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

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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
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The Honorable Loretta Lynch
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U.S. Department of Justice
950 Pennsylvania, NW
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The Honorable Chuck Rosenberg
Drug Enforcement Administration
7000 Army-Navy Dr
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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

EXHIBIT 1

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

EXHIBIT 2

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]

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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