

**SUPPLEMENTARY INFORMATION:****I. Background**

We are announcing the availability of a guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of May 20, 2019 (84 FR 22749), we made available a draft guidance for industry entitled “The Use of an Alternate Name for Potassium Chloride in Food Labeling” (“draft guidance”), which was intended to explain to food manufacturers our intent to exercise enforcement discretion for the declaration of the name “potassium chloride salt” in the ingredient statement on food labels as an alternative to the common or usual name “potassium chloride.” The draft guidance considered, in part, a NuTek Food Science citizen petition requesting that we issue guidance recognizing “potassium salt” as an additional common or usual name for potassium chloride (see Citizen Petition from NuTek Food Science, LLC, dated June 27, 2016, FDA–2016–P–1826–0001 at page 1). Additionally, we specifically invited comment on how the use of the name “potassium chloride salt” in the ingredient statement as an alternative to “potassium chloride” would improve consumer understanding of the ingredient and what alternate names to “potassium chloride salt” would better promote consumer understanding of potassium chloride (84 FR 22749 at 22750 through 22751). We gave interested parties until July 19, 2019, to submit comments for us to consider before beginning work on the final version of the guidance.

In response to requests for more time to comment on the draft guidance, we issued a notice in the **Federal Register** of July 10, 2019 (84 FR 32848) extending the comment period to September 17, 2019. We received more than 70 comments on the draft guidance. Many comments expressed concerns that declaration of the alternate name “potassium chloride salt” would be confusing or would not achieve the public health goal of reduced sodium consumption, as food manufacturers would likely not use the alternate name. Food manufacturers, public health and consumer advocacy groups provided

comments and data supporting “potassium salt” as an alternate name to “potassium chloride.”

After careful review and consideration of the comments to the draft guidance, some of which led us to further review of relevant published literature, we have modified the final guidance. Changes to the guidance include:

- Exercising enforcement discretion for declaration of “potassium salt,” rather than “potassium chloride salt,” in the ingredient statement on food labels as an alternative to declaration of the common or usual name “potassium chloride;” and
- Further explaining potassium chloride’s technical role as a partial substitute for sodium chloride in food manufacturing through the inclusion of additional examples and references.

As discussed in the final guidance, we have made these changes with the following considerations in mind: Potential public health benefits to the U.S. population from reduced sodium and increased potassium intake, the recognition that potassium chloride can substitute for sodium chloride in a variety of food manufacturing applications across a number of food categories, and the unlikelihood that the alternate name will mislead consumers.

The guidance announced in this notice finalizes the draft guidance dated May 2019.

**II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381.

**III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 11, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**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:** Final rule.

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

**DATES:** This final rule is effective January 19, 2021.

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**SUPPLEMENTARY INFORMATION:****Legal Authority and Background**

The Controlled Substances Act (CSA) requires all persons who seek to manufacture a controlled substance to obtain a DEA registration.<sup>1</sup> 21 U.S.C. 822(a)(1). The CSA defines “manufacture” to include the “production” of a controlled substance, which in turn includes, among other things, the planting, cultivation, growing, or harvesting of a controlled substance. 21 U.S.C. 802(15), (22). Thus, any person who seeks to plant, cultivate, grow, or harvest marihuana<sup>2 3</sup>

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

<sup>2</sup> This document uses both the CSA spelling “marihuana” and the modern spelling “marijuana” interchangeably.

<sup>3</sup> As defined in Section 802(16).

to supply researchers or for other uses permissible under the CSA (such as product development) must obtain a DEA manufacturing registration. Because marihuana is a schedule I controlled substance, applications by persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. 823(a). See generally 76 FR 51403 (2011); 74 FR 2101 (2009), *pet. for rev. denied*, *Craker v. DEA*, 714 F.3d 17 (1st Cir. 2013). DEA's Administrator has the authority to grant a registration under section 823(a). To do so, the Administrator must determine that two conditions are satisfied: (1) The registration is consistent with the public interest (based on the enumerated factors in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 ("Single Convention" or "Treaty"), 18 U.S.T. 1407.<sup>4</sup>

In 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marihuana for research purposes. See Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846 (Aug. 12, 2016). Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the requirement of section 823(a) that a registration to bulk manufacture a schedule I or II controlled substance must be consistent with United States obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed. As part of this review, in June 2018, the DOJ Office of Legal Counsel (OLC) prepared an opinion ("OLC Opinion"), now publicly available, examining DEA's policies and practices for granting bulk manufacturing registrations to marihuana growers in light of the CSA's requirement that DEA register manufacturers of schedule I and II controlled substances in a manner consistent with the Single Convention.<sup>5</sup>

This rule is being implemented pursuant to the Administrator's authority under the CSA "to promulgate rules and regulations and to charge

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

### Summary of the Notice of Proposed Rulemaking

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

### Discussion of Public Comments

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

### Application Process and Criteria

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

**Issue 1:** Many commenters stated that the approval process for applications takes too long and needs to be streamlined, suggesting that a timeframe

for the approval or denial of applications should be determined, specifically within 30 days, 90 days, or six months of receipt of the application.

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

However, in accordance with 21 U.S.C. 823(i), for applications to manufacture a schedule I or II controlled substance for use only in a clinical trial, DEA will issue a notice of application not later than 90 days after the application is accepted for filing. Additionally, DEA will register the applicant, or serve an order to show cause upon the applicant in accordance with 21 U.S.C. 824(c), not later than 90 days after the date on which the period

<sup>4</sup> 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.

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

for comment pursuant to such notice ends, unless DEA has granted a hearing on the application under 21 U.S.C. 958(i). An applicant that believes it qualifies for review under these procedures should identify itself as an 823(i) applicant in its initial application for registration submitted to DEA. DEA will then determine whether the applicant qualifies for the review timeline specified under section 823(i).

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

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

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

*Response 3:* As mentioned in the NPRM, after the 2016 marijuana grower policy statement issued by DEA,<sup>6</sup> DOJ reviewed DEA's policies and practices for issuing bulk marijuana manufacturing registrations in light of the CSA and determined that DEA needed to amend its policies.<sup>7</sup> DEA has acted as expeditiously as possible to amend its policies to ensure consistency with the Single Convention as required by the CSA, while increasing the number of marijuana growers for research purposes. DOJ and DEA fully support research into the effects of marijuana and the potential medical utility of its chemical constituents, and DEA is working to expand the number of DEA-registered bulk manufacturers of marijuana, including through the finalization of this rule.

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

*Response 4:* As required by the Paperwork Reduction Act (PRA), DEA must receive approval from the Office of Management and Budget (OMB) when a

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

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

*Response 5:* Congress has established by statute the factors that DEA must consider when evaluating whether to grant an application for registration. For an applicant to manufacture a schedule I or II controlled substance, DEA must consider, among other factors, the applicant's "compliance with applicable State and local law;" "prior conviction record . . . under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;" "past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;" and "such other factors as may be relevant to and consistent with the public health and safety." 21 U.S.C. 823(a). An applicant that has manufactured marijuana without obtaining a DEA registration has violated Federal law, *see* 21 U.S.C. 841(a), regardless of whether that manufacturer has violated the laws of the State in which the applicant is located. Such activity is relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety. Moreover, prior conduct in violation of the CSA is relevant to determining whether the applicant can be entrusted with the

responsibilities associated with being a DEA registrant. Indeed, DEA registration is a fundamental component of the CSA, and it is wholly appropriate to consider an applicant's past noncompliance with the CSA when deciding whether to grant a registration under the Act. DEA will consider all relevant factors for each individual applicant, on a case-by-case basis, when determining whether to grant registration, as provided for in 21 U.S.C. 823(a) and the regulatory text at 21 CFR 1318.05. While the DEA Administrator has discretion to weigh the statutory factors and any one factor need not be dispositive, an applicant's prior compliance with Federal law is a relevant consideration when determining whether to grant an application for registration.

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

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

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

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

*Issue 8:* Some commenters suggested that the registration requirement be waived for marijuana growers (manufacturers) who will be supplying

<sup>6</sup> 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).

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

marihuana to researchers under 21 U.S.C. 822(d).

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

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

exempt researchers from the registration requirement.

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

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

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

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

applications whenever a new application is submitted.

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

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

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

Currently, researchers are only permitted to manufacture as a coincident activity in limited quantities as set forth in a protocol approved by DEA in the researcher’s registration application (or re-registration application), and to the extent that manufacture is not for the purposes of dosage form development. 21 CFR 1301.13(e)(1). A researcher’s planting, cultivating, growing, or harvesting of marihuana does not constitute such a coincident activity to research. Rather, the planting, cultivating, growing, or harvesting of marihuana requires a manufacturer registration obtained under 21 U.S.C. 823(a), even when the researcher is growing the marihuana for his or her own research use. See 21 CFR 1301.33(d). As described in response to Issue 9, and in the section on quota that follows, international treaties require that DEA control manufacturing of marijuana and other schedule I and II controlled substances by means of quota. Although regulatory provisions allow for the approval of certain small-

<sup>8</sup> See OLC Op., *supra* note 5, at 7.

scale manufacturing pursuant to a DEA-approved protocol, significant manufacturing, including for research purposes, must be performed pursuant to a quota to maintain effective controls against diversion. As a result, researchers must register with DEA as manufacturers to engage in significant manufacture of controlled substances, even if the manufactured substances will exclusively be used in the grower's own research.

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

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

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

*Issue 13:* Some commenters suggested DEA establish application requirements or committees that ensure diversity and inclusion of minority applicants. Other commenters suggested DEA provide regulatory provisions that afford economic opportunities to communities

that have been disproportionately impacted by substance abuse and illicit drug markets and make application selection inclusive to include rural farmers, racial minorities, and disabled persons.

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

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

*Response 14:* Registrants are permitted to import and export controlled substances, including marihuana, in accordance with the criteria defined at 21 U.S.C. 952(a) (import) and 21 U.S.C. 953(a) (export), and after obtaining registration in accordance with 21 U.S.C. 958. After obtaining a registration to manufacture marihuana, the applicant may form agreements with international firms, but, if the importation or exportation of marihuana or another controlled substance will be involved as part of the agreement, it must ensure that any such importation or exportation complies with 21 U.S.C. 952, 953, and 958, and the relevant implementing regulations. Moreover, in addition to these general regulatory requirements, § 1318.04(b) of this rule specifically requires prior written notice to DEA of each proposed importation or exportation of marihuana, and DEA's express written authorization for the importation or exportation.

#### *Quality of Marihuana*

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

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

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

*Issue 2:* A few commenters suggested that samples of marihuana should be

tested to determine the quality prior to sales transactions and that manufacturers should be allowed to send samples of crops before and after harvest to analytical labs for testing, prior to DEA taking possession.

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

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

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

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

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

in DEA's possession. Other commenters stated that there is no process or remedy for the damage or loss of crops that could occur while in DEA's possession.

*Response 4:* DEA assesses the risk of marijuana crops being lost or damaged while in DEA's possession to be low. DEA does not anticipate retaining possession of marijuana crops for long periods of time; in most instances, they will be transferred quickly from the seller to the buyer, with DEA's possession being as brief as possible to effectuate its role in transferring the marijuana from buyer to seller. In addition, crops in DEA's possession are largely expected to be maintained at the manufacturer's registered location, in a secure location designated by DEA. Accordingly, crops are highly unlikely to be damaged or lost in DEA's possession. To avoid costly and unnecessary disputes related to any loss or damage of crops, § 1318.07 makes clear that DEA has no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marijuana, including but not limited to the quality of the marijuana. In effect, this rule makes clear that buyers and sellers should structure their marijuana transactions to minimize the risk of damage or disputes over quality, rather than expecting DEA to mediate or bear the costs of such disputes.

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

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

*Response 5:* DEA does not have the authority to dictate the strains of marijuana to be produced by growers. Rather, DEA believes that market forces will drive the strains of marijuana materials that growers will produce, and the purchasers will be able to choose which DEA-registered grower they believe will best produce the strains or quality of marijuana that will meet their needs. The factors that the Administrator will consider in granting a registration to grow marijuana will be

consistent with the public interest factors set forth in section 21 U.S.C. 823(a), including the applicant's ability to consistently produce and supply high quality marijuana and defined chemical composition and other criteria as specified in 21 CFR 1318.05.

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

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

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

Moreover, such a change is unnecessary. By registering additional marijuana growers pursuant to this

rule, DEA will expand researchers' access to marijuana in accordance with the CSA, and in a manner that supports the public health.

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

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

#### *Federal Agency Obligations Pertaining to Cannabis Controls*

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

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

*Response 1:* DEA agrees that HHS and other Federal agencies can offer valuable insights into how the Federal government can best oversee the provision of marijuana for legitimate scientific research. DEA is committed to collaborating with HHS and other Federal agencies to ensure marijuana is available to meet the research and scientific needs of the United States, and that this rule is implemented with minimal disruption of the National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP). That said, as a matter of current law, any registration and coordination of legitimate marijuana growing in the United States will be overseen solely by DEA, not

other Federal agencies. In other words, even if DEA preferred other Federal agencies to carry out these functions, as DOJ has interpreted the CSA, including a provision requiring that registrations be consistent with U.S. obligations under the Single Convention, it would be unlawful for DEA to transfer these functions to another Federal agency. Commenters' suggestions that the law should be changed are beyond the scope of this rulemaking: This rulemaking must follow the law, as enacted by Congress.<sup>9</sup>

As discussed above and in the NPRM, under the CSA, DEA may only grant a person a registration to grow marihuana if: (1) The registration is consistent with the public interest, and (2) the registration is consistent with U.S. obligations under the Single Convention. *See* 21 U.S.C. 823(a). Accordingly, DEA may only grant marihuana grower registrations which are consistent with U.S. obligations under the Single Convention. Article 23(2) of the Single Convention, which is applicable to the cultivation of marihuana through Article 28, describes five functions related to the distribution, supervision, and licensing of marihuana cultivation<sup>10</sup> that the United States is obligated to fulfill as part of a regulatory scheme that authorizes the growing of marihuana.

The Single Convention requires that these five functions "be discharged by a single government agency if the constitution of the Party concerned permits it." Single Convention art. 23(3).<sup>11</sup> Nothing in the U.S. Constitution

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

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

<sup>11</sup> The Commentary to the Single Convention notes that this is in order to facilitate national planning and coordinated management of the various tasks imposed upon a country by Article 23, and that in countries where more than one agency is needed to perform these tasks on constitutional

precludes the United States from discharging all five of those controls through one government agency, so a single U.S. Federal agency must perform all five of the controls. Further, by requiring that the functions be discharged by a government agency, the Single Convention prohibits the United States from assigning them to a private government contractor.

Through the CSA, Congress assigned the first three of the Single Convention functions to DEA by authorizing DEA—and, at least at the Federal level, DEA alone—to register and regulate marihuana growers: Under the CSA, DEA effectively designates the area in which the marihuana cultivation is permitted, limits marihuana growers to those it licenses, and specifies the extent of the land on which marihuana cultivation is permitted as required by the Single Convention. Thus, to fully comply with the CSA provision requiring consistency with the Single Convention, DEA also must perform the remaining two functions of Article 23: Taking possession of marihuana crops after harvest and maintaining the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marihuana and its resin. Congress granted DEA the power to enforce these provisions by directing DEA to grant registrations if the registrations are consistent with U.S. obligations under the Single Convention. 21 U.S.C. 823(a).<sup>12</sup>

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

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

*Response 2:* Marihuana research can be enhanced by allowing other growers to supply marihuana to researchers. However, scientific and medical research is likely to benefit from the NIDA DSP's continued involvement in these efforts. As discussed in the NPRM and further discussed below, the NIDA DSP has long played a fundamental role in supplying marihuana to researchers.

grounds, administrative arrangements should be made to ensure the required coordination.

<sup>12</sup> These issues are discussed further in the OLC Opinion.

In doing so, the NIDA DSP has acquired valuable experience and expertise in the production of marihuana. Moreover, because researchers currently obtain their marihuana through the NIDA DSP, the continued operation of the NIDA DSP will allow researchers who wish to continue to receive such NIDA DSP marihuana to do so with minimal disruption. Ultimately, the purpose of this rule is to expand researchers' options for obtaining marihuana, not eliminate them, a result best achieved by allowing the NIDA DSP to continue to operate, while also registering additional marihuana growers.

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

*Response 3:* As a matter of law, the CSA requires that registrations to manufacture schedule I and II controlled substances be consistent with U.S. obligations under the Single Convention, which requires a single government agency to regulate the cultivation of and certain trading in marihuana, including taking possession of marihuana after harvest.<sup>13</sup> The CSA assigns this function to the Attorney General, who has delegated this statutory authority to the DEA Administrator. The CSA therefore requires DEA to grant registrations that are consistent with U.S. obligations under the Single Convention, which includes regulating the cultivation of and certain trading in marihuana. DEA acknowledges some may disagree with these legal conclusions, but DEA is bound by the law as DOJ and DEA understand it. Whether the Single Convention's or the CSA's controls of marihuana should be amended and whether the United States should withdraw from the Single Convention

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

are beyond the scope of this rulemaking and DEA's authority. This rulemaking must be consistent with DEA's obligations under the CSA, including granting registrations which are consistent with the Single Convention as it currently stands.

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

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

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

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

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

*Response 6:* The NPRM satisfied the requirements of the APA, as does this final rule. The NRPM and this rule both set out the legal and practical reasons why DEA is promulgating this rule to increase the availability of marihuana for research consistent with the legal requirements of the CSA, as well as with

DEA's duty to protect the public interest by preventing its diversion and abuse.

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

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

#### *The Meaning of "Medicinal Cannabis"*

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

*Response 1:* Under this rule, DEA will have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations.<sup>14</sup> The term "medicinal cannabis" in this rule is limited to "a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act," and DEA continues to believe this is the most appropriate definition for the term.

Through this rule, DEA is asserting an exclusive right of importing, exporting, wholesale trading and maintaining stocks of marihuana so as to ensure compliance with the CSA, including a provision requiring registrations to be consistent with the Single Convention. The exclusion of medicinal cannabis from this function is based on Single Convention Article 23's exclusion of medicinal opium from parties' obligation to maintain an exclusive right over opium trading (as applied to cannabis through Article 28). The Single

Convention does not define medicinal cannabis, but its definition of "medicinal opium" is limited to opium that "has undergone the processes necessary to adapt it for medicinal use." Single Convention art. 1(o).

Thus, DEA understands "medicinal cannabis" to mean drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured in this rule by requiring that the product be able to be legally marketed under the Food Drug and Cosmetic (FD&C Act). The United States, not State governments, is the relevant party to the Single Convention, and thus "medicinal cannabis" should only include cannabis-derived products that the United States has approved for medical use, not products States may have approved.

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

#### *Security Costs and Requirements Applicable to the Manufacture of Marihuana*

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

*Response 1:* DEA registrants are required to maintain effective controls against diversion. DEA registered manufacturers are responsible for providing proper security during the growing process. The crops must either be delivered and stored in a secure storage mechanism at the manufacturer's registered location, if one is designated by DEA, or delivered

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



to a location designated by DEA. In either case, the registrant must comply with security requirements specified in 21 CFR part 1301. A DEA registrant is also required to adhere to the recordkeeping and reporting requirements set forth in 21 U.S.C. 827 and 21 CFR part 1304, including the requirement to maintain records of all controlled substances which it manufactures, sells, and delivers. Although this regulation does not specify any special measures imposed on a grower for the packaging of a marihuana crop for purchase by DEA, DEA may develop packaging requirements as part of separate agreements between DEA and individual manufacturers;<sup>15</sup> but in all cases, DEA's general security regulations shall apply.

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

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

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

to fulfill its duties under the CSA to reduce the diversion and abuse of controlled substances, including marihuana.

#### *Harvest*

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

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

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

#### *Quotas*

*Issue 1:* A commenter stated there is a significant lag time from when quota is issued to harvest time. This same commenter inquired as to whether the cultivation of marihuana can begin prior to the issuance of quota. Another commenter suggested that DEA provide

a deadline by which DEA must review or approve bona fide supply agreements and make quota determinations based upon them. A commenter also suggested that each manufacturer should be issued IMQ. One commenter suggested that DEA issue a multi-year license for new bulk manufacturers to meet quota needs.

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

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

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

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

<sup>15</sup> DEA routinely enters into memoranda of agreement with certain registrants.

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

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

#### *Costs, Pricing, and Fees of Marihuana for DEA Registrants*

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

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

administrative fee that grower must pay to DEA.

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

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

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

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

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

*Response 4:* As explained in the NPRM, the purpose of the administrative fee is to allow DEA to recover the operational costs of administering the program, as required

under 21 U.S.C. 886a(1)(C). Because DEA anticipates the vast majority of marihuana will be sold to researchers, a waiver of the administrative fee in transactions involving researchers would not allow DEA to properly recover its costs of administering the marihuana growers program under 21 U.S.C. 886a(1)(C).

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

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

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

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

*Issue 6:* One commenter suggested that DEA waive the administrative fee

for any crops that are damaged or lost while in DEA's possession.

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

#### *Out of Scope*

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

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

#### **Section-by-Section Summary of the Final Rule**

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

#### *§ 1301.33: Applying the Marijuana Grower Regulations to All Marijuana Growers*

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

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

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

This change serves two purposes. First, by cross-referencing part 1318 in part 1301, this change ensures that marijuana grower applicants reviewing the general registration and application requirements in part 1301 are made aware of the regulations specific to marijuana growers in part 1318. Second, the Single Convention does not distinguish marijuana grown by a researcher or chemical analyst from that grown by other manufacturers; under the Single Convention, a government agency is required to purchase and take

possession of that marijuana and then oversee its distribution. Thus, both to ensure that DEA complies with the CSA, including a provision requiring consistency with obligations under international treaties such as the Single Convention, and to ensure that these applications are treated as equitably as possible, DEA is amending its regulations to ensure that all marijuana growers are subject to the requirements of both § 1301.33 and part 1318.

#### *§ 1318.01: The Scope of the New Marijuana Grower Regulations*

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

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

Section 1318.01 emphasizes that part 1318 does not apply to all marijuana manufactures, but only to those involved in the planting, growing, cultivating, or harvesting of marijuana.<sup>16</sup> Part 1318 limits itself to marijuana growers, rather than all manufacturers, given the unique obligations the Single Convention places on the United States with regard to the growing of marijuana and the unique diversion risks growing presents.

#### *§ 1318.02: Definitions*

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

<sup>16</sup> The rule refers to those “seeking to plant, grow, cultivate, or harvest marijuana” rather than just to “grow” or “cultivate,” to ensure that all activities related to growth and cultivation are included.

§ 1318.02 specifically defines those terms for the purposes of part 1318.

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

Several provisions of § 1318.02, however, warrant further discussion. First, as discussed in the NPRM and above, the Single Convention exempts “medicinal cannabis” and “cannabis preparations” from certain of its requirements. Following suit, part 1318 likewise exempts these substances from certain of its provisions, and, to facilitate this exemption, § 1318.02 defines “medicinal cannabis” and “cannabis preparations.” Under § 1318.02, “medicinal cannabis” means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the FD&C Act. “Cannabis preparation” means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis or cannabis resin. These definitions track those of the Single Convention, as adapted to account for Federal law.<sup>17</sup>

Finally, § 1301.02(e) clarifies that, when used in part 1318, none of these cannabis-related terms—cannabis, cannabis preparation, cannabis resin, or medicinal cannabis—include substances that fall outside the CSA’s definition of marihuana. Among other things, § 1301.02(e) is intended to reflect the CSA amendments made by the Agriculture Improvement Act of 2018 (AIA), Public Law 115–334. The AIA amended the definition of marihuana to exclude “hemp,” defined as the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of

isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. 1639o(1). Thus, under the AIA, anything that meets this definition of hemp is no longer a controlled substance, and the CSA’s requirements no longer apply to it. This rule is designed to regulate marihuana growers, not hemp growers; and thus § 1301.02(e) ensures that part 1318 does not apply to the cultivation of substances do not meet the definition of marihuana under the CSA, such as hemp.

#### *§ 1318.03: Implementation of the CSA’s Requirements*

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

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

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

an undue burden on growers. These provisions—and how they apply to particular scenarios—are discussed in greater depth both above and in the NPRM.

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

#### *§ 1318.05: Applying the CSA’s Public Interest Factors to Marihuana Grower Applicants*

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

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

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

research with marijuana under 21 CFR 1301.32.

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

Section 1318.05(c) provides that, aside from any applications governed by 21 U.S.C. 823(i), applications DEA accepts for filing after the date this rule becomes effective will not be considered pending until all applications accepted for filing on or before this effective date have been granted or denied by the Administrator. This is because, as explained above, the CSA requires DEA to consider the need to maintain effective controls against diversion by limiting the total number of registered marijuana growers to that necessary to produce an adequate and uninterrupted supply of marijuana under adequately competitive conditions. Thus, DEA must consider all pending applicants together when deciding which applications to grant. Given this requirement, DEA is including this provision to avoid a situation in which the agency is in the midst of evaluating these applications and has to begin its evaluation anew each time it accepts a new marijuana grower application for filing.

#### *§ 1318.06: Factors Affecting Marijuana Prices*

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

work, as well as how DEA will fund its expenses from carrying out these duties.

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

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

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

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

#### *§ 1318.07: DEA's Disclaimer of Liability*

As explained above, DEA generally does not anticipate retaining possession of marijuana crops for significant periods of time: In most instances, they should be transferred quickly from the

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

#### **Regulatory Analyses**

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

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

recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

### I. Need for the Rule

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

### II. Alternative Approaches

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

### III. Analysis of Benefits and Costs

There are two key benefits associated with this rule. First, DEA believes it is possible that the approval of new growers may increase the variety (quality, potency, etc.) of bulk marihuana for research, leading to more effective research and potentially resulting in the development of FDA-

approved drug products. Second, this rule ensures that DEA's regulations comply with the requirements of the CSA by granting registrations that are consistent with the Single Convention relating to marihuana. DEA is unable to quantify these benefits at this time.

DEA analyzed the costs of this rule and estimates an annual cost of \$651,318.<sup>18</sup> The details of the analysis are below.

This rule amends the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow marihuana as bulk manufacturers and adds provisions related to the purchase and sale of this marihuana by DEA. Upon promulgation of this rule, the following key changes are anticipated: More persons will be authorized to grow marihuana, DEA will purchase and take title to the crops of marihuana, and DEA will, with respect to marihuana, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks. These changes mean that authorized purchasers of bulk marihuana to be used for research, product development, and other purposes permitted by the CSA may only purchase from DEA, except that DEA's exclusive rights do not extend to medicinal cannabis or cannabis preparations. The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies,<sup>19</sup> and purchasers (generally medical and scientific researchers). To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the three affected groups.

#### Current System

To date, DEA has authorized one grower, the National Center for Natural Products Research (National Center), to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana from seeds supplied initially by NIDA for use in research studies.<sup>20</sup> 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,

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

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

<sup>20</sup> 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>.

and made available as bulk marihuana or other purified elements of marihuana to use for research.<sup>21</sup> NIDA obligated approximately \$1.5 million in Fiscal Year 2015 under this contract.<sup>22</sup> 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,<sup>23</sup> DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately \$2.9 million.<sup>24</sup> 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.<sup>25</sup>

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,"<sup>26</sup> the current policy is to provide the marihuana at no charge.<sup>27</sup>

#### Changes to Growers

Upon promulgation of this rule, DEA anticipates approving more than one

<sup>21</sup> 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>.

<sup>22</sup> 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>.

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

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

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

<sup>26</sup> 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>.

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

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

In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marihuana to supply research.<sup>28</sup> Since the publication of the 2016 policy statement, DEA has received approximately 38 pending applications for registration as bulk manufacturer of marihuana for research. As indicated above, the CSA requires DEA to limit the total number of registered bulk manufacturers of a given schedule I or II controlled substance to that necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. Therefore, DEA believes a range of three to 15 growers is a reasonable estimate for purposes of this economic analysis, with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marihuana that is necessary for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.<sup>29</sup> 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.<sup>30</sup>

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

#### Changes to Authorizing Agencies—Cost to DEA

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

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

analysis, the estimated transfer and working capital requirement is assumed to be \$2.9 million.

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

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

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

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

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

For each collection, DEA estimates \$2,071 of labor cost<sup>31</sup> and \$116 of vehicle cost<sup>32</sup> for a total of \$2,187 per

<sup>31</sup> 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.

<sup>32</sup> \$116 is based on Internal Revenue Service standard mileage rates for 2019 of \$0.58 per mile

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

<sup>29</sup> 21 CFR 1303.11(a).

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

collection. DEA understands that some growers, employing certain growing methods, may have more harvests per year. However, DEA does not have a basis to estimate these growers' methods or the number of harvests per year. Therefore, DEA believes three harvests per year is a reasonable estimate. Assuming three collections per year per grower, there would be nine collections with three approved growers and 45 collections with 15 approved growers. Applying the estimated cost of \$2,187

per collection, DEA estimates a transport cost of \$19,683 and \$98,415 for scenarios with three and 15 growers, respectively. Additionally, DEA anticipates it will need additional personnel resources to operate this program. There are many unknowns and no decisions have been made on hiring. However, for the purposes of this analysis, DEA estimates three full-time-equivalent (FTE) professional staff in the Diversion Control Division will be needed,

consisting of two FTE diversion investigator (DI), and one FTE professional/administrative (PA) resources.

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

TABLE 1—COST OF PERSONNEL RESOURCES

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

In summary the estimated cost to DEA is:

- \$19,683 or \$98,415 per year to purchase and take title to the bulk

marihuana for scenarios with 3 or 15 authorized growers, respectively;
 

- \$592,269 per year for three DEA FTE employees;
- The estimated total annual cost is \$611,952 with three growers and

\$690,684 with 15 growers and no offsetting cost savings at NIDA. Using the average of the two values, the estimated cost to DEA is \$651,318. Table 2 summarizes the costs.

TABLE 2—DEA COST SUMMARY

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

Changes Affecting Researchers

DEA anticipates minimal procedural change for authorized researchers who plan to acquire bulk marihuana for research. The only anticipated procedural change is that some researchers will acquire the bulk marihuana from DEA, rather than from NIDA. As discussed earlier, the only new cost associated with this regulation is the cost to DEA of \$651,318, an average of high and low scenarios, which will be recovered by adding an administrative fee of \$326 per kg. The administrative fee was updated from \$304 per kg in the NPRM to \$326 per kg in this final rule because there is a change in the personnel required to administer the program.<sup>33</sup> As discussed

earlier, the administrative fee will be adjusted annually.

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

Cost Summary

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

DEA's purchase of bulk marihuana is not a new cost (to the economy); it is a transfer from NIDA to DEA. However, \$611,952 to \$690,684 in operating costs will be incurred by DEA. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marihuana by selling the marihuana to the buyer at the negotiated

multiplied by the estimated 200 miles driven, roundtrip.

<sup>33</sup>In the NPRM, DEA estimated personnel requirements to administer the program was one

DEA Diversion Investigator and two Professional/Administrative personnel. After further review, DEA has estimated in this final rule that two DEA Diversion Investigators and one Professional/Administrative personnel are needed to administer

the program. The two Diversion Investigators are needed to provide adequate oversight of reporting and recordkeeping requirements associated with distribution.



sale price, between the grower and the buyer, plus the administrative fee assessed on a per kg basis.

The net present values (NPV) of the low cost estimate of \$611,952 per year over 10 years are \$5.2 million and \$4.3 million at a three percent discount rate and seven percent discount rate,

respectively. The NPVs of the high cost estimate of \$690,684 over 10 years are \$5.9 million and \$4.9 million at a three percent discount rate and seven percent discount rate, respectively. The average of the estimated low and high costs is \$651,318. The NPVs of the average of

\$651,318 over 10 years are \$5.6 million and \$4.6 million at three percent and seven percent discount rates, respectively. Table 3 summarizes the estimated annual effect and NPVs calculation for each of the transfers and the three scenarios.

TABLE 3—SUMMARY OF ANNUAL EFFECT AND NPVS

	Annual effect (\$)	NPVs at 3% (\$M)	NPVs at 7% (\$M)
Cost (Low) .....	611,952	5.2	4.3
Cost (Average) .....	651,318	5.6	4.6
Cost (High) .....	690,684	5.9	4.9

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

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

*Executive Order 12988 (Civil Justice Reform)*

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

*Executive Order 13132 (Federalism)*

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

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

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

*Regulatory Flexibility Act*

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will

not, if promulgated, have a significant economic impact on a substantial number of these small entities.

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

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

The changes described above affect three primary groups of entities: Growers and prospective growers, the authorizing agencies (including NIDA and DEA), and purchasers (generally researchers). Because any economic impact on Federal agencies is outside the scope of the RFA, the transfer of economic activity between the agencies

is excluded from this discussion. To examine the impact of the rule, DEA first reviewed the current system for growing and distributing bulk marihuana, then examined the impact on each of the two affected non-Federal groups: Growers (bulk manufacturers of marihuana) and researchers.

Current System

To date, DEA has authorized one grower, the National Center, to cultivate marihuana for research. NIDA contracts with the National Center to grow marihuana for use in research studies.<sup>34</sup> 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.<sup>35</sup> As explained previously, DEA estimates NIDA's expenses under the contract with the National Center (and any related subcontracts) for the bulk marihuana for 2019 were approximately \$2.9 million.<sup>36</sup> 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.<sup>37</sup>

<sup>34</sup> 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>.

<sup>35</sup> 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>.

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

<sup>37</sup> 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.

Researchers may obtain marijuana for use in research through NIDA's DSP. Bulk marijuana plant material produced under the NIDA DSP is available at no cost to research investigators who are supported by an NIH grant. Marijuana is also available to research investigators who are funded through non-Federal sources. Although NIDA considered charging for marijuana on a "cost-reimbursement basis,"<sup>38</sup> the current policy is to provide the marijuana at no charge.<sup>39</sup>

#### Impact on Growers

Upon promulgation of this rule, DEA anticipates approving more than one person to cultivate and harvest bulk marijuana. In 2016, DEA issued a policy statement regarding applications to become registered to manufacture marijuana to supply research.<sup>40</sup> Since the publication of the 2016 policy statement, there are approximately 38 pending applications for registration as bulk manufacturer of marijuana for research. Additionally, some applicants may not meet the statutory and regulatory criteria for holding a registration as a bulk manufacturer and will be denied. Therefore, for the purposes of this analysis, DEA will estimate the economic impact of this rule at three and 15 growers with the understanding that the actual number could vary considerably.

The APQ, which includes the MQ, represents the annual quantity of marijuana 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.<sup>41</sup> Therefore, given a constant MQ, if more growers are approved to produce bulk marijuana, the quantities of bulk marijuana produced and the cost of production (and reimbursement of their production cost through sales) is

<sup>38</sup> 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>.

<sup>39</sup> See note 23.

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

<sup>41</sup> 21 U.S.C. 826(a).

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.<sup>42</sup>

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

#### Affected Number of Small Entities

This rule affects the current and prospective bulk manufacturers of marijuana for research and researchers. Based on the discussion above, DEA anticipates up to 15 bulk manufacturers are affected by this rule. Additionally, based on a discussion with NIDA,<sup>43</sup> DEA estimates 40 researchers are affected by this rule. The 40 researchers represent the approximate number of

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

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

researchers that receive marijuana from NIDA's marijuana 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:<sup>44</sup>

- 421 firms related to 'Medicinal and Botanical Manufacturing' (325411)<sup>45</sup>
- 9,634 firms related to 'Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)' (541712)<sup>46</sup>

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.<sup>47</sup>

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

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

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

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

<sup>45</sup> 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>.

<sup>46</sup> *Ibid.*

<sup>47</sup> 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.

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 rule. The 14 affected small entity bulk manufacturers represent four percent of the estimated 392 small entities in the ‘Medicinal and Botanical Manufacturing’ (325412) industry, and the 38 affected small entity researchers represent 0.4 percent of the estimated

9,090 small entities in the ‘Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)’ (541712) industry. Table 5 summarizes the calculations for the percentage of small entities that are affected by the rule.

TABLE 5—PERCENT OF SMALL ENTITIES AFFECTED BY INDUSTRY

NAICS description	Number of firms	SBA size standard	Estimated 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 rule.

DEA generally considers impacts that are greater than three percent of annual revenue to be a “significant economic impact” on an entity. As discussed earlier, DEA estimates that there will be a new cost to DEA of \$611,952 to \$690,684 per year, or the average of the high and low estimates of \$651,318 per year. DEA will recover the costs of carrying out the new aspects of the diversion control program relating to marijuana by selling the marijuana to the buyer at the negotiated sale price,

between the grower and the buyer, plus the administrative fee assessed on a per kg basis. Based on the average of the high and low estimates of \$651,318 and MQ of 2,000 kgs, the administrative fee is \$326 per kg, adjusted annually.

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

researchers is not a substantial number of small entities in their respective industries.

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

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, DEA has determined that this action will not result “in 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. 3501–3521, DEA is revising existing information collection 1117–0012. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <https://www.reginfo.gov/>.

#### A. Collections of Information Associated With the Rule

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

*OMB control number:* 1117–0012.

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

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

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

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

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

This rule amends the regulations governing applications by persons seeking to become registered with DEA to grow marijuana as bulk manufacturers and adds provisions related to the purchase and sale of this marijuana by DEA. Persons seeking to become registered with DEA to grow marijuana as bulk manufacturers will still apply for registration using the same DEA Form 225 as other bulk manufacturers, but there will be a new supplemental questionnaire unique to marijuana manufacturers in order to gather additional information about applicants. There will also be new questionnaires used for importer

applicants and non-marijuana bulk manufacturer applicants. Forms 225, 225A, and 225B will all receive minor revisions to improve clarity and usability for registrants.

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

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

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

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

#### *Congressional Review Act*

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

#### *National Environmental Policy Act*

DEA has analyzed the impacts of this Final Rule on the human environment pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, and has determined that it is categorically excluded under 28 CFR part 61, Appendix B. Categorical exclusions are actions identified in an agency's NEPA implementing procedures that normally do not have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion,

the agency must also consider whether extraordinary circumstances are present that would warrant preparation of an EA or EIS. This action is covered by the categorical exclusion for registration of persons authorized to handle controlled substances listed in 28 CFR part 61, Appendix B.

#### List of Subjects

##### *21 CFR Part 1301*

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

##### *21 CFR Part 1318*

Administrative practice and procedure, Drug traffic control.

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

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

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

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

- 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 marijuana that involves the planting, cultivating, growing, or harvesting of marijuana 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 MARIJUANA**

Sec.

1318.01 Scope of this part.

1318.02 Definitions.

1318.03 Implementation of statutory requirements.

1318.04 Specific control measures applicable to the bulk manufacture of marijuana.

- 1318.05 Application of the public interest factors.
- 1318.06 Factors affecting prices for the purchase and sale by the Administration of cannabis.
- 1318.07 Non-liability of the Drug Enforcement Administration.

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

(b) The Administration shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. The Administration may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. The Administration shall require prior written notice of each proposed importation, exportation, or distribution

of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with part 1312 of this chapter, as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of the Administration.

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

(d) A registered manufacturer authorized to grow cannabis may distribute small quantities of cannabis to a registered analytical lab for chemical analysis by such analytical lab prior to the Administration purchasing and taking physical possession of the crop. The cannabis delivered to the analytical lab under such circumstances need not be delivered to the Administration pursuant to paragraph (a), provided such cannabis is destroyed by the analytical lab upon completion of the testing. Any such distribution of cannabis by a registered manufacturer to a registered analytical lab must comply with all applicable requirements of the Act and this subchapter, including but not limited to security and recordkeeping requirements.

**§ 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 marijuana 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 marijuana research protocol by a registered schedule I researcher seeking to grow cannabis for its own research or product

development as evidence of the necessity of the applicant's registration under this factor.

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

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

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

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

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

(1) Bulk growers of cannabis shall negotiate directly with registered researchers and manufacturers authorized to handle cannabis to determine a sale price for their cannabis. Upon entering into a contract for the provision of bulk cannabis and prior to the exchange of cannabis, the parties shall pay to the Administration an administrative fee assessed based on

the number of kgs to be supplied. The administrative fee shall not be recoverable in the event that delivery is rejected by the buyer.

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

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

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

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

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

**§ 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.

**Timothy J. Shea,**  
*Acting Administrator.*

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

**BILLING CODE 4410-09-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9925]

RIN 1545-BP23

#### Meals and Entertainment Expenses Under Section 274; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations; correction.

**SUMMARY:** This document contains corrections to the final regulations (Treasury Decision 9925) that published in the **Federal Register** on October 9, 2020. The final regulations provide guidance under section 274 of the Internal Revenue Code (Code) regarding certain recent amendments made to that section. Specifically, the final regulations address the elimination of the deduction under section 274 for expenditures related to entertainment, amusement, or recreation activities, and provide guidance to determine whether an activity is of a type generally considered to be entertainment.

**DATES:** These corrections are effective on December 18, 2020 and applicable for taxable years that begin on or after October 9, 2020.

**FOR FURTHER INFORMATION CONTACT:** Patrick Clinton of the Office of the Associate Chief Counsel (Income Tax and Accounting), (202) 317-7005 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background

The final regulations (TD 9925) that are the subject of this correction are issued under section 274 of the Internal Revenue Code.

##### Need for Correction

As published the final regulations (TD 9925) contain errors that need to be corrected.

##### Correction of Publication

Accordingly, the final regulations (TD 9925), that are the subject of FR Doc.

2020-21990, published on October 9, 2020 (85 FR 64026), are corrected as follows:

1. On page 64031, third column, the second line, the language “*in Sutherland Lumber*” is corrected to read “*in Sutherland Lumber-Southwest*”.

2. On page 64031, third column, the ninth line of the second full paragraph, the language “§ 1.274-10(a)(2)(ii)(C)(2)” is corrected to read “§ 1.274-10(a)(2)(ii)(C)(2)”.

3. On page 64032, second column, the second line, the language “or gross income is zero, whether zero is” is corrected to read “or gross income is zero (other than due to a reimbursement by the recipient), whether zero is”.

4. On page 64032, second column, the thirteenth line from the top of the page, the language “(e)(9) do not apply.” is corrected to read “(e)(9) generally do not apply.”.

5. On page 64032, second column, the thirteenth line from the top of the page, the language “Similarly, the exceptions in section 274(e)(2) and (e)(9) do not apply if” is corrected to read “However, the exceptions in section 274(e)(2) and (e)(9) will apply if the recipient reimburses the taxpayer for a portion of the value of the food or beverages even if the value exceeding the reimbursed amount is properly excluded from the recipient's compensation and wages or gross income. In this case, however, the taxpayer must apply the dollar-for-dollar rule as described in § 1.274-12(c)(2)(i)(D). In cases in which”.

6. On page 64032, second column, the second and last sentence from the bottom of the first partial paragraph, remove the language “. In that case, however,”.

7. On page 64032, third column, the third line of the second full paragraph, the language “regulations confirm” is corrected to read “regulations confirmed”.

8. On page 64032, third column, the twelfth line of the second full paragraph, the language “demonstrates” is corrected to read “demonstrated”.

#### Crystal Pemberton,

*Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. 2020-26860 Filed 12-17-20; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2020-0694]

#### Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Madeira Beach FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations; request for comments.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Welch Causeway (SR 699) Bridge, mile 122.8 at Madeira Beach, Florida. A request was made to place the drawbridge on a daily operating schedule to alleviate vehicle congestion due to on demand bridge openings. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding these proposed changes.

**DATES:** This deviation is effective from 12:01 a.m. on January 1, 2021 through 11:59 p.m. on June 25, 2021.

Comments and relate material must reach the Coast Guard on or before February 25, 2021.

**ADDRESSES:** You may submit comments identified by docket number USCG-2020-0694 using Federal eRulemaking Portal at <https://www.regulations.gov>.

See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this test deviation, call or email LT Clark W. Sanford, U.S. Coast Guard, Sector Saint Petersburg Waterways Management Division; telephone 727-824-7506, email [Clark.W.Sanford@uscg.mil](mailto:Clark.W.Sanford@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Background, Purpose and Legal Basis

The Welch Causeway (SR699) Bridge across the Gulf Intracoastal Waterway, mile 122.8, at Madeira Beach, Florida is a double-leaf bascule bridge with a 25 foot vertical clearance at mean high water in the closed position and an 89 foot horizontal clearance between fenders. The normal operating schedule for the bridge is found in 33 CFR 117.287(h). Navigation on the waterway is commercial and recreational.

The City of Madeira Beach Florida has requested the current operating