FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List 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(f), 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 FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 2004 Jet Routes

J–2

From Mission Bay, CA; Imperial, CA; Bard, AZ; INT Bard 089° and Gila Bend, AZ, 261°radials; Gila Bend; Tucson, AZ; El Paso, TX; Fort Stockton, TX; Junction, TX; San Antonio, TX; Humble, TX; Lake Charles, LA; Fighting Tiger, LA; Semmes, AL; Crestview, FL; to INT Crestview 091°and Seminole, FL, 290°radials.

J–14

From Panhandle, TX; via Will Rogers, OK; Little Rock, AR; to Vulcan, AL.

J–24

From Myton, UT, to Hayden, CO. From Hugo, CO, Hays, KS; via Salina, KS; Kansas City, MO; St. Louis, MO; Brickyard, IN; Falmouth, KY; Charleston, WV; to Montebello, VA.

J–37

From Hobby, TX, via INT of the Hobby 090° and Harvey, LA, 266° radials; Harvey; Semmes, AL; to Montgomery, AL.

J–39

From Montgomery, AL; Vulcan, AL, Nashville, TN; Louisville, KY, to Rosewood, OH.

J–42

From Delicias, Mexico, via Fort Stockton, TX; Abilene, TX; Ranger, TX; Texarkana, AR; Memphis, TN; Nashville, TN; Beckley, WV; Montebello, VA; to Gordonsville, VA.

J–52

From Vancouver, BC, Canada; via Spokane, WA; Salmon, ID; Dubois, ID; Rock Springs, WY; Falcon, CO; Hugo, CO; Lamar, CO; Liberal, KS; INT Liberal 137° and Ardmor, OK 309° radials; Ardmore; Texarkana, AR; Sidon, MS; Bigbee, MS; to Vulcan, AL.

J–55 [Remove]

J–61

From Westminster, MD; to Philipsburg, PA.

J–62 [Remove]

J–68

From Gopher, MN, INT Gopher 109° and Dells, WI, 310° radials; Dells; Badger, WI; INT Badger 086° and Flint, MI, 278° radials; to Flint.

J–79 [Remove]

J–109 [Remove]

J–121 [Remove]

J–150 [Remove]

J–165 [Remove]

J–174 [Remove]

J–191 [Remove]

J–193 [Remove]

J–222 [Remove]

J–225 [Remove]

J–230 [Remove]

J–506 [Remove]

J–561 [Remove]

J–563 [Remove]

J–570 [Remove]

J–573 [Remove]

J–582 [Remove]

J–585 [Remove]

Paragraph 2006 United States Area Navigation Routes.

Q–108 [Remove]

Issued in Washington, DC, on March 11, 2020.

Scott M. Rosenbloom,

Acting Manager, Airspace Policy Group.

[FR Doc. 2020–05857 Filed 3–20–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1318

[Docket No. DEA–506]

RIN 1117–AB54

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

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

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

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

• *Electronic Comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the

online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

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

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

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Background and Purpose of This Proposed Rule

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

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

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

A. Relevant Provisions of the Single Convention

Because the terminology used in the Single Convention is somewhat different from that in the CSA, a brief explanation is warranted. The Single Convention uses the terms ''cannabis,'' ''cannabis plant,'' and ''cannabis

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

[2] This document uses both the CSA spelling ''marihuana'' and the modern spelling ''marijuana'' interchangeably.

[3] Section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be ''consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' The Single Convention entered into force for the United States on June 24, 1967. *See* Single Convention, 18 U.S.T. 1407.

resin''—all of which are generally encompassed by the CSA definition of ''marihuana'' in 21 U.S.C. 802(16)).[4] The Single Convention defines ''cannabis plant'' as ''any plant of the genus Cannabis.'' Single Convention art. 1(1)(c). The Single Convention defines ''cannabis'' as the ''flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted.'' *Id.* art. 1(1)(b). The Single Convention defines ''cannabis resin'' as the ''separated resin, whether crude or purified, obtained from the cannabis plant.'' *Id.* art. 1(1)(d).

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

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

> The system of control over all stages of the drug economy which the Single Convention provides has two basic features: Limitation of narcotic supplies of each country . . . to the quantities that it needs for medical and scientific purposes, and authorization of each form of participation in the drug economy, that is, licensing of producers, manufacturers and traders . . . . *In the case of the production of opium, coca leaves, cannabis and cannabis resin, this régime is supplemented by the requirement of maintaining government monopolies for the wholesale and international trade in these drugs in countries which produce them* . . . .
>
> Secretary-General of the United Nations, Commentary on the Single Convention on Narcotic Drugs, 1961, 263 (1973) (emphasis added) (footnotes omitted).[5]

Article 23(2) of the Single Convention, made applicable to marijuana cultivation by Article 28, contains five requirements for the supervision, licensing, and distribution of marijuana.[6]

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

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

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

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

(e) Have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis and cannabis resin, except that this exclusive right need not extend to medicinal cannabis, cannabis preparations, or the stocks of cannabis and cannabis resin held by manufacturers of such medicinal cannabis and cannabis preparations.[7]

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

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

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

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

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

[4] As discussed below, the Agriculture Improvement Act of 2018, Public Law 115–334, removed hemp from the CSA definition of marihuana. This proposed rule applies only to cannabis that is included in the CSA definition of marihuana.

[5] The United Nations' Economic and Social Council requested that the Secretary-General prepare the Commentary ''in the light of the relevant conference proceedings and other material'' in order to aid governments in applying the Single Convention. The Commentary (1973) is not binding on Parties to the Convention. Economic and Social Council Resolution 1962/914(XXXIV) D (Aug. 3, 1962).

[6] The Single Convention provides that the five functions of article 23, paragraph 2 ''shall be discharged by a single government agency if the constitution of the Party concerned permits it.'' Single Convention art. 23(3). Nothing in the Constitution would preclude the United States from discharging all of those controls through one government agency. The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed on constitutional grounds, administrative arrangements should be made to ensure the required coordination.

[7] The meanings of the terms ''medicinal cannabis'' and ''cannabis preparations'' are addressed later in this document. Article 23, paragraph 2(e) also refers to ''opium alkaloids.'' However, due to distinctions between the opiates derived from the opium poppy and the cannabinoids derived from the cannabis plant, the notion of ''cannabis alkaloids'' is inapplicable.

authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in 21 CFR part 1301.

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

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

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

The exceptions made for ''medicinal cannabis or cannabis preparations'' also warrant explanation. In view of the text of the Single Convention, and taking into account the current wording of Federal law,[8] the regulations being proposed would define these terms as follows:

- Medicinal cannabis means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the Federal Food, Drug, and Cosmetic Act. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana.
- Cannabis preparation means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana.

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

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

(1) DEA-registered manufacturers of (a) an FDA-approved marihuana-derived drug (*i.e.,* ''medicinal cannabis''), and (b) ''cannabis preparations'' would be permitted to maintain stocks of cannabis materials obtained from DEA for the purpose of producing such drugs or preparations; [9] and

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

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

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

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

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

For applicants within this category, within four months of harvest, DEA would travel to the DEA-registered location, purchase, and take title to the crop by issuing the grower a DEA Form 222.[10] Once DEA has taken title to the

[8] Among other things, these definitions take into account the current CSA definition of marihuana (21 U.S.C. 802(16)), which was amended in 2018 to exclude ''hemp'' as defined in section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639*o*(1)).

[9] As indicated above, the requirement that registered growers deliver all cannabis to DEA no later than four months after the end of the harvest applies in *all* situations—even where the cannabis will later be distributed by DEA back to the grower for further use. Thus, the above exception that allows DEA-registered manufacturers of medicinal cannabis and cannabis preparations to maintain stocks of cannabis materials for the purpose of producing such drugs or preparations only applies where the raw cannabis material was previously delivered to DEA.

[10] DEA would take title to an amount up to the applicant's manufacturing quota. Growing marihuana in excess of a manufacturing quota is a violation of federal law. 21 U.S.C. 842(b). Thus, any marihuana grown in excess of a manufacturing

Continued

crop, it would then distribute a quantity of marihuana that does not exceed the company's DEA-issued procurement quota back to that same manufacturer. In this way, DEA would take physical possession of the crop and control its distribution. Additionally, the material owned by the government will be maintained at the DEA-registered manufacturer's location and DEA would maintain its ability to access the storage location at which such crops are located as it deemed necessary.

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

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

For applicants that fall within this sub-set, within four months of harvest, DEA would travel to the DEA-registered location, purchase, and take title to the crop by issuing the grower a DEA Form 222.[11] For this reason, each grower must provide written notice to DEA of its proposed date of harvest at least fifteen days prior to the commencement of the harvest. Once DEA has purchased and taken title to the crop, the material would be maintained, under seal, in DEA's possession in the manufacturer's schedule I vault until such time that a distribution is necessary. In this scenario, DEA may distribute (or export) the marihuana directly or may choose to authorize the grower to distribute marihuana on the government's behalf. Again, marihuana owned by the government is maintained at the DEA-registered manufacturer's site where DEA would maintain its ability to access the storage location at which such crops are located as it deemed necessary.

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

Over the last several decades, NIDA has administered a contract to produce high quality marihuana for use by researchers who have obtained federal funding (grants) for such research.[12] This contract has been awarded to the National Center for Natural Products Research at the University of Mississippi (National Center). In accordance with that contract and DEA regulations, NIDA assesses the quantity of marihuana that is necessary to be grown for research purposes in a given year and communicates that information to both the National Center and DEA. The National Center applies for, and must first obtain, a manufacturing quota from DEA and is then authorized to grow marihuana up to the limit established by their DEA-issued quota. At the time of harvest, a portion of that material is held in inventory at the National Center while other portions are distributed to another DEA registrant, Research Triangle Institute (RTI). Currently, at the direction of NIDA, both RTI and the National Center may prepare marihuana in a manner which is suitable for research studies and ship it to researchers. In these instances, marihuana held in inventory at the National Center and RTI are the property of NIDA. The regulations proposed in this notice of proposed rulemaking (NPRM) are intended to enhance and improve upon existing DEA regulations that supported the NIDA DSP and will facilitate research that may lead to the development of FDA-approved medicines.

This regulation, if finalized, would require changes to the current scheme described above. Although NIDA can, and would, continue to administer the contract in support of its DSP and the National Center (or other NIDA contract holder) could continue to grow and produce marihuana in support of research pursuant to that contract (for as long as that contract is renewed), within four months of harvest, DEA would travel to the National Center at the time of harvest and take title and possession to the crop by issuing the National Center a DEA Form 222.[13] Once DEA has taken title and possession of the crop, the material would be maintained, under seal, in DEA's possession in the National Center's schedule I vault until such time that a distribution to another DEA registrant is authorized. In this scenario, DEA may distribute (or export) the marijuana directly or may choose to authorize the National Center to distribute marihuana on the government's behalf. In both situations, DEA's distributions would be in accordance with NIDA's recommendation. And, as such, DEA does not envision a scenario in which it would deny or delay a distribution to a duly registered schedule I researcher authorized to handle marihuana. Marihuana owned by DEA would be maintained at the National Center, where DEA would maintain its ability to access the storage location at which its crops are located.

C. Application of the Public Interest Factors

As indicated, in addition to the foregoing treaty considerations, DEA may grant a registration to manufacture a schedule I or II controlled substance only where the Administrator determines that the registration is consistent with the public interest, based on the criteria listed in 21 U.S.C. 823(a). The first of those criteria, set forth in subsection 823(a)(1), provides that, for the purpose of maintaining effective controls against diversion, the number of registered bulk manufacturers of a given schedule I or II controlled substance should be limited to that which can produce an adequate and uninterrupted supply of marihuana under adequately competitive conditions.[14]

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

quota would be subject to seizure and destruction. *See id.* 881(g).

[11] As in the first scenario, DEA only would take title to an amount up to the applicant's manufacturing quota. Any marihuana grown in excess of a manufacturing quota would be subject to seizure and destruction. *See* 21 U.S.C. 842(b), 881(g).

[12] The Department of Health and Human Services maintains procedures for providing this same marihuana to non-NIH funded researchers as well.

[13] As above, DEA only would take title to an amount up to the National Center's manufacturing quota, with amount grown in excess of the manufacturing quota subject to seizure and destruction. *See* 21 U.S.C. 842(b), 881(g).

[14] For a detailed explanation of subsection 823(a)(1), see 74 FR at 2127–33.

the extent authorized by its approved research protocol.

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

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

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

The preceding criteria are designed to result in registration of those manufacturers of marihuana that can most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality.[15] These criteria are further aimed at selecting applicants that can be entrusted with the responsibility of a DEA registration and complying with the corresponding obligations under the CSA and DEA regulations.

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

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

The Agriculture Improvement Act of 2018 (AIA), Public Law 115–334, which became effective December 20, 2018, contained various provisions regarding the cultivation of hemp. The AIA definitions hemp as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. 1639*o*(1). The AIA amended the CSA definition of marihuana to exclude hemp. Thus, anything that falls within the foregoing definition of hemp is no longer a controlled substance, and the CSA's requirements no longer apply to such substances. Accordingly, this proposed rule would apply only to persons seeking authorization under the CSA (*i.e.,* seeking a DEA registration) to manufacture marihuana that involves the planting, cultivation, growing, or harvesting of marihuana as that term is currently defined in the CSA (21 U.S.C. 802(16)).[16]

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

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

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

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

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

Variable Administrative Fee = $607,644/2,000 kg = $304 per kg[17]

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

[15] The proposed rule provides that, in determining the legitimate demand for marihuana and its derivatives in the United States, the Administrator shall consult with the Department of Health and Human Services, including its components.

[16] The United States Department of Agriculture has issued regulations and guidance to implement a program for the commercial production of industrial hemp in the United States under the framework of the AIA. *See Establishment of a Domestic Hemp Production Program,* 84 FR 58522 (Oct. 31, 2019).

[17] Rounded to nearest whole dollar. The cost of $607,644 is explained below.

Regulatory Analyses

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

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

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

I. Need for the Rule

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

II. Alternative Approaches

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

III. Analysis of Benefits and Costs

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

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

This proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and add provisions related to the purchase and sale of this marihuana by DEA. If this proposed rule is promulgated, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes would mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights would not extend to medicinal cannabis or cannabis preparations. The changes described above would affect three primary groups of entities: Growers and prospective growers, the authorizing agencies,[18] and purchasers (generally medical and scientific researchers). To examine the impact of the proposed rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

Current System

Under current regulations, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.[19] The National Center has designated a secure plot of land or indoor grow facility where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[20] NIDA obligated approximately $1.5 million in Fiscal Year 2015 under this contract.[21] This amount included costs unrelated to growing and cultivating marihuana, such as extracting chemical components and producing marihuana cigarettes and other marihuana-related material. However, based on recent discussion with NIDA,[22] DEA estimates NIDA's expenses under the contract with the National Center (and any related

[18] The ''authorizing agency'' refers to federal government agencies, including NIDA and DEA.

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

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

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

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

subcontracts) for the bulk marihuana for 2019 are approximately $2.9 million.[23] The $2.9 million includes compensation for the cultivating and the 2019 manufacturing quota (MQ) of 2,000 kgs for NIDA (National Center) as well as all other duties required in the contract.[24]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is currently available at no cost to research investigators supported by a NIH grant. Marihuana is also available to research investigators who are funded through non-federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [25] the current policy is to provide the marihuana at no charge.[26]

Changes to Growers

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

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[27] Since the publication of the 2016 policy statement, DEA has received approximately 35 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of 3 to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The Aggregate Production Quota (APQ), which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[28] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and the reimbursement of production cost through sales) is transferred from the single incumbent grower to new growers. This means that there is only a transfer of economic activity rather than any new cost. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[29]

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

Changes to Authorizing Agencies—Cost to DEA

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

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

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

1. After marihuana is harvested and prepared for delivery to DEA, the registered manufacturer will contact

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

[24] The 2019 Aggregate Production Quota for all marihuana is 2,450 kgs. 2,000 of the 2,450 kgs are for the NIDA (National Center) cultivating and manufacturing quota of bulk marihuana. *See* 83 FR 67348.

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

[26] *See* note 22.

[27] Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). This proposed rule, if adopted, would supersede the 2016 policy statement.

[28] 21 CFR 1303.11(a).

[29] The phrase ''multiple growers'' includes the possibility that the current grower is one of ''multiple growers.''

DEA to inform it that the marihuana is ready for collection.

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

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

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

For each collection, DEA estimates $2,071 of labor cost [30] and $116 of vehicle cost [31] for a total of $2,187 per collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of $2,187 per collection, DEA estimates a transport cost of $19,683 and $98,415 for scenarios with three and 15 growers, respectively.

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

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

TABLE 1—COST OF PERSONNEL RESOURCES

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

In summary the estimated cost to DEA is:

- $19,683 or $98,415 per year to purchase and take title to the bulk marihuana for scenarios with 3 or 15 authorized growers, respectively;
- $548,595 per year for three DEA FTE employees;
- The estimated total annual cost is $568,278 with three growers and $647,010 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is $607,644. Table 2 summarizes the costs.

TABLE 2—DEA COST SUMMARY

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

Changes Affecting Researchers

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

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

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

[31] $116 is based on IRS standard mileage rates for 2019 of $0.58 per mile multiplied by the estimated 200 miles driven, roundtrip.

used in research, via grants to researchers.

Cost Summary

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

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

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

TABLE 3—SUMMARY OF ANNUAL EFFECT AND NPVS

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

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

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

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 13132 (Federalism)

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

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

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

Regulatory Flexibility Act

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

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

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

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

Current System

Under current regulations, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for

use in research studies.[32] The National Center designates a secure plot of land where marihuana crops are grown every few years, based on current and expected demand. The marihuana is grown, harvested, stored, and made available as bulk marihuana or other purified elements of marihuana to use for research.[33] As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 are approximately $2.9 million.[34] The $2.9 million includes compensation for the cultivating and the 2019 MQ of 2,000 kgs for NIDA as well as all other duties required in the contract.[35]

Researchers may obtain marihuana for use in research through NIDA's DSP. Bulk marihuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marihuana is also available to research investigators who are funded through non-federal sources. Although NIDA considered charging for marihuana on a ''cost-reimbursement basis,'' [36] the current policy is to provide the marihuana at no charge.[37]

Impact on Growers

If this proposed rule is implemented, DEA anticipates approving more than one person to cultivate and harvest bulk marihuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.[38] Since the publication of the 2016 policy statement, there are approximately 35 pending applications for registration as bulk manufacturer of marihuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacture and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this proposed rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.[39] Therefore, given a constant MQ, if more growers are approved to produce bulk marihuana, the quantities of bulk marihuana produced and the cost of production (and reimbursement of their production cost through sales) is transferred from the incumbent grower to new growers. This means that there is no new cost; instead, there is only a transfer of economic activity. The estimated economic activity of $2.9 million is transferred from the existing single grower to multiple growers.[40]

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

Impact on Researchers

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

Affected Number of Small Entities

This proposed rule affects the current and prospective bulk manufacturers of marihuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this proposed rule. Additionally, based on a discussion with NIDA,[41] DEA estimates 40 researchers are affected by this proposed rule. The 40 researchers represent the approximate number of researchers that receive marihuana from NIDA's marihuana DSP.

Based on a review of representative North American Industry Classification System (NAICS) codes for bulk manufacturers and researchers, the following number of firms may be affected: [42]

- 421 firms related to 'Medicinal and Botanical Manufacturing' (325411) [43]
- 9,634 firms related to 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712) [44]

The United States Small Business Administration (SBA) sets size standards that determine how large an entity can be and still qualify as a small business for federal government programs. For the most part, size standards are based on the average annual receipts or the average number of employees of a firm. The SBA size standard for both industries identified by the NAICS codes above is 1,000 employees.[45]

Comparing the SBA size standards to the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) detailed data on establishment size by NAICS code for each affected industry, DEA estimates

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

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

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

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

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

[37] *See* note 22.

[38] Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (2016). This proposed rule, if adopted, would superseded the 2016 policy statement.

[39] 21 U.S.C. 826(a).

[40] The phrase ''multiple growers'' includes the possibility that the current grower is one of the ''multiple growers.''

[41] *See* note 22.

[42] For the purposes of this analysis, the term ''firms'' is synonymous with ''entities.''

[43] 2015 SUSB Annual Datasets by Establishment Industry, U.S. & States, NAICS, Detailed Employment Sizes (U.S., 6-digit and States, NAICS Sectors), United States Census Bureau, *https://www.census.gov/data/datasets/2015/econ/susb/2015-susb.html*.

[44] *Ibid.*

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

the following number of small entities and percent of firms that are small entities by industry:

- 392 (93.1 percent of total) firms in the area of 'Medicinal and Botanical Manufacturing' (325411)
- 9,090 (94.4 percent of total) firms in the area of 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712)

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

TABLE 4—NUMBER OF SMALL ENTITIES BY INDUSTRY

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

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

TABLE 5—PERCENT OF SMALL ENTITIES AFFECTED BY INDUSTRY

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

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

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

Furthermore, NIH-funded or other third-party funded researchers are likely to request and receive enough funding

for the full price of marihuana, including the administrative fee. There would be no impact to these researchers. However, DEA does not have sufficient information to estimate the number of small entity researchers that would fall under this category. Although DEA is unable to quantify the economic impact for the estimated 14 small entity bulk manufacturers and 38 small entity researchers, the number of affected small entity manufacturers and researchers is not a substantial number of small entities in their respective industries.

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

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

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

A. Collections of Information Associated With the Proposed Rule

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

OMB control number: 1117–0012.

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

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

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

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

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

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

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

- *Number of respondents:* 15,919.
- *Frequency of response:* 1 per respondent per year.
- *Number of responses:* 15,919.
- *Burden per response:* 0.1304 hours.
- *Total annual burden in hours:* 2,076.

B. Request for Comments Regarding the Proposed Collections of Information

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

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information shall have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

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

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

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1318

Administrative practice and procedure, Drug traffic control.

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

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

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

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

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

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

* * * * *

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

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

■ 3. Add part 1318 to read as follows:

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

Sec.

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

§ 1318.01 Scope of this part.

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

§ 1318.02 Definitions.

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

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

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

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

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

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

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

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

§ 1318.03 Implementation of statutory requirements.

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

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

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

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

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

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

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

§ 1318.05 Application of the public interest factors.

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

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

competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 1318.07 Non-liability of Drug Enforcement Administration.

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

Dated: March 16, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–05796 Filed 3–20–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 209

[COE–2016–0016]

RIN 0710–AA72

Use of U.S. Army Corps of Engineers Reservoir Projects for Domestic, Municipal & Industrial Water Supply; Withdrawal

AGENCY: Army Corps of Engineers, DoD.

ACTION: Proposed rule; withdrawal.

SUMMARY: As a result of a policy determination by the Assistant Secretary of the Army (Civil Works), the U.S. Army Corps of Engineers (Corps) is withdrawing the proposed rule titled ''Use of U.S. Army Corps of Engineers Reservoir Projects for Domestic, Municipal & Industrial Water Supply,'' which was published on December 16, 2016.

DATES: The Corps is withdrawing the proposed rule published December 16, 2016 (81 FR 91556) as of March 23, 2020.

ADDRESSES: U.S. Army Corps of Engineers, 441 G Street NW, Washington, DC 20314.

FOR FURTHER INFORMATION CONTACT: Amy K. Frantz, Planning and Policy (CECW–P); telephone number: (202) 761–0106; email address: *WSRULE2016@usace.army.mil*; or Daniel Inkelas, Chief Counsel's Office (CECC–L); phone number (202) 761–0345; email address: *WSRULE2016@usace.army.mil*.

SUPPLEMENTARY INFORMATION: None.

Dated: March 16, 2020.

R.D. James,

Assistant Secretary of the Army, (Civil Works).

[FR Doc. 2020–05919 Filed 3–20–20; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket No. ED–2020–OPE–0044]

Proposed Waiver and Extension of the Project Period for the Predominantly Black Institutions Competitive Grant Program

AGENCY: Office of Postsecondary Education (OPE), Department of Education.

ACTION: Proposed waiver and extension of project period.

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations that generally prohibit project periods exceeding five years and project period extensions involving the obligation of additional Federal funds. The proposed waiver and extension would enable 23 projects under CFDA number 84.382A to receive funding for an additional period, not to exceed September 30, 2021.

DATES: We must receive your comments on or before April 22, 2020.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), we strongly encourage you to convert the PDF to print-to-PDF format or to use some other commonly used searchable text format. Please do not submit the PDF in a scanned format. Using a print-to-PDF format allows the Department to electronically search and copy certain portions of your submissions.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Help.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* The Department strongly encourages commenters to submit their comments electronically. However, if you mail or deliver your comments about the proposed waiver and extension, address them to: The Predominantly Black Institutions Competitive Grant Program, CFDA number 84.382A, Attention: Bernadette Miles, U.S. Department of Education, 400 Maryland Avenue SW, Room 250–22, Washington, DC 20202.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Bernadette Miles, U.S. Department of Education, 400 Maryland Avenue SW, Room 250–22, Washington, DC 20202. Telephone: 202–453–7892. Email: *Bernadette.Miles@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this proposed waiver and extension.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 13771 and their overall requirement of reducing regulatory burden that might result from this proposed waiver and extension. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed waiver and extension of the project period in Room 5059, 550 12th Street SW, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week, except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other