Village

The term "Alaska Native Village" has the same meaning as the term "Native village" in section 1602 of title 43.

(C) Indian reservation

The term "Indian reservation"—

(i) has the same meaning as the term "Indian country" in section 1151 of title 18, except that such term does not include—

(I) any lands that are located within a State in which a tribe did not exercise governmental jurisdiction on December 21, 2000, unless that tribe is recognized after December 21, 2000, by either an Act of Congress or pursuant to regulations of the Secretary of the Interior for the administrative recognition that an Indian group exists as an Indian tribe (part 83 of title 25, Code of Federal Regulations); and

(II) lands taken into trust or acquired by an Indian tribe after December 21, 2000, if such lands are not located within the external boundaries of an

Indian reservation or former reservation or are not contiguous to the lands held in trust or restricted status on December 21, 2000; and

(ii) in the State of Oklahoma, means lands that—

(I) are within the jurisdictional areas of an Oklahoma Indian tribe (as determined by the Secretary of the Interior); and

(II) are recognized by the Secretary of the Interior as eligible for trust land status under part 151 of title 25, Code of Federal Regulations (as in effect on December 21, 2000).

(7) Agricultural commodity

The term "agricultural commodity" has the same meaning as in section 5602 of title 7.

(q) Definitions relating to veterans

In this chapter, the following definitions apply:

(1) Service-disabled veteran

The term "service-disabled veteran" means a veteran with a disability that is service-connected (as defined in section 101(16) of title 38).

(2) Small business concern owned and controlled by service-disabled veterans

The term "small business concern owned and controlled by service-disabled veterans" means a small business concern—

(A) not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(B) the management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(3) Small business concern owned and controlled by veterans

The term "small business concern owned and controlled by veterans" means a small business concern—

(A) not less than 51 percent of which is owned by one or more veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(B) the management and daily business operations of which are controlled by one or more veterans.

(4) Veteran

The term "veteran" has the meaning given the term in section 101(2) of title 38.

(5) Relief from time limitations

(A) In general

Any time limitation on any qualification, certification, or period of participation imposed under this chapter on any program that is available to small business concerns shall be extended for a small business concern that—

(i) is owned and controlled by—

(I) a veteran who was called or ordered to active duty under a provision of law specified in section 101(a)(13)(B) of title 10 on or after September 11, 2001; or

(II) a service-disabled veteran who became such a veteran due to an injury or illness incurred or aggravated in the active military, naval, or air service during a period of active duty pursuant to a call or order to active duty under a provision of law referred to in subclause (I) on or after September 11, 2001; and

(ii) was subject to the time limitation during such period of active duty.

(B) Duration

Upon submission of proper documentation to the Administrator, the extension of a time limitation under subparagraph (A) shall be equal to the period of time that such veteran who owned or controlled such a concern was on active duty as described in that subparagraph.

(C) Exception for programs subject to Federal Credit Reform Act of 1990

The provisions of subparagraphs (A) and (B) shall not apply to any programs subject to the Federal Credit Reform Act of 1990 (2 U.S.C. 661 et seq.).

(r) Definitions relating to small business lending companies

As used in section 650 of this title:

(1) Small business lending company

The term "small business lending company" means a business concern that is authorized by the Administrator to make loans pursuant to section 636(a) of this title and whose lending activities are not subject to regulation by any Federal or State regulatory agency.

(2) Non-Federally regulated SBA lender

The term "non-Federally regulated SBA lender" means a business concern if—

(A) such concern is authorized by the Administrator to make loans under section 636 of this title;

(B) such concern is subject to regulation by a State; and

(C) the lending activities of such concern are not regulated by any Federal banking authority.

(s) Major disaster

In this chapter, the term "major disaster" has the meaning given that term in section 5122 of title 42.

(t) Small business development center

In this chapter, the term "small business development center" means a small business development center described in section 648 of this title.

(u) Region of the Administration

In this chapter, the term "region of the Administration" means the geographic area served by a regional office of the Administration established under section 633(a) of this title.

(v) Multiple award contract

In this chapter, the term "multiple award contract" means—

(1) a multiple award task order contract or delivery order contract that is entered into under the authority of sections 4101, 4103, 4105, and 4106 of title 41; and

(2) any other indefinite delivery, indefinite quantity contract that is entered into by the head of a Federal agency with 2 or more sources pursuant to the same solicitation.

(w) Presumption

(1) In general

In every contract, subcontract, cooperative agreement, cooperative research and development agreement, or grant which is set aside, reserved, or otherwise classified as intended for award to small business concerns, there shall be a presumption of loss to the United States based on the total amount expended on the contract, subcontract, cooperative agreement, cooperative research and development agreement, or grant whenever it is established that a business concern other than a small business concern willfully sought and received the award by misrepresentation.

(2) Deemed certifications

The following actions shall be deemed affirmative, willful, and intentional certifications of small business size and status:

(A) Submission of a bid or proposal for a Federal grant, contract, subcontract, cooperative agreement, or cooperative research and development agreement reserved, set aside, or otherwise classified as intended for award to small business concerns.

(B) Submission of a bid or proposal for a Federal grant, contract, subcontract, cooperative agreement, or cooperative research and development agreement which in any way encourages a Federal agency to classify the bid or proposal, if awarded, as an award to a small business concern.

(C) Registration on any Federal electronic database for the purpose of being considered for award of a Federal grant, contract, subcontract, cooperative agreement, or cooperative research agreement, as a small business concern.

(3) Certification by signature of responsible official

(A) In general

Each solicitation, bid, or application for a Federal contract, subcontract, or grant shall contain a certification concerning the small business size and status of a business concern seeking the Federal contract, subcontract, or grant.

(B) Content of certifications

A certification that a business concern qualifies as a small business concern of the exact size and status claimed by the business concern for purposes of bidding on a Federal contract or subcontract, or applying for a Federal grant, shall contain the signature of an authorized official on the same page on which the certification is contained.

(4) Regulations

The Administrator shall promulgate regulations to provide adequate protections to individuals and business concerns from liability under this subsection in cases of unintentional errors, technical malfunctions, and other similar situations.

(x) Annual certification

(1) In general

Each business certified as a small business concern under this chapter shall annually certify its small business size and, if appropriate, its small business status, by means of a confirming entry on the Online Representations and Certifications Application database of the Administration, or any successor thereto.

(2) Regulations

Not later than 1 year after September 27, 2010, the Administrator, in consultation with the Inspector General and the Chief Counsel for Advocacy of the Administration, shall promulgate regulations to ensure that—

(A) no business concern continues to be certified as a small business concern on the Online Representations and Certifications Application database of the Administration, or any successor thereto, without fulfilling the requirements for annual certification under this subsection; and

(B) the requirements of this subsection are implemented in a manner presenting the least possible regulatory burden on small business concerns.

(y) Policy on prosecutions of small business size and status fraud

Not later than 1 year after September 27, 2010, the Administrator, in consultation with the Attorney General, shall issue a Government-wide policy on prosecution of small business size and status fraud, which shall direct Federal agencies to appropriately publicize the policy.

(z) Aquaculture business disaster assistance

Subject to section 647(a) of this title and notwithstanding section 647(b)(1) of this title, the Administrator may provide disaster assistance under section 636(b)(2) of this title to aquaculture enterprises that are small businesses.

(aa) Venture capital operating company

In this chapter, the term "venture capital operating company" means an entity described in clause (i), (v), or (vi) of section 121.103(b)(5) of title 13, Code of Federal Regulations (or any successor thereto).

(bb) Hedge fund

In this chapter, the term "hedge fund" has the meaning given that term in section 1851(h)(2) of title 12.

(cc) Private equity firm

In this chapter, the term "private equity firm" has the meaning given the term "private equity fund" in section 1851(h)(2) of title 12.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 801, *et seq*

801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 802

802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 352(d) of this title; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous systems; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and

includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(16) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise

permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (B), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.
(H) Phenylacetic acid, its esters, and its salts.
(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
(J) Piperidine and its salts.
(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
(L) 3,4-Methylenedioxyphenyl-2-propanone.
(M) Methylamine.
(N) Ethylamine.
(O) Propionic anhydride.
(P) Insosafrole.
(Q) Safrole.
(R) Piperonal.
(S) N-Methylepherdrine.
(T) N-methylpseudoephedrine.
(U) Hydriotic acid.
(V) Benzaldehyde.
(W) Nitroethane.
(X) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:
(A) Acetic anhydride.
(B) Acetone.
(C) Benzyl chloride.
(D) Ethyl ether.
(E) Repealed. Pub. L. 101–647, title XXIII, §2301(b), Nov. 29, 1990, 104 Stat. 4858.
(F) Potassium permanganate.
(G) 2-Butanone.
(H) Toluene.

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless—

(I)(aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient; or

(bb) the Attorney General has determined under section 814 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General; or

(v) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes—

(i) boldenone,
(ii) chlorotestosterone,
(iii) clostebol,
(iv) dehydrochlormethyltestosterone,
(v) dihydrotestosterone,
(vi) drostanolone,
(vii) ethylestrenol,
(viii) fluoxymesterone,
(ix) formebulone,
(x) mesterolone,
(xi) methandienone,
(xii) methandranone,
(xiii) methandriol,
(xiv) methandrostenolone,

(xv) methenolone,
(xvi) methyltestosterone,
(xvii) mibolerone,
(xviii) nandrolone,
(xix) norethandrolone,
(xx) oxandrolone,
(xxi) oxymesterone,
(xxii) oxymetholone,
(xxiii) stanolone,
(xxiv) stanozolol,
(xxv) testolactone,
(xxvi) testosterone,
(xxvii) trenbolone, and
(xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(42) The term "international transaction" means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms "broker" and "trader" mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;
(B) serving as an agent or intermediary; or
(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(43) The term "felony drug offense" means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, or depressant or stimulant substances.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 811

811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the

Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic

Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the

Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph [1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States

obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under

this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential

(1) The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug may, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) Temporary scheduling to avoid imminent hazards to public safety

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. Such an order may not be issued before the expiration of thirty days from—

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

CONTROLLED SUBSTANCES ACT

21 U.S.C § 812

812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended [1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmathadol.[2]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Propheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.

(6) Dimethyltryptamine.
(7) 4-methyl-2,5-diamethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca [3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.

(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

Schedule IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 821

821. Rules and regulations

The Attorney General is authorized 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 and to listed chemicals.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 822

822. Persons required to register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25) [1] of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 871

871. Attorney General

(a) Delegation of functions

The Attorney General may delegate any of his functions under this subchapter to any officer or employee of the Department of Justice.

(b) Rules and regulations

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

(c) Acceptance of devices, bequests, gifts, and donations

The Attorney General may accept in the name of the Department of Justice any form of device, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

CONTROLLED SUBSTANCES ACT

21 U.S.C. § 877

877. Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

CONSOLIDATED APPROPRIATIONS ACT, 2016, Pub. L. No. 114-113

§ 763, 129 Stat. 1175, 2285 (2016)

SEC. 763. None of the funds made available by this Act or any other Act may be used— (1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or (2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.

FURTHER CONTINUING AND SECURITY ASSISTANCE APPROPRIATIONS ACT, 2017

§ 101, 130 Stat. 1005, 1005-06

SEC. 101. The Continuing Appropriations Act, 2017 (division C of Public Law 114–223) is amended by— Further Continuing Appropriations Act, 2017. Further Continuing and Security Assistance Appropriations Act, 2017. Dec. 10, 2016 [H.R. 2028] VerDate Sep 11 2014 12:34 Jan 11, 2017 Jkt 069139 PO 00254 Frm 00001 Fmt 6580 Sfmt 6581 E:\PUBLAW\PUBL254.114 PUBL254 dkrause on DSKHT7XVN1PROD with PUBLAWS 130 STAT. 1006 PUBLIC LAW 114–254—DEC. 10, 2016 (1) striking the date specified in section 106(3) and inserting ''April 28, 2017''; (2) striking ''0.496 percent'' in section 101(b) and inserting ''0.1901 percent''; and (3) inserting after section 145 the following new sections: ''SEC. 146. Amounts made available by section 101 for 'Department of Agriculture—Farm Service Agency—Agricultural Credit Insurance Fund Program Account' may be apportioned up to the rate for operations necessary to fund loans for which applications are approved. ''SEC. 147. Amounts made available by section 101 for 'Department of Agriculture—Food and Nutrition Service—Child Nutrition Programs' to carry out section 749(g) of the Agriculture Appropriations Act of 2010 (Public Law 111–80) may be apportioned up to the rate for operations necessary to ensure that the program can be fully operational by May, 2017. ''SEC. 148. Section 26(d) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769g(d)) is amended in the first sentence by striking '2010 through 2016' and inserting '2010 through 2017'. ''SEC. 149. Amounts made available by section 101 for 'Department of Agriculture—Rural Utilities Service' may be transferred between appropriations under such heading as necessary for the cost of direct telecommunications loans authorized by section 305 of the Rural Electrification Act of 1936 (7 U.S.C. 935). ''SEC. 150. Amounts made available by Section 101 for 'Department of Agriculture—Rural Housing Service—Rural Housing Insurance Fund Program Account' for the section 538 Guaranteed MultiFamily Housing Loan Program may be apportioned up to the rate necessary to fund loans for which applications are approved. ''SEC. 151. Amounts made available by section 101 for 'Department of Commerce—National Oceanic and Atmospheric Administration—Procurement, Acquisition and Construction' may be apportioned up to the rate for operations necessary to maintain the planned launch schedules for the Joint Polar Satellite System. ''SEC. 152. Amounts made available by section 101 for 'Department of Commerce—Bureau of the Census—Periodic Censuses and Programs' may be apportioned up to the rate for operations necessary to maintain

the schedule and deliver the required data according to statutory deadlines in the 2020 Decennial Census Program. ‘‘SEC. 153. Amounts made available by section 101 for ‘National Aeronautics and Space Administration—Exploration’ may be apportioned up to the rate for operations necessary to maintain the planned launch capability schedules for the Space Launch System launch vehicle, Exploration Ground Systems, and Orion Multi-Purpose Crew Vehicle programs. ‘‘SEC. 154. In addition to the amount otherwise provided by section 101, and notwithstanding section 104 and section 109, for ‘Department of Justice—State and Local Law Enforcement Activities—Office of Justice Programs—State and Local Law Enforcement Assistance’, there is appropriated $7,000,000, for an additional amount for the Edward Byrne Memorial Justice Assistance Grant program for the purpose of providing reimbursement of extraordinary law enforcement overtime costs directly and solely associated with protection of the President-elect incurred from November 9, 2016 until the inauguration of the President-elect as President:

H.R. 5, 115th Cong. (2017)

Regulatory Accountability Act of 2017

TITLE I--REGULATORY ACCOUNTABILITY ACT

Regulatory Accountability Act

(Sec. 103) This bill revises federal rulemaking procedures under the Administrative Procedure Act (APA) to require a federal agency to make all preliminary and final factual determinations based on evidence and to consider: (1) the legal authority under which a rule may be proposed; (2) the specific nature and significance of the problem the agency may address with a rule; (3) whether existing rules have created or contributed to the problem the agency may address with a rule and whether such rules may be amended or rescinded; (4) any reasonable alternatives for a new rule; and (5) the potential costs and benefits associated with potential alternative rules, including impacts on low-income populations.

Rulemaking notice requirements are revised to require agencies to:

- publish in the Federal Register advance notice of proposed rulemaking involving a major or high-impact rule, a negative-impact-on-jobs-and-wages rule, or a rule that involves a novel legal or policy issue arising out of statutory mandates;
- consult with the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) before issuing a proposed rule and after the issuance of an advance notice of proposed rulemaking;
- provide interested persons an opportunity to participate in the rule making process;
- hold a hearing before the adoption of any high-impact rule;
- expand requirements for the adoption of a final rule, including requiring that the agency adopt a rule only on the basis of the best evidence and at the least cost; and
- grant any interested person the right to petition for the issuance, amendment, or repeal of a rule.

A "major rule" or "major guidance" is a rule or guidance that OIRA determines is likely to impose: (1) an annual cost on the economy of $100 million or more, adjusted annually for inflation; (2) a major increase in costs or prices; (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. enterprises to compete with foreign-based enterprises; or (4) significant impacts on multiple sectors of the economy.

The bill defines: (1) "high-impact rule" as a rule that OIRA determines is likely to have an annual cost on the economy of $1 billion or more, adjusted annually for inflation; and (2) "negative-impact-on-jobs-and-wages rule" as any rule likely to reduce employment or wages in certain economic sectors or industry areas by specified amounts over specified periods.

The bill specifies the minimum amount of information that must be included in an advance notice of a proposed rulemaking.

After notice or advance notice of a proposed rulemaking, the agency making the rule is prohibited from: (1) advocating for the submission of information to form part of the record of review, (2) appealing to the public to undertake advocacy, or (3) communicating for publicity or propaganda within the United States in a manner not authorized by Congress. The agency may request comments or information in an impartial manner.

The notice of final rulemaking that agencies must publish when they adopt a final major rule shall include a report, to be revised every five years, on the benefits and costs to regulated entities. If an agency determines in a revised report that the cost to regulated entities has exceeded the anticipated cost at the time the final rule was issued, the agency must submit to Congress an assessment of whether the rule: (1) is accomplishing its regulatory objective; and (2) has been rendered unnecessary considering changes in the subject area, other government regulations, and alternatives that might impose smaller burdens or achieve lower costs. Upon delivery of such an assessment about a rule exceeding the anticipated cost, the agency must: (1) reopen the public docket to receive additional comments, and (2) consider modifications or alternatives that reduce costs and increase benefits to regulated entities or individuals.

OIRA must issue guidelines to promote coordination, simplification, and harmonization of agency rules during the rulemaking process.

The bill exempts from such revised procedures rulemakings that concern monetary policy proposed or implemented by the Federal Reserve Board (FRB) or the Federal Open Market Committee (FOMC).

(Sec. 104) The bill imposes new requirements for issuing any major guidance or guidance that involves a novel legal or policy issue arising out of statutory mandates.

OIRA may issue guidelines for agencies in issuing major guidance or other guidance.

(Sec. 105) The bill provides for electronic access to transcripts of testimony, exhibits, and other papers filed in a rulemaking proceeding.

The record of decision in a rulemaking proceeding must include information from a hearing under the Information Quality Act (IQA) or on a high-impact rule.

Agencies must grant a petition for a hearing in the case of a major rule, unless the agency reasonably determines that a hearing would not advance consideration of the rule or would unreasonably delay completion of the rulemaking. Exempted from this requirement are rulemakings that concern monetary policy proposed or implemented by the FRB or the FOMC.

(Sec. 106) An agency's denial of an IQA petition, or a failure to grant or deny such petition within 90 days, is reviewable by a court as a final action. The bill allows immediate judicial review of interim rules, other than in cases involving national security interests, issued without compliance with the notice requirements of this bill.

(Sec. 107) The bill revises standards for the scope of judicial review of agency rulemaking to prohibit a court from deferring to an agency's: (1) determination of the costs and benefits or other economic or risk assessment if the agency failed to conform to guidelines on such determinations and assessments established by OIRA, (2) determinations made in the adoption of an interim rule, or (3) guidance.

(Sec. 108) The bill defines "substantial evidence" for purposes of evaluating agency adjudications and for rulemaking under the APA as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion in light of the record considered as a whole, taking into account whatever in the record fairly detracts from the weight of the evidence relied upon by the agency to support its decision.

(Sec. 109) The amendments made by this title shall not apply to any rulemakings pending or completed on the date of enactment date of this title.

TITLE II--SEPARATION OF POWERS RESTORATION ACT

Separation of Powers Restoration Act

(Sec. 202) This title modifies the scope of judicial review of agency actions to authorize courts reviewing agency actions to decide de novo (without giving deference to the agency's interpretation) all relevant questions of law, including the interpretation of: (1) constitutional and statutory provisions, and (2) rules made by agencies. If the reviewing court determines that a statutory or regulatory provision relevant to its decision contains a gap or ambiguity, the court shall not interpret or rely on that gap or ambiguity as: (1) an implicit delegation to the agency of legislative rulemaking authority, or (2) a justification for interpreting agency authority expansively or for deferring to the agency's interpretation on the question of law.

No law may exempt such a civil action from the application of the amendments made by this bill except by specific reference to these provisions.

TITLE III--SMALL BUSINESS REGULATORY FLEXIBILITY IMPROVEMENTS ACT

Small Business Regulatory Flexibility Improvements Act

(Sec. 302) This title amends the Regulatory Flexibility Act of 1980 (RFA) and the Small Business Regulatory Enforcement Act of 1996 (SBREFA) to revise and expand the rulemaking requirements and procedures of federal agencies (excluding Congress, U.S. courts, U.S. territories and possessions, and the District of Columbia) that affect small entities.

The RFA is amended to adopt the broader definition of "rule" set forth in the APA, but to exclude from such definition: (1) rules that pertain to the protection of veterans' rights and benefits and to consumer credit extended to service members and dependents, or (2) rules of particular applicability relating to rates, wages, and other financial indicators. The concept of "economic impact" is added to the RFA to require agencies to consider any direct economic effect of a proposed rule on small entities and any indirect economic effect on such entities that is reasonably foreseeable and that results from such rule.

The applicability of the RFA is expanded to cover: (1) rules that have a beneficial significant economic impact on small entities, (2) rules that affect tribal organizations, (3) land management plans developed by the U.S. Forest Service and

the Bureau of Land Management, and (4) certain collection-of-information and record keeping activities of the Internal Revenue Service.

The definition of "small organization" under the RFA is revised to mean any not-for-profit enterprise, including a local labor organization, with a net worth not exceeding $7 million and with no more than 500 employees.

(Sec. 303) Each agency is required to: (1) include in its regulatory agenda (published in the Federal Register every April and October) a brief description of the sector of the North American Industrial Classification System that is primarily affected by a proposed or promulgated rule that is likely to have a significant economic impact on a substantial number of small entities, and (2) prominently display a plain language summary of the information in the regulatory agenda on its website.

(Sec. 304) RFA requirements relating to an initial regulatory flexibility analysis are expanded to require an analysis to contain a detailed statement (instead of merely a statement) of information relating to a proposed rule. The analysis must include an estimate of the additional cumulative impact of the proposed rule on small entities, a description of any disproportionate economic impact on small entities or a specific class of small entities, and a description of any impairment of the ability of small entities to have access to credit.

A final regulatory flexibility analysis must include a detailed description of any disproportionate economic impact on small entities or a specific class of small entities.

An agency's certification that a rule will not have a significant economic impact on a substantial number of small entities must include an economic assessment to support the certification.

The standard for measuring the economic impact of a proposed rule on small entities is expanded to require a quantifiable or numerical description of the effects of a proposed or final rule on such entities.

(Sec. 305) The authority of an agency to waive or delay the completion of regulatory flexibility analyses is eliminated.

The Chief Counsel for Advocacy of the Small Business Administration (SBA) is given expanded authority to issue, modify, or amend rules governing agency compliance with RFA requirements and to intervene in agency adjudications.

(Sec. 306) RFA procedures for the participation of small entities in the promulgation of a proposed rule are modified to require the rulemaking agency to: (1) notify the SBA Chief Counsel for Advocacy, and (2) provide the Chief Counsel with all materials prepared or utilized by the agency in making the proposed rule and with information on the potential adverse and beneficial economic impacts of the rule on small entities.

The Chief Counsel is specifically charged with: (1) convening a review panel with representation from the SBA Office of Advocacy, the agency making the rule, and the OMB; and (2) reporting to the rulemaking agency on the economic impact of the proposed rule on small entities with respect to energy and startup costs and on alternatives that will minimize adverse or maximize beneficial economic impacts on small entities.

The Chief Counsel is empowered to waive the review panel requirements if they are deemed impracticable, unnecessary, or contrary to the public interest.

(Sec. 307) RFA requirements for periodic review of rules affecting small entities are expanded to require: (1) mandatory review of all rules that have a significant impact on a substantial number of small entities; (2) a detailed statement on how an agency will conduct outreach activities to include small businesses, including those owned and controlled by women, veterans, and socially and economically disadvantaged individuals; (3) annual agency reports on the results of its review of rules; and (4) annual publication in the Federal Register and on the agency website of a list of rules to be reviewed, with a solicitation of public comments.

(Sec. 308) Judicial review under the RFA is expedited to allow an individual who is aggrieved by an agency rule to initiate judicial review of agency compliance with the RFA without waiting for final agency action on such rule.

(Sec. 309) Exclusive jurisdiction is granted to the U.S. Court of Appeals to review challenges by small entities to rules promulgated by the SBA Chief Counsel for Advocacy for implementing the RFA.

(Sec. 310) The Small Business Act is amended to: (1) authorize the SBA Chief Counsel for Advocacy to specify size standards for small business concerns for purposes of any enactment other than the Small Business Act or the Small Business Investment Act of 1958, and (2) permit a party who seeks judicial review of a small business size determination approved by the SBA Chief Counsel for Advocacy to join the Chief Counsel as a party in an action for such review.

(Sec. 312) The SBREFA is amended to require agencies, in developing small entity compliance guides, to solicit input from affected small entities or associations of small entities.

(Sec. 313) The Government Accountability Office (GAO) must complete and publish a study that examines whether the SBA Chief Counsel for Advocacy has the capacity and resources to carry out duties under this title.

TITLE IV--REQUIRE EVALUATION BEFORE IMPLEMENTING EXECUTIVE WISHLISTS ACT

Require Evaluation before Implementing Executive Wishlists Act or the REVIEW Act

(Sec. 402) This title prohibits a final agency rule from being published or taking effect until the agency submits the rule to OIRA and OIRA makes a determination as to whether the rule is a high-impact rule that may impose an annual cost on the economy of at least $1 billion. The agency shall publish such determination with the final rule.

An agency shall postpone the effective date of a high-impact rule until the final disposition of all actions seeking judicial review of the rule.

If no person seeks judicial review of a high-impact rule during any period explicitly provided for such review under the authorizing statute or during the 60-day period after the rule is published if no such period is explicitly provided, the rule may take effect as early as the date the applicable period ends.

TITLE V--ALL ECONOMIC REGULATIONS ARE TRANSPARENT ACT

All Economic Regulations are Transparent Act or the ALERT Act

(Sec. 502) This title requires each federal agency to submit a monthly report to OIRA for each rule such agency expects to propose or finalize during the following 12 months. The reports must include: (1) a summary of the nature of the rule, (2) the objectives of and legal basis for issuance of the rule, (3) the stage of the rulemaking as of the date of submission, and (4) whether the rule is subject to periodic review as a rule with a significant economic impact.

Each agency must submit a monthly report for any rule expected to be finalized during the following 12 months for which the agency has issued a general notice of proposed rulemaking. The reports must include: (1) an approximate schedule for completing action on the rule; (2) estimates of its cost, economic effects, and any imposition of unfunded mandates; and (3) a list of influential scientific information disseminated by the agency relating to the rule, including any peer review plans for the information.

OIRA must make such monthly reports publicly available on the Internet.

OIRA must publish, not later than October 1 of each year, in the Federal Register: (1) information that OIRA receives from each agency under this title; (2) the number of rules and a list of each such rule that was proposed by each agency and each rule that was finalized by each agency; (3) the number of agency actions that repealed a rule, reduced the scope or cost of a rule, or accelerated the expiration date of a rule; (4) the total cost of all rules proposed or finalized and of any proposed unfunded mandates; and (5) the number of rules for which an estimate of the cost of the rule was not available.

OIRA must make publicly available on the Internet, not later than October 1 of each year: (1) the analysis of the costs or benefits of each proposed or final rule issued by an agency for the preceding year, (2) the docket number and regulation identifier number for each such rule, (3) the number of rules reviewed by the OMB for the preceding year, (4) the number of rules for which a review by the head of an agency was completed, (5) the number of rules submitted to the GAO, and (6) the number of rules for which a resolution of disapproval was introduced in Congress.

The bill prohibits a rule from taking effect until the information required by this title is posted on the Internet for not less than six months, unless: (1) the agency proposing the rule claims a "good cause" exemption from notice-and-comment rulemaking procedures under the APA; or (2) the President determines by executive order that such rule is necessary because of an imminent threat to health or safety or

other emergency, for the enforcement of criminal laws, for national security, or to implement an international trade agreement. Such requirement becomes effective eight months after enactment of this title.

TITLE VI--PROVIDING ACCOUNTABILITY THROUGH TRANSPARENCY ACT

Providing Accountability Through Transparency Act

(Sec. 602) This title requires the general notice of proposed rulemaking by a federal agency to include the Internet address of a plain-language summary, not exceeding 100 words, of the proposed rule, which shall be posted on the regulations.gov website.