

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 of 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.

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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:

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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 marijuana.

Why a New Code Number Is Needed

The United Nations Conventions on international drug control treats extracts from the cannabis plant somewhat differently than marijuana or tetrahydrocannabinols. The creation of a new drug code in the DEA regulations for marijuana 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 marijuana 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 marijuana/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 cannabinoids.

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 marijuana 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 cannabinoids 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 marijuana plant may have therapeutic potential. The comment further clarified that the broader term “cannabinoid” includes both cannabinol-type

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.

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 marijuana extract; however, use of the term “cannabinoid” necessitates that the DEA clarify that the new marijuana 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 “marijuana 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 marijuana) contains a variety of “cannabinoids” and will continue to be regulated as marijuana under drug code 7360. The new drug code for marijuana extracts under 21 CFR 1308.11(d)(58) will exclude the resin. Cannabis resin and marijuana resin remain captured under the drug code for marijuana (drug code 7360), thus differentiating this material from marijuana 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) Marijuana 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 marijuana extracts allows for more appropriate accounting of such materials consistent with treaty provisions. Such marijuana

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.

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Dated: December 7, 2016.

Chuck Rosenberg,
Acting Administrator.

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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