

air HPT front seal from service before accumulating 4,000 cycles since being reconfigured, or within 50 cycles after the effective date of this AD, whichever occurs later.

(h) Definition

For the purpose of this AD, “reconfigured” occurs when a rotating air HPT front seal has been removed from the original HPT disk and re-assembled to a different HPT disk.

(i) Installation Prohibition

After the effective date of this AD, do not assemble any rotating air HPT front seal with greater than 0 cycles since new onto a HPT disk unless it is the same S/N HPT disk on which it has previously been assembled.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. You may email your request to: ANE-AD-AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7120; fax: 781-238-7199; email: chris.mcguire@faa.gov.

(2) For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877-432-3272; fax: 877-432-3329; email: aviation.fleetsupport@ge.com. You may view this referenced service information at the FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759.

Issued in Burlington, Massachusetts, on October 18, 2019.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1303 and 1315

[Docket No. DEA-455]

RIN 1117-AB49

Management of Quotas for Controlled Substances and List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to revise existing regulations that manage the quotas for controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, held by DEA-registered manufacturers. This rule is being proposed to: Define the types of quotas, update the method to abandon quota, clarify the current language to ensure that both manufacturers and distributors are required to obtain certification of a buyer's quota, reduce overall inventories, formalize the existing practice of use-specific subcategories for individual manufacturing and procurement quotas, and modify existing deadlines to fix/issue quotas. The DEA is also amending certain regulations to implement updates to the Controlled Substances Act made by the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act. The DEA emphasizes that all of these revisions and amendments would apply to both bulk and dosage-form manufacturers, as well as importers of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The changes are necessary to reduce the potential for diversion, and would align regulations with current manufacturing business practices.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before December 23, 2019.

All comments concerning collection of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before December 23, 2019.

ADDRESSES: To ensure proper handling of comments, please reference “RIN-1117-AB49/Docket No. DEA-455” on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted

electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you, however, wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted 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-AB49/Docket No. DEA-455.

FOR FURTHER INFORMATION CONTACT:

Scott A. Brinks, Regulatory Drafting & Policy Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by DEA for public inspection online at <http://www.regulations.gov> and in DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place

all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

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

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

I. Executive Summary

A. Summary of the Purposes and Provisions of Rule

1. Types of Quota

Through this Notice of Proposed Rulemaking (NPRM), the DEA is proposing to add new sections to the regulations that would introduce and define the types of quotas for controlled substances in schedules I and II and the list I chemicals¹ ephedrine, pseudoephedrine, and phenylpropanolamine. The types of quotas are as follows:

- Aggregate production quota (APQ) (for controlled substances);
- Assessment of Annual Needs (AAN) (for listed chemicals);
- Individual Manufacturing Quota (for controlled substances and listed chemicals);
- Procurement Quota (for controlled substances and listed chemicals); and
- Import Quota (for listed chemicals).

Also, the DEA is proposing a change in the regulations to stay up to date with modern technology. The proposed

¹ For the purposes of this document only, “list I chemicals” refers to ephedrine, pseudoephedrine, and phenylpropanolamine for legitimate medical, scientific, research, and industrial needs. The phrase “list I chemical(s)” will be used going forward.

change would involve formalizing the current practice of filing to abandon quota with the United Nations (UN) Reporting and Quota Section in the online Quota Management System.

2. Conforming Changes From the Substance Use-Disorder Prevention That Promotes Opioid Recovery Treatment for Patients and Communities Act

In accordance with the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act (hereinafter “the SUPPORT Act”),² the DEA is performing an update to the current regulations to comply with the new law. The SUPPORT Act now gives the Administrator, by way of delegation from the Attorney General, the authority to establish APQs, individual manufacturing quotas, and procurement quotas in terms of pharmaceutical dosage-form prepared from or containing a controlled substance. This Act also changed the deadline by which the DEA is to fix the individual manufacturing quota for schedules I and II controlled substances. The SUPPORT Act defines the phrase “covered controlled substance” and mandates that the amount of diversion of a covered controlled substance be estimated when establishing any quota. When estimating diversion, the DEA must consult with the Department of Health and Human Services (HHS) on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substances and may take into consideration other sources of information the DEA deems reliable. The SUPPORT Act requires that “appropriate quota reductions” be made after estimating diversion. The Act does not require quota increases.

3. Procurement Quota Certification

The DEA is proposing to change the regulations to provide that both manufacturers and distributors selling to a manufacturer would be required to obtain certification of the buyer's quota when an order is placed. This change would be implemented by changing the words “importer,” “manufacturer,” and “bulk manufacturer” to “registrant.”

4. Reduction of Inventory Allowances

The DEA proposes to revise the regulations to reduce the allowable individual inventory held by both bulk and dosage-form manufacturers of controlled substances in schedules I and II and list I chemicals, which would decrease the risk of diversion while

ensuring the needs of the United States are met. The proposed amendments are:

- Decrease the inventory allowance issued by the DEA for individual manufacturing quotas to 30 percent;
- Decrease the inventory allowance issued by the DEA for procurement quotas to 30 percent;
- Suspend quota issued by the DEA if a registrant's inventory exceeds 45 percent of the registrant's estimated net disposal; and
- Grant request of additional quota by registrant if inventory is less than 20 percent of the registrant's estimated net disposal.

5. Subcategories for Quotas

The DEA is proposing the addition of use-specific subcategories for individual manufacturing and procurement quotas to formalize the current, on-going practice of the use of these subcategories by registrants. The use-specific subcategories are:

- Quota for Commercial Sales;
- Quota for Transfer;
- Quota for Product Development;
- Quota for Replacement; and
- Quota for Packaging/Repackaging and Labeling/Relabeling.

6. New Deadlines To Establish Quotas

With this NPRM, the DEA proposes to change the deadlines for fixing or establishing the different types of quotas to allow more time for processing and communicating with applicants and to make the regulations consistent with the SUPPORT Act. The proposed changes are as follows:

- Deadline to establish the APQ and the AAN: Change to September 1.
- Deadline to issue procurement quota, import quota, and individual manufacturing quota: Change to December 1.
- Deadline to adjust individual manufacturing quota: Change to July 1.

B. Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of the DEA (by delegation from the Attorney General) to promulgate rules and regulations that he deems necessary and appropriate for the efficient execution of his functions under subchapter I (Control and Enforcement) and subchapter II (Import and Export) of the Act, 21 U.S.C. 871(b) and 958(f). Subchapter I includes provisions which require the Administrator to establish the APQ for each basic class of controlled substance listed in schedules I and II and the AAN for the list I chemicals to be manufactured in the United States each calendar year to provide for the estimated medical,

² The SUPPORT for Patients and Communities Act, Public Law 115-271.

scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. 21 U.S.C. 826. The Administrator shall take the following quota actions for a basic class of controlled substance or list I chemical pursuant to stipulated conditions: Limit or reduce individual production quotas for each registered manufacturer,³ and fix individual manufacturing quotas for registrants.⁴

On October 24, 2018, Congress made revisions to the CSA through the SUPPORT Act. These revisions will be noted and included in these proposed regulations, where applicable. Through this Act, the Administrator, by way of delegation from the Attorney General, may now set quota in terms of the pharmaceutical dosage-form.

C. Summary of the Benefits and Costs of the Proposed Rule

There are six key provisions in this proposed rule, five of which are anticipated to have benefits and costs. As explained below, some of these provisions are mandated by Congress under recent legislation, and some others are being proposed pursuant to the DEA's general rulemaking authority under the CSA. The anticipated effect of each provision is summarized in this section. The following discussion is only a summary; for a complete analysis of the benefits and costs of each provision, see the Regulatory Analysis section.

1. Defining Types of Quota and Filing To Abandon Quota

These provisions of the proposed rule will codify two existing DEA practices. It will formally define the different types of quota issued by the DEA for schedules I and II controlled substances and list I chemicals. It will also formalize the current reporting practice for a registrant to abandon quota in the DEA's online Quota Management System. The formal definition of quota types will have no practical impact on registrants, and formalizing the procedure to abandon quota is simply a codification of existing DEA practice. While these proposed provisions will have no economic costs or benefits, the DEA believes there are benefits to accurately codifying existing practices. These proposed provisions are expected to enhance clarity, certainty, and efficiency.

³ 21 U.S.C. 826(b).

⁴ 21 U.S.C. 826(d).

2. Conforming Revisions Related to the SUPPORT Act

The SUPPORT Act gives the DEA discretionary authority to establish quotas in terms of pharmaceutical dosage-form. The DEA's current practice is to establish quotas necessary for the manufacture of finished dosage-forms in terms of kilograms, and manufacturers then determine how to allocate those kilograms to different Food and Drug Administration (FDA) approved dosage-forms. While the SUPPORT Act gives the DEA the authority to establish quotas in terms of pharmaceutical dosage-form, the DEA will continue to use its current process of establishing quota in terms of kilograms, for the time being. While it is impossible to know all the circumstances in which this authority would be used, it is the DEA's current intention that any implementation of dosage-form quotas will be rare occurrences in response to specific events, and will coexist alongside kilogram quotas. The DEA recognizes that dosage-form manufacturers are in the best position to understand the demand for their products, in dosage-form. However, if the DEA were to reallocate a manufacturer's quota to prevent diversion or alleviate shortages based on specific dosage-form, or to prevent an overproduction, the DEA would make this adjustment for a manufacturer that is producing those specific FDA-approved dosage-forms, and who therefore is able to shift production with minimal disruption or delay. Therefore, this provision of the proposed rule will have minimal impact.

The SUPPORT Act also requires the DEA to estimate the amount of diversion when establishing quota for a "covered controlled substance" (fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone) using all reliable information, including information from HHS. This requirement will expand upon the DEA's current practice, as it has considered the amount of diversion when establishing quotas for covered controlled substances when data has been made available. Therefore, considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional cost. Also included in these SUPPORT Act updates are extending the DEA's deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December, which will also have minimal impact on registrants or the DEA.

3. Procurement Quota Certification

This provision requires that manufacturers purchasing their active pharmaceutical ingredients (API) from distributors, as well as other manufacturers, first certify in writing that quantities ordered do not exceed the requesting manufacturer's quota for the year. Current regulations stipulate that only entities registered as "importer," "manufacturer," or "bulk manufacturer" must certify quota before a purchase.⁵ This provision is expected to result in more accountability for affected distributors and manufacturers and bring them into compliance with the CSA and regulations as intended.

This new requirement that manufacturers produce and submit certification of quota to be reviewed by the distributor will impose costs on both manufacturers and distributors. The DEA estimates the cost of this provision to be \$35,241 per year (\$23,494 of which is incurred by manufacturers while the remaining \$11,747 is incurred by distributors).

4. Reduction of Inventory Allowances

This provision has one key benefit: It is expected to reduce the potential for the diversion of schedules I and II controlled substances and list I chemicals by lowering the inventory allowance from one year to the next year from 50% to 30%. Practically speaking, this equates to a reduction from half of a year's sales supply allowed to be held as inventory to nearly four months. Since regulations governing inventory allowances were first implemented, the number of firms manufacturing controlled substances and list I chemicals has grown. For example, the DEA records show that the number of registered manufacturers grew by 17.3 percent from 330 to 387 during the period of 2008 to 2018. Because of this expansion of suppliers, the lower inventory allowance authorized per firm is not expected to increase the likelihood of drug shortages. Generally, there are now more manufacturers that can increase production to meet demand if one or more manufacturers were to have production issues.

Regarding costs, the DEA believes a reduction of inventory allowance to 30%, with flexibility to produce up to 45% at any given point in a year, would have minimal impact on registrants while continuing to provide adequate inventory for registrants to respond to fluctuations in demand in pharmaceutical markets. Over a ten year period from 2008 to 2017, as reported to

⁵ 21 CFR 1303.12(f) and 1315.32(h).

the U.N., year-end inventories for manufacturers averaged 39%, well within the 30% to 45% range allowed by this rule. For this reason DEA believes this provision will have a minimal impact on registrants.

See the Regulatory Analysis section for a complete discussion of the impact of this provision.

5. Subcategories for Quotas

The benefit of the formalization of subcategories is in the alignment of regulatory language with current DEA practice, which removes any ambiguity that may be perceived by regulated entities. Because these subcategories are already in use, through voluntary and cooperative efforts between registrants and DEA, the DEA believes this provision will have no economic impact on registrants or the DEA.

6. New Deadlines To Establish Quota

By updating the deadlines for establishing and publishing the APQ, AAN, procurement, import, individual manufacturing, and adjusted individual manufacturing quotas, registrants are expected to benefit from having the regulations accurately reflect realistic deadlines. This will allow registrants to plan their production year appropriately and remove any uncertainty related to these publication dates. The DEA estimates there would be no cost associated with this provision.

II. Background

A. Types of Quota

1. APQ and AAN

Section 306 of the CSA⁶ requires the Attorney General to establish APQ and AAN each year for each basic class of controlled substance listed in schedules I and II and the list I chemicals, respectively.⁷ The APQ and AAN represent the total quantity of each basic class of controlled substance listed in schedules I and II and list I chemicals necessary to be manufactured during the calendar year to provide 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. The APQs are issued as individual manufacturing and procurement quotas to DEA-registered manufacturers. The AANs are issued as individual

manufacturing, procurement and import quotas. The quota system is meant to ensure an adequate and uninterrupted supply of schedules I and II controlled substances and list I chemicals for legitimate medical and scientific needs, while preventing the production of excess quantities, which present an increased risk of diversion.

DEA-registered manufacturers apply for individual manufacturing, import, or procurement quotas based on their manufacturing activities and projected needs. Manufacturing activities authorized under a manufacturer registration include dosage-form manufacturing (both commercial and product development), manufacturing of other substances, as well as packaging, labeling, repackaging, or relabeling efforts. Projected needs may include product development for new suppliers or new process requirements, increased commercial sales, estimated improved market share based on new customers, purchase orders in hand, or the launch of new FDA-approved drug products. Registrants can include any other factor they want DEA to consider when evaluating their applications for quota.

2. Individual Manufacturing Quota

An individual manufacturing quota represents the maximum quantity of a schedule I or II controlled substance or list I chemical a manufacturer is authorized to manufacture in a calendar year.⁸ The sum total of all individual manufacturing quotas issued to bulk manufacturers for a particular basic class of controlled substance in schedule I or II or list I chemical must be equal to or lower than the established APQ for that basic class or AAN for that chemical as determined in accordance with 21 CFR 1303.11 and 1315.11. A bulk manufacturer may request an increase in any of the quotas for a schedule I or II controlled substance or list I chemical at any time during the calendar year for which it applies.⁹ Procurement and import quotas inform the amount of individual manufacturing quotas. Only DEA-registered bulk manufacturers may apply for, and subsequently be issued, individual manufacturing quotas and/or procurement quotas.

Any manufacturer assigned an individual manufacturing quota for a schedule I or II controlled substance or list I chemical may at any time abandon their right to manufacture all or any part of such quota pursuant to 21 CFR 1303.27 and 1315.27. Currently, to

abandon all or part of an individual manufacturing quota for a schedule I or II controlled substance, a manufacturer files a written notice with the Drug & Chemical Evaluation Section. To abandon any part of an individual manufacturing quota for a list I chemical, a manufacturer would file a written notice with the UN Reporting & Quota Section of DEA.

3. Procurement Quota

A DEA-registered manufacturer who procures a schedule I or II controlled substance or list I chemical for the purpose of conducting non-bulk manufacturing activities such as dosage-form manufacturing, product development, packaging, labeling, repackaging or relabeling, or transfer, must apply¹⁰ for and receive a procurement quota. A procurement quota represents the maximum quantity of a schedule I or II controlled substance or list I chemical a registrant is authorized to acquire in a calendar year for the purpose of manufacturing controlled substances into dosage-forms or to acquire to convert into another schedule I or II controlled substance (with corresponding individual manufacturing quota for that new drug code) and also for packaging, repackaging, labeling, and relabeling.¹¹ Finished dosage-form manufacturers and packagers may apply for procurement quota only.

Under the current regulations, when a person with a procurement quota orders a quantity of a basic class of a schedule I or II controlled substance or a list I chemical, they have to certify that the quantity ordered does not exceed their unused and available procurement quota for that current calendar year. This certification is required only if purchasing from a manufacturer. Because of the wording of the regulations, many registrants do not have to certify their purchases. Outsourcing facilities are an example of this. An “outsourcing facility” is defined as a facility at one geographic location or address that is engaged in compounding sterile drugs, either with or without prescriptions for identified individual patients, that elects to register with the FDA and complies with the statutory requirements in section 503B of the Federal Food, Drug, and Cosmetic Act.¹² Because outsourcing facilities compounding controlled substances meet the CSA

⁶ 21 U.S.C. 826.

⁷ The responsibility for the establishment of the APQs and individual manufacturing and procurement quotas for DEA-registered manufacturers of schedules I and II controlled substances and list I chemicals has been delegated to the Administrator of DEA, 28 CFR 0.100.

⁸ 21 CFR 1303.21 and 1315.21.

⁹ 21 CFR 1303.12(d), 1303.25(a), 1315.25(a), 1315.32(g), and 1315.36(b).

¹⁰ 21 CFR 1303.12 and 1315.32(a).

¹¹ 21 CFR 1303.12 and 1315.32.

¹² 21 U.S.C. 353b(d)(4).

definition of “manufacturer,”¹³ the DEA has registered these newly designated facilities as manufacturers. Currently, outsourcing facilities registered with DEA as manufacturers are not required to follow the procurement quota regulations, because they buy their API from distributors rather than another manufacturer. DEA has discussed the issue with manufacturers. Several manufacturers have stated that 21 CFR 1303.12(f) does not apply to them because they are not purchasing material from another manufacturer. This proposed rule would make these changes.

4. Import Quota

DEA-registered importers that import list I chemicals must apply for and receive an import quota. 21 CFR 1315.34(a). An import quota represents the maximum amount of a list I chemical an importer may bring into the United States during the calendar year. Importers of list I chemicals may apply for import quota only.

B. Conforming Changes From the SUPPORT Act

While the Administrator of DEA, as delegated by the Attorney General, has always been required¹⁴ annually to establish APQs and individual manufacturing quotas by the CSA and procurement quotas by DEA’s regulations,¹⁵ there was no authorization given or a requirement to establish APQs, individual manufacturing quotas or procurement quotas in terms of pharmaceutical dosage-forms prior to the SUPPORT Act. Before the signing of the SUPPORT Act, the CSA¹⁶ stated that quotas for controlled substances should only be established in terms of quantities and not in terms of individual pharmaceutical dosage-forms. The DEA had no authority to issue the APQ based on separate forms of drugs. The DEA could not demand that quota be used for a specific dosage-form. Also, prior to the SUPPORT Act, the individual manufacturing quota had to be fixed on or before October 1. Furthermore, the CSA did not expressly require the estimation of diversion for any controlled substance.

C. Reduction of Inventory Allowances

The DEA’s mandate by the CSA is to provide 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, while preventing the diversion of controlled substances and list I chemicals. The current regulations¹⁷ contribute to increased inventories at multiple manufacturing processes/steps which can lead to an increased risk of diversion.

The 2017 National Survey on Drug Use and Health from the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that about 6.6% (18 million) of people ages 12 or older misused prescription psychotherapeutic drugs (pain relievers, tranquilizers, stimulants and sedatives) in the past year and 4.1% (11 million) misused pain relievers (*i.e.*, hydrocodone, oxycodone, and morphine).¹⁸

According to the 2014 National Drug Threat Assessment Summary from the DEA, between 2009 and 2013 there was a 222% increase in the total U.S. drug seizures for oxycodone, hydrocodone and hydromorphone.¹⁹ According to the Healthcare Cost and Utilization Project from the Agency for Healthcare Research and Quality (AHRQ) between the year 2008 and 2015, the rate of opioid-related Emergency Department visits increased by 120.7% (*i.e.*, from 94.6 per 100,000 population in 2008 to 208.8 per 100,000 population in 2015).²⁰ Data from the SAMHSA Treatment Episode Data Set revealed that between 2005 and 2015, there was a 75% increase (from 71,499 to 124,943) in the number of hospital admissions (ages 12 and older) due to or caused by primary non-heroin opiates/ synthetics.²¹

The purpose of the inventory allowance is to provide for efficiency and flexibility in managing the sale and distribution of schedule I and II controlled substances and list I chemicals so that the manufacturer can meet the actual or reasonably estimated demand for the schedule I and II controlled substances and list I chemicals. Under the current inventory

allowance issued with the quota is intended to: 1. Provide saleable material for approximately four months of sales (net disposal) into the next calendar year while the manufacturer begins new production in the next calendar year; 2. Manage an unexpected uptick in sales during the calendar year; and 3. Address incidents limiting manufacturing or supply such as natural disasters or labor strikes. Manufacturers are encouraged to apply for adjustments to their quota at any time during the calendar year with appropriate documented supporting justification.²²

The mission of the DEA is to prevent diversion of controlled substances and list I chemicals while still providing sufficient availability for the legitimate medical, scientific, research, and industrial needs of the United States. The DEA is committed to ensuring the availability of controlled substances in schedules I and II and list I chemicals to manufacturers to meet the legitimate medical, scientific, research, and industrial needs of the United States. However, the DEA must strike an appropriate balance between ensuring the availability of drug products containing controlled substances in schedules I and II and list I chemicals to meet these needs, and the risk to the public health and safety. The DEA has observed an increase in the production of many controlled substances over the years, including those substances requiring quotas. The changes in the industry, including the increase in the number of manufacturers, has led to accumulations of inventory.

When the current regulations were promulgated, there were only one or two bulk-manufacturing suppliers and finished dosage-form manufacturers for each controlled substance. Each manufacturer needed enough material to ensure the safe and continuous coverage of the market place for legitimate patient needs and a significant amount of inventory (50%) to handle potential market fluctuations in case the other manufacturer had an emergency or other disruptive situation. However, the number of generic dosage-form manufacturers entering the marketplace has grown significantly, especially since the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). When the DEA considers each manufacturer’s portion of the market, the amount of inventory each manufacturer needs to hold in reserve to ensure legitimate medical needs are met, due to other manufacturers’ potential production disruptions, is

¹⁷ 21 CFR 1303.24 and 1315.24.

¹⁸ SAMHSA, Center for Behavioral Health Statistics and Quality, 2017 National Survey on Drug Use and Health, available at <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.pdf>.

¹⁹ National Drug Threat Assessment 2014, (p. 45) available at <https://www.dea.gov/resource-center/dir-ndta-unclass.pdf>.

²⁰ Agency for Healthcare Research and Quality (2017), Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2008–2015. <http://www.hcup-us.ahrq.gov/faststats/landing.jsp>.

²¹ Department of Health and Human Services (Feb 2017). Treatment Episode Data Set (TEDS) 2005–2015 State Admissions to Substance Abuse Treatment Services.

¹³ 21 U.S.C. 802(15).

¹⁴ 21 U.S.C. 826.

¹⁵ 21 CFR 1303.12(a).

¹⁶ 21 U.S.C. 826(a).

²² 21 CFR 1303.25.

much smaller than when the CSA was originally written. There are currently so many brand and generic manufacturers for each controlled substance with an FDA-approved drug product, that if one or two manufacturers ceased production, the overall market would not be affected. For instance, in 2007, the DEA registered nine bulk manufacturers who could provide oxycodone to 88 dosage-form (non-bulk) manufacturers. By contrast, as of 2015, the DEA registered 11 bulk manufacturers of oxycodone who could provide bulk oxycodone to 166 dosage-form (non-bulk) manufacturers. As of March 2017, these non-bulk manufacturers were responsible for producing FDA-approved dosage-forms including 10 branded and 30 generic products, each of which has multiple strengths and various immediate and extended release formulations. These manufacturers are all competing for the U.S. market and an increasing export market.

D. Formalization of Subcategories

Administering the quota provisions of the CSA is becoming more complex as registrants increasingly engage in product development efforts and subcontract various aspects of the manufacturing process to other DEA-registered manufacturers, thus moving away from single source production of pharmaceutical drug products. A key objective of the quota system is to track how much of a controlled substance or list I chemical is available so the DEA can fulfill its mandate of ensuring that there is sufficient material to meet the estimated medical, scientific, research, and industrial needs of the United States, for lawful exports, and for the establishment and maintenance of reserve stocks. The large number of manufacturing registrants that move material from one manufacturer to another presents a growing challenge in that multiple quotas have to be issued for the various stages of manufacturing, while at the same time, avoiding “double counting” the legitimate needs as the material moves from registrant to registrant which would artificially increase the APQ.

E. New Deadlines To Establish Quotas

Under current regulations (established nearly 50 years ago), the DEA is unduly burdened by unreasonable deadlines for establishing and granting quotas. Since the establishment of the original deadlines, the number of manufacturers has more than tripled and the number of requests for quota has increased 560 percent, yet the deadlines have remained the same. Because there have

been no accommodations made for the substantial increases in both manufacturers and quota requests, the DEA is required to work within challenging parameters in order to meet the current deadlines. Under current regulations, the DEA is required to publish the APQ and the AAN by May 1.²³ This deadline constitutes an undue burden given the applications for import and procurement quota are due April 1²⁴ and manufacturing quota are due May 1.²⁵ The DEA cannot provide a thorough and careful assessment of the quota needs and the assessment of annual needs for the following year in 30 days or less, particularly given the substantial increase in the number of applications the DEA must consider at the time it proposes the APQ and AAN.

In 2016, the DEA issued 548 initial individual manufacturing quotas, 1,083 initial procurement quotas, 33 import quotas, and adjusted 250 individual manufacturing quotas. Under the current regulations, the DEA is required to issue individual manufacturing, procurement, and import quotas by July 1²⁶ of the calendar year preceding the year in which the quota is to be used. The individual manufacturing quota is to be adjusted by March 1²⁷ of the calendar year in which the quota is to be used. The DEA needs sufficient time to compile and consider all requests for quota in order to ensure that each manufacturer is provided with an adequate amount of quota for their legitimate production requests, in light of legitimate medical, scientific, research, and industrial needs, while also ensuring that quotas are not unwarranted, causing an increase in the risk of diversion. It is imperative that the DEA not be forced to make a choice between staying within the deadlines established in the regulations and providing a thorough and accurate review of each application for quota.

III. Provisions of the Proposed Rule

A. Types of Quota

The DEA proposes adding sections 21 CFR 1303.03 and 1315.06 to introduce and define the types of quotas in the current quota system. The DEA proposes creating 21 CFR 1303.03 to define the three types of quota for schedule I and II controlled substances: APQ, individual manufacturing quotas, and procurement quotas. The DEA would use the creation of 21 CFR

1315.06 to define the four types of quotas available for list I chemicals: AAN, individual manufacturing quotas, procurement quotas and import quotas.

As previously stated, the regulations were written many years ago before DEA had the advanced, modern technology that we know today. As the years have passed, DEA has turned to managing many aspects of the quota system online. To abandon any or all parts of the individual manufacturing quota for schedule I and II controlled substances, the DEA is proposing that 21 CFR 1303.27 be updated to require that the manufacturer must now submit a quota application with the UN Reporting and Quota Section in the online Quota Management System, instead of a written notice submitted to the Drug and Chemical Evaluation Section. For list I chemicals, 21 CFR 1315.27 would be updated to mandate that a manufacturer also file in the online Quota Management System, as the regulations were previously updated²⁸ to change the name of the Section.

B. Conforming Changes From the SUPPORT for Communities and Patients Act

Pursuant to the SUPPORT Act, the Administrator of the DEA (by delegation from the Attorney General) now has the authority to establish APQ, individual manufacturing quotas and procurement quotas in terms of pharmaceutical dosage-forms, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. The SUPPORT Act does not require the DEA to grant quotas in terms of dosage-form, it just grants the authority to do so, if it will be helpful. This authorization will be added to DEA's regulations using 21 CFR 1303.11(a), 1303.12(a) and 1303.21(a). The SUPPORT Act also revised the CSA by changing the dates to fix the individual manufacturing quota from “on or before October 1” to “on or before December 1.” DEA will be revising 21 CFR 1303.21(a) and 1315.21 to keep the dates for fixing individual manufacturing quotas in accordance with the statute.

As a result of the SUPPORT Act, the CSA has also been amended to require the Administrator to estimate the amount of diversion of a “covered controlled substance” in the United States when establishing quotas for that covered controlled substance and make appropriate reductions. Furthermore, when estimating diversion, information deemed reliable by the Administrator, in consultation with the Secretary of

²³ 21 CFR 1303.11(c) and 1315.11(c).

²⁴ 21 CFR 1303.12(b), 1315.32(e), and 1315.22.

²⁵ 21 CFR 1303.22.

²⁶ 21 CFR 1303.21(a), 1315.21, 1303.12(c), 1315.32(f) and 21 CFR 1315.34(f).

²⁷ 21 CFR 1303.23(c) and 1315.23(c).

²⁸ 81 FR 96992, December 30, 2016.

HHS, about rates of overdose deaths and abuse and public health impact must be considered. The Administrator may also consider any other sources of information that he determines to be reliable. Moving forward, any year where the approved APQ for a covered controlled substance is higher than that of the previous year, the Administrator must consult with the Secretary of HHS and explain in the final order “why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.” Congress defines a “covered controlled substance” as fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone.

C. Procurement Quota Certification

Regarding certification of procurement quota, this proposed rule would clarify the current language in 21 CFR 1303.12(f) and 1315.32(h) and ensure that both manufacturers and distributors are required to obtain certification of a buyer’s quota for the requested schedule I and II controlled substances, as well as list I chemicals when the buyer is a manufacturer.

In the 2000s, DEA began to notice a subset of manufacturers reporting purchases and distributions of schedule II controlled substances, even though they were not granted procurement quota. The DEA determined that this subset of manufacturers was conducting packaging/repackaging and labeling/ relabeling activities. These activities constitute manufacturing as the term is defined in the CSA,²⁹ and as such, require quota when the product falls within schedules I or II or is a list I chemical. These manufacturers appear to fill a niche market of providing their customers with drug products in packaged count sizes that regular manufacturers do not market. While DEA is not averse to manufacturers fulfilling legitimate medical needs, DEA is required to ensure that enough quota is granted to meet legitimate medical, scientific, and research needs, while preventing diversion. To prevent diversion, the DEA maintains a closed distribution system for schedule I and II controlled substances and list I chemicals when manufacturers follow the laws and regulations of the CSA and CFR. One method of doing this is to hold manufacturers to the requirement of providing proof of quota through certification, which ensures that purchases and distributions do not

exceed the procurement quota set by DEA.

In order to ensure the system is closed, the DEA manages the quota process by providing each manufacturer a letter stating the quantity of controlled substance(s) and/or list I chemical(s) the manufacturer may obtain during a calendar year. This letter provides legal documentation that the manufacturer is authorized to obtain a specified quantity of the controlled substance(s) and/or list I chemical(s). The CSA and the DEA’s implementing regulations require proof of quota when transferring controlled substances and list I chemicals between manufacturers. When the CSA and DEA’s regulations were first drafted, neither contemplated that distributors would be used to move controlled substances and list I chemicals between manufacturers.

When distributors provided schedule II controlled substances to this subset of manufacturers without verification of the manufacturers’ quota authorization, it circumvented the quota process of verifying quota to the supplier. This prevents the DEA from performing its oversight responsibilities and leads to unauthorized distribution of drug products. These unauthorized distributions are only noted as sales, which artificially inflates the estimation of legitimate medical need, a heavily weighted factor in the setting and revising of the APQ. By requiring that all manufacturers provide a certification of quota before receiving any quantity of controlled substance or list I chemical, DEA is better able to maintain the closed distribution system.

D. Reduction of Inventory Allowances

The DEA proposes to revise 21 CFR 1303.24 and 1315.24 to reduce the overall inventory held by DEA- registered bulk and dosage-form manufacturers. These revisions are necessary, in light of the increasingly complex controlled substances manufacturing business practices, to reduce the potential for the diversion of schedule I and II controlled substances and list I chemicals.

The DEA has noticed inventory fluctuation changes at various stages of the manufacturing process for certain schedule II controlled substances and changes in market conditions. The market conditions have changed from being a vertically integrated manufacturing practice to a horizontal manufacturing structure, which includes an increased number of manufacturers and demand for lower cost generic drug products containing controlled substances. This proposed rule would address the need to reduce

the overall inventory allowance for each individual manufacturer.

The proposed revisions are as follows:

- 21 CFR 1303.24(a)—decreases the inventory allowance issued by DEA for individual manufacturing quotas from 50 to 30 percent for schedules I and II controlled substances;
- 21 CFR 1303.24(b)—establishes an inventory allowance issued by DEA for procurement quotas of 30 percent for schedules I and II controlled substances;
- 21 CFR 1303.24(c)—suspends quota issued by DEA if inventory exceeds 45 percent of the registrant’s estimated net disposal for schedules I and II controlled substances;
- 21 CFR 1303.24(d)—grants request of additional quota by registrant if inventory is less than 20 percent of the registrant’s estimated net disposal for schedules I and II controlled substances;
- 21 CFR 1315.24(a)—decreases the inventory allowance issued by DEA for individual manufacturing quotas from 50 to 30 percent for the list I chemicals;
- 21 CFR 1315.24(b)—decreases the inventory allowance issued by DEA for procurement quotas from 50 to 30 percent for the list I chemicals;
- 21 CFR 1315.24(c)—suspends quota issued by DEA if inventory exceeds 45 percent of the registrant’s estimated net disposal for the list I chemicals; and
- 21 CFR 1315.24(d)—grants request of additional quota by registrant if inventory is less than 20 percent of the registrant’s estimated net disposal for the list I chemicals.

Lowering all manufacturers to a 30 percent inventory allowance will allow the DEA to better manage individual quotas based on fluctuations in market shares from the entrance of the new manufacturers. The decrease in inventory will prevent excess accumulation of drug product or bulk API by the manufacturers who lose market share, lowering the risk of diversion. By reducing the percentage of the inventory allowance from 50 percent to 30 percent, the DEA will be able to prevent the manufacture of unnecessary quantities of controlled substances and list I chemicals, while still ensuring adequate availability for the legitimate medical, scientific, research, and industrial needs of the United States, thereby decreasing the overall risk of diversion to illicit purposes.

The DEA understands that manufacturers of controlled substances and list I chemicals need to maintain an additional inventory in case of market fluctuations while balancing the risks of public health and safety, but believes that a 50 percent inventory allowance is too large. An inventory allowance of 50 percent is half of a year’s sales supply

²⁹ 21 U.S.C. 802(15).

(net disposal) for each manufacturer, which the DEA believes increases the risk of potential diversion and abuse. For example, the increase in oxycodone dosage-form manufacturers from 2007 to 2017 shows multiple firms vying for an existing market. Their contract and purchase order negotiations frequently require the DEA to reallocate quotas during the same calendar year to maintain a balance between manufacturer production and patient needs. During the calendar year, if the inventory of a basic class held by a manufacturer exceeds 45 percent of estimated net disposal, the quota for that class would be automatically suspended and would remain suspended until inventory is less than 40 percent of the estimated net disposal. The current inventory allowance of 50 percent for each individual manufacturer is too high when compared to individual manufacturer market share necessary to support legitimate medical, scientific, research, and industrial needs for a specific controlled substance or list I chemical.

The DEA believes that a decrease to a 30 percent inventory allowance is necessary because it reflects nearly four months of sales supply (net disposal) for each manufacturer, which allows for market fluctuations among all manufacturers of that class without disruption to patients. Under this proposed rule, manufacturers would continue to receive manufacturing and procurement quotas sufficient to meet their manufacturing and inventory requirements to sustain the domestic demand for controlled substances and list I chemicals within the United States. DEA invites comment on whether the proposed reductions will lead to shortages or delays in drug supply.

The complexity of current business practices is multifactorial and includes increased specialization in the manufacturing process itself, the development of niche markets for specifically formulated drug products, a change from vertically integrated manufacturing practices to a much more horizontal manufacturing structure, and the increasing numbers of manufacturers receiving FDA approval to market generic products. Due to this evolution of complexity in the pharmaceutical industry and the inflexible nature of the regulations by which the DEA must calculate inventory allowances for manufacturers of controlled substances and list I chemicals, the current inventory allowances provide an opportunity for the disproportionate accumulation of controlled substance for United States

needs. These proposed revisions would rectify a situation where the DEA's ability under the statute and regulations to strike an appropriate balance between ensuring the availability of controlled substances and list I chemicals to patients and reducing the risk to public health and safety is compromised. DEA invites comment, including studies, data, or other evidence, as to whether the reductions will result in less diversion.

E. Subcategories for Quotas

The DEA proposes formalizing the addition of use-specific subcategories by adding 21 CFR 1303.04 and 1315.07. As a practical matter, the DEA acknowledges that the subcategories proposed within this rule are already in use through voluntary and cooperative efforts of the DEA registrants.

This proposed rule would codify DEA's current utilization of subcategories while facilitating the issuance of individual manufacturing quotas. The formalization of subcategories also provides benefits to the registrant, by allowing for a more detailed level of communication with the DEA as to why a registrant requires specific controlled substances and list I chemicals and how those substances will be utilized.

Additionally, as the number of manufacturers continues to increase and industry practices and specializations change, the ability to methodically track movements of material between registrants at all stages of manufacturing becomes more critical. The specification of quota subcategories improves the efficiency of the application and reporting process for DEA-registered manufacturers.

Use-specific quota subcategories reflect the manufacturing activity of the applying DEA registrant and have facilitated the issuance of manufacturing and procurement quotas and provided a more accurate calculation of the APQs for the United States. These subcategories are: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. The specification of subcategories for manufacturing and procurement quotas enhances the DEA's ability to administer and manage the APQs and individual manufacturing, importation, and procurement quotas consistent with Congress' intent that the DEA monitor and track controlled substances and list I chemicals as they move through a closed system of distribution. Additionally, as the

number of manufacturers continues to increase and industry practices and specializations continue to evolve, the DEA's ability to track movement of material between registrants at all stages of manufacturing is critical.

By amending sections 21 CFR 1303.12(b), 1303.22, 1315.22, and 1315.32(a), the DEA proposes to revise the procedure for applying for both manufacturing and procurement quotas. Through adding new sections 21 CFR 1303.04(d) and 1315.07(d), the DEA proposes to revise the application process for a request of replacement quota for schedules I and II controlled substances to include either a completed DEA Order Form, or Form for Inventory Surrendered, (Form DEA-222 and DEA-41, respectively) to justify a replacement quota application.

The new subcategories for quota are as follows:

1. Quota for Commercial Sale: This subcategory applies to both bulk manufacturers and dosage-form manufacturers. This subcategory identifies the amount of bulk API manufactured and acquired by a DEA registrant for the dosage-form manufacturer of FDA-approved controlled substance and list I chemical drug products, the amount of API acquired by FDA-registered 503B outsourcing facilities, as well as amounts needed for research, scientific, and industrial purposes. Any bulk manufacturer that produces API for sale to a manufacturer for the purpose of finished dosage-form development receives individual manufacturing quota for commercial sale. Any manufacturer that receives material and conducts blending into dosage-form for sale receives procurement quota for commercial sale. By keeping this item as a separate category, DEA calculates how much bulk API needs to be manufactured for a particular calendar year, which assists DEA in setting the APQs and AANs. An appropriate inventory allowance is established for this type of quota, as specified in 21 CFR 1303.24 and 1315.24. Manufacturing and procurement quotas for commercial sale are not able to be used to support product development efforts.

2. Quota for Transfer: This subcategory captures material moved from one manufacturing registrant back to the preceding registrant through the closed distribution system during the manufacturing process. The intent of this category is to track quota used to support the transfer of schedules I and II controlled substances, as well as the list I chemicals, whether it is bulk API, in-process material, or finished dosage-

forms, from one DEA-registered manufacturer to another. This quota is not to be used to assist the DEA in setting APQs and AANs because the material was previously captured and applied against the APQ and AAN when it was originally manufactured; therefore, the transfer of the material cannot be counted against the APQ and AAN again. This subcategory of procurement quota is ideal to track the return of finished material to the manufacturer to complete the manufacturing process and disposition after the occurrence of any of the aforementioned manufacturing activities or return of rejected material to the upstream manufacturer for destruction or additional processing.

3. Quota for Product Development: In recent years, the DEA has observed a sizeable increase in requests for quota to conduct product development and FDA validation batches. These activities obscure how much material is commercially available to patients for legitimate medical purposes because a registrant's individual quota currently represents both commercial manufacturing efforts, as well as product development and validation efforts. It is critical to accurately capture the amount of material being utilized specifically for product development versus commercial manufacturing. This subcategory of individual manufacturing quota and procurement quota specifically grants the quota for development of new drug product(s), reformulation work, validation, and development manufacturing efforts. The product development quota is limited only to the development efforts noted in the application; it cannot be used or substituted for commercial production or the development of a different product. All products manufactured under this subcategory are non-saleable, with the exception of validation batches post-FDA approval. This subcategory is used to assist the DEA in setting the APQs and AANs. No inventory allowance is provided for this type of procurement quota.

4. Quota for Replacement: Replacement quota is intended to replace material from the current quota year and not a means to replace disposed samples, analytical samples of product development material or inventory acquired or manufactured under previous quota years. This subcategory of individual manufacturing quota and procurement quota includes quota granted to a registrant after the registrant obtained material that was initially intended for commercial sale, but is unable to be marketed. Examples include failed

batches due to a contaminant, material that is out of specification and can no longer be used, lots that reached their expiration date, or unusable material from a dosage-form manufacturer.

Replacement quota is granted on a case-by-case basis. The merit of the request is determined by the specifics of the registrant's justification and situation. The DEA reviews the submitted DEA Form 41 or DEA Form 222 documenting the destruction of the controlled substance and evaluates the justification for the destruction to determine if replacement quota is the appropriate course of action and whether or not the destroyed material is required to meet the legitimate demand of the market. Replacement quota is also considered in setting the APQ and the AAN.

5. Quota for Packaging/Repackaging and Labeling/Relabeling: In recent years, the DEA has a rise in specialty manufacturers that only conduct packaging of controlled substances. This results in frequent movement of materials from one facility to another facility for the performance of packaging/repackaging and labeling/ relabeling activities. The performance of packaging/repackaging and labeling/ relabeling activities can occur within a company with multiple manufacturing locations and thus multiple DEA registration numbers, between a contract packager performing the activity for a manufacturer or a third party, or a packaging/repackaging and labeling/ relabeling company who will bring the product to market. The formalization of a subcategory for packaging quota allows the DEA to be more efficient in accounting for these types of manufacturing activities. This subcategory is used to assist the DEA in setting the AAN, but not the APQ. This subcategory of quota is considered in determining the AAN because most of the finished dosage-forms and bulk API required to meet US legitimate need are imported rather than manufactured domestically. The accounting is necessary to prevent circumvention of the quota system as it applies to the list I chemicals specifically mentioned by Congress in the Combat Methamphetamine Epidemic Act (2005).

Assigning quota to specific subcategories allows the DEA to indicate how much of a registrant's quota may be used to receive bulk material, in-process, or finished dosage units, as well as how much may be used for product development, commercial production, or the launching of new products. Additionally, registrants are prevented from using their quota for a

purpose other than that originally intended and justified to DEA.³⁰

F. New Deadlines for the Establishment of Quotas

The DEA is proposing to revise 21 CFR 1303.11(c), and 1315.11(c) to change the deadlines for the establishment of the APQ and the AAN. This modification will allow a more reasonable amount of time for processing and responding to applications for quota. The DEA also proposes to revise 21 CFR 1303.23(c) and 1315.23(c) to modify the existing deadlines for adjusting the individual manufacturing quotas, allowing more time for reviewing applications for adjustment of individual manufacturing quotas and responding to each applicant. Along with the deadline change for individual manufacturing quotas, the DEA proposes to revise 21 CFR 1303.12(c), 1315.32(f), and 1315.34(f), which would change the deadlines for the establishment of procurement quotas for both schedules I and II controlled substances and list I chemicals, as well as the deadline for import quota of list I chemicals. The proposed changes to the import quota and the procurement quotas are necessary to stay in accordance with the deadline for individual manufacturing quota, as they are all published at the same time when the DEA establishes the APQ and AAN.

The DEA continues to collect various data to administer the United States quota system. Moving the deadlines previously established would allow the DEA to obtain additional relevant data from multiple Federal and state agencies, which would enable better analysis of legitimate demand, strengthening the DEA's ability to allocate quota to the appropriate manufacturers of these substances. These revisions would allow DEA sufficient time to compile and consider all requests for quota in order to ensure that each manufacturer is provided with an adequate amount of quota for their legitimate production needs, while also ensuring that quotas are not unwarranted, which increases the risk of diversion.

The proposed changes are as follows:

- Establishment of the APQ and the AAN: Change from May 1 to September 1.
- Deadline to issue procurement quota: Change from July 1 to December 1.
- Deadline to issue import quota: Change from July 1 to December 1.

³⁰ 21 U.S.C. 842(b).

- Deadline to adjust individual manufacturing quota: Change from March 1 to July 1.

Establishment and Publication of the APQ and AAN: The DEA is seeking to move the publication date for the APQ and the AAN to September 1. Allowing additional time to review applications for import, procurement, and individual manufacturing quota would provide the DEA enough time to assess the needs of industry within the new established timeline for publication of the APQ and AAN, while still maintaining the statutory deadline of December 1³¹ for issuing individual manufacturing quotas.

Issuing Procurement Quotas: Under the proposed rule, this deadline would be moved to December 1 to allow DEA an adequate amount of time to review each application for procurement quota, identify the corresponding bulk manufacturing quota, and then respond to each application. In addition, as stated previously, moving the deadline would allow the continuation of the current practice of issuing the quota at the same time as the individual manufacturing quota.

Issuing Import Quotas: Here, the DEA proposes to move the deadline for issuing import quotas to December 1 (three months after publication of the AAN) to allow the DEA an adequate time to identify the corresponding procurement quotas and then respond to each application. Moving the deadline also allows the import quota to be issued in the same document.

Adjusting Individual Manufacturing Quotas: The DEA proposes to move this deadline to July 1 to allow the DEA an adequate time to review each application for adjusting individual manufacturing quota, revise the APQ, and respond to each application.

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 has been developed in accordance with the principles of Executive Orders 12866 and 13563. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, public health and safety, and environmental advantages, distributive

impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. The Executive Order 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, 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.

While this proposed rule is not economically significant, it is a significant regulatory action under Executive Order 12866, section 3(f) subjecting it to review by OMB. The DEA analyzed the economic impact of each provision of this proposed rule and estimated the annual cost to be \$35,241. Certain provisions are estimated to also have benefits; however, the DEA does not have a basis to estimate those benefits due to many unknowns. Because of this, the benefits of this proposed rule are discussed qualitatively. The rule contains clarification of regulatory language and the codification of existing DEA and registrant practices regarding subcategories for quotas, certification of procurement quota, and additional considerations for revisions to APQs. The results of the analysis of each provision are as follows:

Defining Types of Quota and Filing To Abandon Quota

These provisions simply codify existing DEA practices, and will result in no economic impact on registrants or the DEA. The formal definition of quota types will have no practical impact on registrants, and formalizing the procedure to abandon quota is simply a codification of DEA’s current procedure. While these proposed provisions will have no economic costs or benefits, DEA believes there are benefits to accurately codifying existing practices. These proposed provisions are expected to enhance clarity, certainty, and efficiency.

Conforming Revisions Related to the SUPPORT Act

As indicated above, the SUPPORT Act gives the DEA discretionary authority to establish quotas in terms of pharmaceutical dosage-form. At the present time, the DEA is not deviating from its current practice of establishing quotas necessary for the manufacture of finished dosage-forms in terms of kilograms, and allowing manufacturers to determine how to best allocate those kilograms to different FDA-approved dosage-forms. While the SUPPORT Act gives DEA the authority to establish quotas in terms of pharmaceutical dosage-form, the DEA will continue to use its current process of establishing quota in terms of kilograms, for the time being. While it is impossible to know all the circumstances in which this authority would be used, it is the DEA’s current intention that any implementation of dosage-form quotas will be the exception rather than the rule, and will coexist alongside kilogram quotas. The DEA recognizes that dosage-form manufacturers are in the best position to understand the demand for their products, in dosage-form. Because, at the present time, the DEA is likely to use this authority sparingly, and only adjust quotas for manufacturers producing the dosage-form, the DEA anticipates that this provision of the proposed rule will have minimal impact.

The SUPPORT Act also requires the DEA to estimate the amount of diversion when establishing quota for a covered controlled substance using all reliable information, including information from HHS and other agencies. The DEA has considered information and data regarding the amount of diversion for covered controlled substances when applicable during the process of determining the APQ. This function is a regular part of DEA’s operations. Therefore, considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional cost.

The SUPPORT Act updates also extend the DEA’s deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December, and formally define the phrase “covered controlled substance” to include fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone. The deadline extension will have minimal impact on registrants, as the DEA currently does not meet the October deadline. This extension will align the regulations with reality for registrants

³¹ 21 U.S.C. 826(c).

and the DEA. Defining “covered controlled substance” will not change how those substances or the registrants that are authorized to handle those substances are regulated. Therefore, these provisions will have minimal impact on registrants or the DEA.

While the benefits of the SUPPORT Act updates were not quantified due to many unknowns, it is possible to discuss some of these benefits in qualitative terms. With these conforming revisions related to the SUPPORT Act, DEA has the ability to respond to adverse market conditions with increased speed and flexibility in order to minimize public harm. Dosage-form quotas would be used by the DEA to alleviate the rare occurrence of a drug shortage in the market by targeting the specific dosage-forms that are in short supply instead of simply increasing the total amount of kilograms of a drug to be produced, resulting in a benefit to the public. Another benefit is that updating the deadlines for setting individual manufacturing quotas so they reflect DEA’s current practice removes regulatory uncertainty for manufacturers. Regulations that realistically reflect current DEA and industry practice will benefit the planning processes of current and future market participants. Therefore, the DEA believes the benefits of these conforming revisions related to the SUPPORT Act outweigh their minimal costs.

Procurement Quota Certification

The proposed rule would require that all DEA registrants supplying schedules I and II controlled substances and list I chemicals to DEA manufacturers obtain certification of the manufacturer’s quota before completing the transaction. In practice, this certification may be any written declaration issued by manufacturers to distributors. This provision prevents manufacturers from purchasing their API or finished dosage-forms from distributors without quota verification as currently required when manufacturers request API or finished dosage-forms from other manufacturers. Current regulations stipulate that only entities registered as “importer,” “manufacturer,” or “bulk manufacturer” must certify³² quota before a sale.

In order to estimate the cost of this provision, the DEA utilized internal data tracking the sale of schedules I and II controlled substances and list I chemicals from distributors to manufacturers during the three year period of January 1, 2015 to December 31, 2017. DEA’s analysis revealed that

over this three year period, distributors filled an average of 3,000 orders to manufacturers per year. Using Bureau of Labor Statistics (BLS) wage data for Compliance Officers, the type of registrant employee that would be tasked with certifying quota, the DEA estimated the labor cost of quota certification to distributors and manufacturers. Based on its knowledge of registrant business operations, DEA estimates a manufacturer compliance officer requires 10 minutes to draft a quota certification letter after placing a purchase request to a distributor, while the distributor compliance officer requires five minutes to review and verify the manufacturer’s certification letter. This results in a combined labor burden of 15 minutes (0.25 hours). Multiplying the loaded median hourly wage rate for compliance officers by 0.25 and applying that to the estimated 3,000 certification letters per year yields a total yearly labor cost of \$35,241 (\$23,494 of which is incurred by manufacturers while the remaining \$11,747 is incurred by distributors).

Reduction of Inventory Allowances

The proposed rule would reduce the inventory allowance for manufacturers of controlled substances and list I chemicals from 50 percent to 30 percent of the registrant’s estimated net disposal. The 30 percent inventory allowance would be for the purposes of determining the quota for the coming year and to allow inventory at the beginning of a manufacturer’s new quota year. Manufacturers may exceed the 30 percent inventory allowance during the year. If at any time during the year, the inventory of a basic class held by a manufacturer exceeds 45 percent of estimated net disposal, the quota for that class is automatically suspended and would remain suspended until inventory is less than 40 percent of the estimated net disposal. Practically speaking, the inventory allowance equates to a reduction from half of a year’s sales supply (50 percent) allowed to be held as inventory to nearly four months (30 percent). Additionally, the 45 percent maximum inventory during the year would give manufacturers the flexibility to have inventory equal to nearly six months of sales supply in order to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year.

DEA expects this reduction in allowance will result in minimal to no economic impact on affected registrants as the following data show. From 2008 to 2017, as reported to the U.N., end-of-year combined average inventory

balances for holders of both manufacturing and procurement quotas of internationally controlled narcotics ranged from 32 percent to 46 percent, for a 10-year average of 39 percent. This average is a result of the bulk manufacturing quotas, which by regulation have a 50 percent inventory allowance, and procurement quota inventories, which are not explicitly stated in the regulations, but are held to a range of 30–50 percent based on specific risk factors, including increased documentation of misuse and abuse discovered by various components within HHS and the Department of Justice (DOJ). The reduction of inventory allowance to 30 percent, with flexibility to produce up to 45 percent at any given point in a year, is not anticipated to impact the current operations of registrants, given that over a 10-year period, the average year-end inventories for manufacturers was 39 percent.

Registrants also routinely request adjustments to their quota throughout the year due to fluctuations in market conditions. This is a normal part of a manufacturer’s business operations. The DEA quickly responds to these requests within six to eight weeks, ensuring legitimate business is not disrupted, and will continue to do so once this rule is promulgated. For example, in 2017 (the last year in which data are available), the DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota.

For these reasons, the DEA believes a reduction of inventory allowance to 30 percent would have minimal impact on registrants while continuing to provide adequate inventory for registrants to respond to fluctuations in demand in pharmaceutical markets. However, DEA invites public comment on its assumption that the market supply of controlled substances and list I chemicals will not be impacted by the reduction in inventory allowance.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the proposed rule is a codification of existing voluntary and cooperative efforts between registrants and the DEA that have been in place since 2001 and allows a more accurate calculation of APQs for the United States. The establishment of subcategories of (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling are already being utilized by

³² 21 CFR 1303.12(f) and 1315.32(h).

the DEA with full cooperation from all registrants. Therefore, this provision simply updates 21 CFR 1303.03, 1303.04, 1315.06, and 1315.07 to reflect current DEA procedure for the establishment of quota. Therefore, this provision of the proposed rule will have no economic impact on registrants or the DEA.

New Deadlines for Establishing Quotas

The proposed rule would modify the deadlines for establishing and publishing the APQ, AAN, procurement quota, and manufacturing quotas and any adjustments to manufacturing quotas. The current publishing deadlines for the establishment of the APQ and the AAN of May 1, and the issuing of individual procurement, manufacturing and import quotas of July 1 are frequently missed by the DEA due to the expansion of the market and the increase in the number of manufacturers and importers since that deadline was implemented almost 50 years ago.

Applications for import and procurement quota are due April 1, giving the DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that the DEA has historically missed these deadlines, since it must take adequate time to provide a thorough and careful assessment of each application, both the DEA and industry have already become accustomed to a delayed publishing schedule. Therefore, this provision is expected to have minimal economic impact as it simply aligns the regulatory deadlines with the current business practices of the DEA and industry.

DEA invites public comment on the preceding discussion of the potential impact of this proposed rule.

Executive Order 13771 was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017. 82 FR 9339. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, Section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from OMB, issued on April 5, 2017, explains that the above requirements only apply to each new “significant regulatory action that . . . imposes costs.” The same OMB guidance also clarifies that: “*de minimis* costs may qualify for an exemption . . .

[if, for example] the agency estimates the action would have present value costs of \$50,000 spread over a large number of persons and/or entities.” The DEA expects the costs of this proposed rule to be *de minimis*. Therefore, this proposed rule is not expected to be an Executive Order 13771 regulatory action.

Executive Order 12988, Civil Justice Reform

This rulemaking meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), the DEA evaluated the impact of this rule on small entities. The 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 it 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. The DEA evaluated the impact of this rule on small entities and discussions of its findings are below.

As discussed in the “Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)” section above, this

proposed rule has six key components as described below.

Defining Types of Quota and Filing To Abandon Quota

This provision simply codifies existing DEA practices, and will result in no economic impact on registrants or the DEA. The formal definition of quota types will have no practical impact on registrants, and formalizing the procedure to abandon quota is simply a codification of DEA’s current procedure. Therefore, this proposed provision will have no costs.

Conforming Revisions Related to the SUPPORT Act

While the SUPPORT Act gives the DEA the authority to establish quotas in terms of pharmaceutical dosage-form, the DEA will continue to use its current process of establishing quota in terms of kilograms. Therefore, this provision of the proposed rule will have no impact.

Additionally, the SUPPORT Act defines the phrase “covered controlled substance” to include fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone and requires the DEA to estimate the amount of diversion when establishing quota for covered controlled substances by consulting with the Secretary of HHS and considering reliable information on the rates of overdose deaths and abuse and overall public health impact in the U.S. that is determined to be reliable. The DEA has considered the amount of diversion when establishing quotas when data has been available, and this is a regular part of DEA’s operations. Therefore, considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional cost.

The SUPPORT Act updates also extend the DEA’s deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December. The deadline extension will have minimal impact on registrants, as the DEA currently does not meet the October deadline. This extension will align the regulations with reality for registrants. Therefore, these provisions will have minimal impact on registrants or the DEA.

Procurement Quota Certification

The proposed rule would require that all DEA registrants supplying schedules I and II controlled substances and list I chemicals to DEA manufacturers to obtain certification of the manufacturer’s quota before completing the transaction. In practice, this certification must be a written

declaration issued by manufacturers to distributors containing the information as required in the regulations.³³ This provision prevents manufacturers from purchasing their API or finished dosage-forms from distributors without quota verification as currently required when manufacturers request API or finished dosage-forms from other manufacturers. Current regulations stipulate that only entities registered as “importer,” “manufacturer,” or “bulk manufacturer” must certify³⁴ quota before a sale.

In order to estimate the cost of this provision, the DEA utilized internal data tracking the sale of schedules I and II controlled substances and list I chemicals from distributors to manufacturers during the three year period of January 1, 2015 to December 31, 2017. DEA’s analysis revealed that over this three year period, distributors filled an average of 3,000 orders to manufacturers per year. Using BLS wage data for Compliance Officers, the type of registrant employee that would be tasked with certifying quota, the DEA estimated the labor cost of quota certification to distributors and manufacturers. Based on its knowledge of registrant business operations, DEA estimates a manufacturer compliance officer requires 10 minutes to draft a quota certification letter after placing a purchase request to a distributor, while the distributor compliance officer requires five minutes to review and verify the manufacturer’s certification letter. This results in a combined labor burden of 15 minutes (0.25 hours). Multiplying the loaded median hourly wage rate for compliance officers by 0.25 and applying that to the estimated 3,000 certification letters per year yields a total yearly labor cost of \$35,241 (\$23,494 of which is incurred by manufacturers while the remaining \$11,747 is incurred by distributors).

Reduction of Inventory Allowances

The proposed rule would reduce the inventory allowance for manufacturers of controlled substances and list I chemicals from 50 percent to 30 percent of the registrant’s estimated net disposal. The 30 percent inventory allowance would be for the purposes of determining the quota for the coming year and to allow inventory at the beginning of a manufacturer’s new quota year. Manufacturers may exceed the 30 percent inventory allowance during the year. If at any time during the year, the inventory of a basic class held by a manufacturer exceeds 45 percent of estimated net disposal, the quota for

that class is automatically suspended and would remain suspended until inventory is less than 40 percent of the estimated net disposal. Practically speaking, the inventory allowance equates to a reduction from half of a year’s sales supply (50 percent) allowed to be held as inventory to nearly four months (30 percent). Additionally, the 45 percent maximum inventory during the year would give manufacturers the flexibility to have inventory equal to nearly six months of sales supply in order to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year.

DEA expects this reduction in allowance will result in minimal to no economic impact on affected registrants as the following data show. From 2008 to 2017, as reported to the U.N., end-of-year combined average inventory balances for holders of both manufacturing and procurement quotas of internationally controlled narcotics ranged from 32 percent to 46 percent, for a 10-year average of 39 percent. This average is a result of the bulk manufacturing quotas, which by regulation have a 50 percent inventory allowance, and procurement quota inventories, which are not explicitly stated in the regulations, but are held to a range of 30–50 percent based on specific risk factors, including increased documentation of misuse and abuse discovered by various components within HHS and DOJ. For example, the DEA currently sets the inventory allowance for fentanyl, hydrocodone, hydromorphone, and oxycodone procurement quotas at 30 percent for FDA-approved dosage-forms. The reduction of inventory allowance to 30 percent, with flexibility to produce up to 45 percent at any given point in a year, is not anticipated to impact the current operations of registrants, given that over a 10-year period, the very upper range of year-end inventories for manufacturers was 46 percent.

Registrants also routinely request adjustments to their quota throughout the year due to fluctuations in market conditions. This is a normal part of a manufacturer’s business operations. The DEA quickly responds to these requests within six to eight weeks, ensuring legitimate business is not disrupted, and will continue to do so once this rule is promulgated. For example, in 2017 (the last year for which data are available), the DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota.

For these reasons, the DEA believes a reduction of inventory allowance to 30 percent would have minimal impact on

registrants while continuing to provide adequate inventory for registrants to respond to fluctuations in demand in pharmaceutical markets. However, DEA invites public comment on its assumption that the market supply of controlled substances and list I chemicals will not be impacted by the reduction in inventory allowance.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the proposed rule is a codification of existing voluntary and cooperative efforts between registrants and the DEA that have been in place since 2001 and allows a more accurate calculation of APQs for the United States. The establishment of subcategories of (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling are already being utilized by the DEA with full cooperation from all registrants, therefore this provision simply updates 21 CFR 1303.03, 1303.04, 1315.06, and 1315.07 to reflect current DEA procedure for the establishment of quota. Therefore, this provision of the proposed rule will have no economic impact on registrants or the DEA.

New Deadlines for Establishing Quotas

The proposed rule would modify the deadlines for establishing and publishing the APQ, AAN and procurement and manufacturing quotas and any adjustments to manufacturing quotas. The current publishing deadlines for the establishment of the APQ and the AAN of May 1, and the issuing of individual procurement, manufacturing and import quotas of July 1 are frequently missed by the DEA due to the expansion of the market and the increase in the number of manufacturers and importers since that deadline was implemented almost 50 years ago. Applications for import and procurement quota are due April 1, giving the DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that the DEA has historically missed these deadlines since it must take adequate time to provide a thorough and careful assessment of each application, both the DEA and industry have already become accustomed to a delayed publishing schedule. Therefore, this provision is expected to have minimal economic impact as it simply aligns the regulatory deadlines with the current business practices of the DEA and industry.

³³ 21 CFR 1303.12(f) and 1315.32(h).

³⁴ *Id.*

Summary

In summary, only the Procurement Quota Certification requirement imposes a cost, \$23,494 to all manufacturers combined and \$11,747 to all distributors combined for a grand total cost of \$35,241.

Description and Estimate of the Number of Small Entities

This proposed rule has the potential to affect entities registered with the DEA as manufacturers, distributors and importers of controlled substances and list I chemicals. Based on a review of respective representative North American Industry Classification System (NAICS) codes for manufacturers,³⁵ distributors and

importers³⁶ there are the following number of firms:³⁷

- 935 'Pharmaceutical Preparation Manufacturing' (325412)
- 6,666 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210)

The U.S. Small Business Administration (SBA) considers a size standard as the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm. The SBA Size Standards for the two industries are 1,250 employees for Pharmaceutical Preparation Manufacturing and 250 employees for

Drugs and Druggists' Sundries Merchant Wholesalers.³⁸

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, the DEA estimates the following number of small entities (and percent of establishments that are small entities) by industry:

- 866 (92.6% of total) 'Pharmaceutical Preparation Manufacturing' (325412)
- 6,394 (95.9% of total) 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210)

The table below summarizes the calculation for the estimated number of small entities (establishments) above.

DETAILED ANALYSIS OF PERCENTAGE OF ENTITIES THAT ARE SMALL ENTITIES BY INDUSTRY

NAICS description	Firm size by average employees	Firms	Establishments	SBA size standard	Small entities	Small entities (%)
325412—Pharmaceutical Preparation Manufacturing.	Total	935	1170	1,250	866	92.6
	<500	833	856	1,250	833	100
	500–749	19	32	1,250	19	100
	750–999	10	16	1,250	10	100
	1,000–1,499	7	14	1,250	4	50
	1,500–1,999	5	9	1,250	0	0
	2,000–2,499	7	12	1,250	0	0
	2,500–4,999	19	67	1,250	0	0
424210—Drugs and Druggists' Sundries Merchant Wholesalers.	5,000+	35	164	1,250	0	0
	Total	6,666	9,915	250	6,394	95.9
	<100	6,369	6,380	250	6,225	100
	100–149	102	137	250	102	100
	150–199	42	59	250	42	100
	200–299	50	73	250	25	50
	300–399	29	58	250	0	0
	400–499	18	90	250	0	0
	500–749	35	55	250	0	0
	750–999	17	31	250	0	0
	1,000–1,499	21	109	250	0	0
	1,500–1,999	12	23	250	0	0
	2,000–2,499	12	24	250	0	0
	2,500–4,999	34	114	250	0	0
	5,000+	69	2,762	250	0	0

Because DEA registrants frequently hold more than one registration for separate locations, many registrations may be held by one entity. The DEA estimates the number of affected entities by multiplying the number of DEA registrations in each business activity by its "firm-to-establishment" ratio in

order to find the total amount of entities. The firm-to-establishment ratio is calculated by dividing the number of firms in each industry NAICS code by the total number of establishments found in the third and fourth columns of the previous table.³⁹ The DEA analyzed how each provision of the

proposed rule will affect DEA registrants, including how many entities will be affected by each provision, and found that 550 DEA registered entities will be affected by at least one provision of this proposed rule. A summary of this analysis is detailed in the table below:

³⁵ The DEA believes 'Pharmaceutical Preparation Manufacturing' (325412) includes 503B outsourcing facilities.

³⁶ The DEA believes 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210) includes both distributors and importers of controlled substances and (human form) list I chemicals.

³⁷ For the purposes of this analysis, the term "firm" is synonymous with "entities."

³⁸ SBA "Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective October 1, 2017."

³⁹ For example, the firm-to-establishment ratio for NAICS 325412 is obtained by dividing the 935 total firms in the industry by the 1170 total establishments in the industry, yielding a ratio of .80. The exact same calculation for NAICS code 424210 yields a ratio of .67.

SUMMARY OF DEA REGISTERED ENTITIES AFFECTED BY PROVISION OF PROPOSED RULE

Activity	DEA registrants	Provisions						Affected entities*
		Inventory allowance	APQ and AAN dates	Subcategories	SUPPORT Act	Definitions	Quota cert	
Manufacturer CS, Bulk	34	Yes	Yes	Yes	Yes	Yes	No	27
Manufacturer List I, Bulk		Yes	Yes	Yes	Yes	Yes	No	
Manufacturer CS, Dosage	417	Yes	Yes	Yes	Yes	Yes	Yes	334
Manufacturer List I, Dosage		Yes	Yes	Yes	Yes	Yes	Yes	
Importer List I	35	No	Yes	No	No	Yes	No	23
Distributor CS	143	No	No	No	No	Yes	Yes	96
Distributor List I	104	No	No	No	No	Yes	Yes	70
Total	550

* Firm-to-establishment ratios of .80 for manufacturers and .67 for distributors and importers were used to calculate the number of affected entities.

After accounting for how many DEA registered entities are affected by each provision, DEA applied the estimated percentage of establishments that are small entities to each respective business activity in order to estimate the number of affected small entities. The

DEA estimates that of the 550 affected entities 515 are small entities: 159 distributors, 334 manufacturers and 22 importers. In summary, the percentages of small entities affected are as follows:

- 38.6% 'Pharmaceutical Preparation Manufacturing' (325412)

- 2.8% 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210)

The table below summarizes the estimated number of small entities, number of affected small entities, and the percentage of small entities affected.

SUMMARY OF INDUSTRY, SBA SIZE STANDARD, AND AFFECTED SMALL ENTITIES

NAICS code	NAICS description	Small entity threshold/SBA size standard	Estimated number of small entities (establishments)	Estimated number of affected small entities	Percentage of small entities affected
325412	Pharmaceutical Preparation Manufacturing	1,250	866	334	38.6
424210	Drugs and Druggists' Sundries Merchant Wholesalers	250	6,394	* 181	2.8
Total	7,260	515	N/A

* 159 distributors and 22 importers.

As described above, if promulgated this proposed rule is estimated to cost \$23,494 to all manufacturers combined and \$11,747 to all distributors or an average cost of \$70 (\$23,494/334) per affected manufacturer and \$71 (\$11,747/166) per distributor. The DEA generally uses 30 percent as a "substantial" number of affected small entities. The analysis reveals that a non-substantial

amount (2.8 percent) of small distributor entities will be affected, while a substantial amount (38.6 percent) of small manufacturing entities will be affected by this proposed rule. The DEA generally considers impacts that are greater than 3 percent of yearly revenue to be a "significant economic impact" on an entity. The DEA compared the compliance cost of \$70 and \$71 to the

average annual receipts of manufacturers and distributors/imports, respectively, for each size range.⁴⁰ For even the smallest of entities, the costs calculated above are much less than 3 percent of yearly revenue and are insignificant.

The table below summarizes the analysis.

SUMMARY OF ANALYSIS

NAICS code	NAICS description	Small entity threshold/SBA size standard	Estimated number of small entities (establishments)	Estimated number of affected small entities	Percentage of small entities affected	Economic impact of compliance
325412	Pharmaceutical Preparation Manufacturing.	1,250	866	334	38.6% (Substantial)	Not significant.
424210	Drugs and Druggists' Sundries Merchant Wholesalers.	250	6,394	* 181	2.8% (Not Substantial) ...	Not Significant.

* 159 distributors and 22 importers.

⁴⁰ Small Business Administration, Office of Advocacy "Table 2—Number of firms,

establishments, receipts, employment, and payroll by firm size (in receipts) and industry, 2012."

<https://www.sba.gov/advocacy/firm-size-data>, accessed 5/24/2018.

The DEA examined the economic impact of the proposed rule for each affected industry for various size ranges. Based on the analysis above, and because of these facts, the DEA believes this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule 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 for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed subject to the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), this action would revise existing information collections 1117–0006, 1117–0008, and 1117–0047, and create one new information collection. The DEA is proposing to amend its regulations for establishing quotas for United States companies manufacturing schedules I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine, and for procurement quota certification and recordkeeping requirements. The DEA has submitted these collection requests to the Office of Management and Budget (OMB) for review and approval.

A. Collections of Information Associated With the Proposed Rule

1. *Title:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0006.

DEA Form Number: DEA–189.

The DEA is proposing to formally implement the use of subcategories to facilitate the issuance of manufacturing quotas and provide a more accurate calculation of the aggregate production quotas for the United States. The DEA proposes the addition of the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota could be requested using the same application and format registrants are accustomed to using, in an online form. Manufacturers of schedules I and II controlled substances and list I chemicals would

continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and the DEA would retain greater control over the amount of these controlled substances and listed chemicals produced, thereby reducing the amount of inventories at risk of diversion.

The DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 33.
- *Frequency of response:* Annually/As-needed (26,0303 average).
- *Number of responses:* 859.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 430.

2. *Title:* Application for Procurement Quota for Controlled Substances and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0008.

DEA Form Number: DEA–250.

The DEA is proposing to formally implement the use of subcategories to facilitate the issuance of procurement quotas and provide a more accurate calculation of the aggregate production quotas for the United States. The DEA proposes the addition of the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota could be requested using the same application and format registrants are accustomed to using, in an online form. Manufacturers of schedules I and II controlled substances and list I chemicals would continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and the DEA would retain greater control over the amount of these controlled substances and listed chemicals produced, thereby reducing the amount of inventories at risk of diversion.

The DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 344.
- *Frequency of response:* Annually/As-needed (8,9128 average).
- *Number of responses:* 3,066.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 1,533.

3. *Title:* Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

OMB Control Number: 1117–0047.

DEA Form Number: DEA–488.

The DEA is proposing to formally implement the use of subcategories to facilitate the issuance of import quotas

and provide a more accurate calculation of the assessment of annual needs for the United States. The DEA proposes the addition of the following five subcategories for quota: (1) Quota for Commercial Sales; (2) Quota for Transfer; (3) Quota for Product Development; (4) Quota for Replacement; and (5) Quota for Packaging/Repackaging and Labeling/Relabeling. All types of quota could be requested using the same application and format registrants are accustomed to using, in an online form. Importers of list I chemicals would continue to receive import quotas appropriate to their manufacturing and inventory requirements, and the DEA would retain greater control over the amount of these listed chemicals produced, thereby reducing the amount of inventories at risk of diversion.

The DEA estimates the following number of respondents and burden associated with reporting:

- *Number of respondents:* 49.
- *Frequency of response:* Annually/As-needed (2,5714 average).
- *Number of responses:* 126.
- *Burden per response:* 0.5 hour.
- *Total annual hour burden:* 63.

4. *Title:* Procurement Quota Certification and Recordkeeping Requirements.

OMB Control Number: 1117–New.

DEA Form Number: N/A.

This proposed rule would require all DEA registrants supplying schedules I and II controlled substances or list I chemicals to DEA manufacturers to obtain certification of the manufacturer's procurement quota before completing the transaction. This provision would prevent manufacturers from purchasing active pharmaceutical ingredients from distributors, rather than other manufacturers, without including a quota certification. Current DEA regulations stipulate only that orders to entities registered as importers, manufacturers, or bulk manufacturers must include quota certifications.⁴¹ Manufacturers procuring schedules I and II controlled substances or list I chemicals must maintain a copy of the certification they provide with their order for a period of two years from the date of the certification. Under the proposed rule, this recordkeeping requirement would apply to certifications included with orders for schedules I and II controlled substances or list I chemicals to all registrants, including distributors.

The DEA estimates that distributors fill an average of 3,000 orders to manufacturers per year, which under

⁴¹ 21 CFR 1303.12(f), 1315.32(h).

this proposed rule, will require 3,000 certification letters to be drafted and retained by manufacturers, and reviewed by distributors. The estimated yearly cost of this activity is \$35,241. The DEA will update the below figures based on public comments received. For the purposes of this proposed rule, the DEA estimates the following number of respondents and burden associated with the proposed requirement that procuring manufacturers create and retain copies of schedules I and II controlled substance and list I chemical quota certifications for two years:

- *Number of respondents:* 500 (334 manufacturers and 166 distributors).
- *Frequency of response:* 9 per year.
- *Number of responses:* 3,000.
- *Burden per response:* .25 (minimal).
- *Total annual hour burden:* 750 (minimal).

B. Request for Comments Regarding the Proposed Information Collections

The DEA is soliciting comment on the following issues related to these information collections:

- The need for the information collection and its usefulness in carrying out the proper functions of the DEA.
- The accuracy of the DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB49/Docket No. DEA-455. All comments must be submitted to OMB on or before December 23, 2019. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

Congressional Review Act

This proposed rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; 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.

List of Subjects

21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

21 CFR Part 1315

Administrative practice and procedure, Chemicals, Drug traffic control, Imports, Reporting and recordkeeping requirements.

For the reasons set forth above, the DEA proposes to amend 21 CFR parts 1303 and 1315 as follows:

PART 1303—QUOTAS

- 1. The authority citation for 21 CFR part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

- 2. Add §§ 1303.03, 1303.04, and 1303.05 immediately following the undesignated center heading "Aggregate Production and Procurement Quotas" to read as follows:

§ 1303.03 Types of quotas.

The three types of quotas are:

(a) Aggregate production quotas, which establish the total quantity of each basic class of schedules I and II controlled substances that may be produced by all manufacturers in a calendar year.

(b) Individual manufacturing quotas, which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may manufacture during a calendar year. This type of quota is only issued to DEA-registered bulk manufacturers.

(c) Procurement quotas, which establish the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances.

§ 1303.04 Subcategories of manufacturing and procurement quotas.

The five subcategories of manufacturing and procurement quotas are:

(a) *Quota for Commercial Sale.* This is a quota for the amount of bulk active pharmaceutical ingredients (API) initially acquired by a registrant for the manufacture of approved schedule I or II controlled substance drug products by the Food and Drug Administration, and bulk API acquired by outsourcing

facilities, manufacturers, etc. This quota category is used to capture bulk API moving from a bulk manufacturer to other registered manufacturers for their commercial manufacturing efforts. This type of quota may only be used to support commercial manufacturing efforts and may not be used to support other manufacturing efforts.

(b) *Quota for Transfer.* This is a quota for the amount of material moved upstream from one registrant to another and does not include material captured under procurement quota for commercial sale. Examples include: 1. Bulk API being transferred back to the original registrant after milling; 2. Transfer of in-process material or finished dosage-forms for additional manufacturing efforts (coating, beading, encapsulation, and so forth) back to the preceding registrant; and 3. Return of material after the specified manufacturing activity has been completed or return of rejected material to the upstream manufacturer for destruction or additional processing.

(c) *Quota for Product Development.* This is a quota for the amount of material needed for product development and validation of manufacturing efforts. This quota is limited to that activity *only* and only for the development efforts noted in the application; it shall not be used or substituted for commercial production or the development of a different product. This quota is issued with the understanding that this material is not intended for commercial use, with the exception of post-FDA approved validation batches. Validation batches shall be noted specifically in an application and shall be considered product development material that will be taken into account for net disposal once a product is FDA-approved for commercial sale. No inventory will be granted for these efforts, nor will replacement quota be considered for destroyed material issued under this quota subcategory.

(d) *Quota for Replacement.* This is a type of individual manufacturing quota or procurement quota that is granted to a registrant after the registrant disposes of material that was initially intended for commercial sale, but for some reason was unable to be marketed. This quota is separate and shall not count against a registrant's other issued quota. Replacement quota will be granted on a case-by-case basis. The merits of the request will be determined by the specifics of the registrant's justification and situation. The DEA will review the submitted DEA Form 41 or DEA Form 222 documenting the destruction of the controlled substance and evaluate the

justification for the destruction to determine if replacement quota is warranted and whether or not the destroyed material is required to meet the legitimate demand of the market. Replacement quota is intended to replace material from the current quota year and not a means to replace disposed samples, analytical samples, product development material, or inventory acquired under previous quota years.

(e) *Quota for Packaging/Repackaging and Labeling/Relabeling.* This is a quota for the amount of material moved to a registrant to undergo packaging and labeling activities. This quota is limited to that activity *only* and only for the packaging/repackaging and labeling/ relabeling noted in the application; it may not be used or substituted for commercial production. Packaging/ Repackaging and Labeling/Relabeling quota is intended for tracking of schedules I and II controlled substances as they undergo packaging/labeling activities; however, packaging/ repackaging and labeling/relabeling quotas shall not be counted against the aggregate production quotas.

§ 1303.05 Estimation of diversion.

(a) In establishing any quota under the sections in this part for a covered controlled substance, the Administrator shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

(b) In estimating diversion under the sections in this part, the Administrator—

(1) Shall consider information the Administrator, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(2) May take into consideration whatever other sources of information the Administrator determines reliable.

(c) After estimating the amount of diversion of a covered controlled substance, the Administrator shall make appropriate quota reductions, as determined by the Administrator, from the quota the Administrator would have otherwise established had such diversion not been considered.

(d) For purposes of this part, the term “covered controlled substances” refers to fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone.

■ 3. Amend § 1303.11 by:

■ a. Adding a sentence to the end of paragraph (a);

- b. Removing “May” and adding in its place “September” in the first sentence of paragraph (c); and
- c. Adding paragraph (d).

The additions read as follows:

§ 1303.11 Aggregate production quotas.

(a) * * * The Administrator may establish an aggregate production quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

* * * * *

(d) For any year for which the approved aggregate production quota for a covered controlled substance, as defined in § 1303.05(d), is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Administrator, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

- 4. Amend § 1303.12 by:
- a. Adding a sentence to the end of paragraph (a);
- b. Revising the first sentence in paragraph (b);
- c. Removing “July” and adding in its place “December” in the introductory text of paragraph (c); and
- d. Removing “manufacturer” and “bulk manufacturer” and adding in their place “registrant”, and removing “Manufacturers” and adding in its place “A registrant” in paragraph (f).

The addition and revision read as follows:

§ 1303.12 Procurement quotas.

(a) * * * The Administrator may establish a procurement quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in schedule I or II (except raw opium being imported by the registrant pursuant to an import permit) for purposes of manufacturing, shall apply on DEA Form 250 for procurement quota and shall state separately for each

subcategory, as defined in 21 CFR 1303.04, each quantity of such basic class. * * *

* * * * *

- 5. Amend § 1303.21 by removing “July” and adding in its place “December” and adding a sentence after the first sentence in paragraph (a). The addition reads as follows:

§ 1303.21 Individual manufacturing quotas.

(a) * * * The Administrator may establish an individual manufacturing quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. * * *

* * * * *

- 6. Amend § 1303.22 by revising the first sentence of the introductory text to read as follows:

§ 1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota and shall state separately for each subcategory, as defined in 21 CFR 1303.04, each quantity of such class. * * *

* * * * *

§ 1303.23 [Amended]

- 7. In § 1303.23, remove “March” and add in its place “July” in the first sentence of paragraph (c).

- 8. Revise § 1303.24 to read as follows:

§ 1303.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1303.23, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory equal to:

(1) For current manufacturers, 30 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 30 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) For the purpose of determining procurement quotas pursuant to § 1303.12, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) For current manufacturers, 30 percent of his average estimated net

disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 30 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(c) During each calendar year, each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 45 percent of his estimated net disposal of that class for that year, as determined at the time his quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 45 percent of his estimated net disposal, his quota for that class is automatically suspended and shall remain suspended until his inventory is less than 40 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph (c) to continue manufacturing and to accumulate an inventory in excess of 45 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(d) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to him under an individual manufacturing quota, and his inventory of that class is less than 20 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 30 percent of the estimated net disposal for that year.

■ 9. Amend § 1303.27 by revising the first sentence to read as follows:

§ 1303.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for any basic class of controlled substance listed in schedule I or II pursuant to § 1303.23 may at any time abandon his right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. * * *

PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

■ 10. The authority citation for 21 CFR part 1315 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 826, 871(b), 952.

■ 11. Add § 1315.06 to read as follows:

§ 1315.06 Assessment of annual needs; types of quotas.

The four types of quotas are:

(a) Assessment of annual needs, which establishes the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine necessary to be manufactured and imported by all manufacturers and importers in a calendar year.

(b) Individual manufacturing quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered manufacturer may manufacture during a calendar year. This type of quota is only issued to DEA-registered bulk manufacturers.

(c) Procurement quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances.

(d) Import quotas, which establish the maximum quantity of ephedrine, pseudoephedrine, and phenylpropanolamine that a registered importer may import during the calendar year for distribution to their DEA-registered customers.

■ 12. Add § 1315.07 to read as follows:

§ 1315.07 Subcategories of manufacturing and procurement quota.

The five subcategories are:

(a) Quota for Commercial Sale is a quota for the amount of bulk active pharmaceutical ingredients (API) initially acquired by a registrant for the manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine products and bulk API acquired by outsourcing facilities, manufacturers, etc. This type of quota shall only be used to support commercial manufacturing efforts and shall not be used to support other manufacturing efforts.

(b) Quota for Transfer is a quota for the amount of material moved from one registrant to another and does not include material captured under procurement quota for commercial sale. Examples include:

(1) Bulk API being transferred back to the original registrant after milling;

(2) Transfer of in-process material or finished dosage-forms for additional manufacturing efforts (coating, beading, encapsulation, and so forth) back to the preceding registrant; and

(3) Return of material after the specified manufacturing activity has been completed.

(c) Quota for Product Development is a quota for the amount of material needed for product development and validation manufacturing efforts. This quota is limited to that activity *only* and only for the development efforts noted in the application; it shall not be used or substituted for commercial production or the development of a different product. This quota is issued with the understanding that this material is not intended for commercial use, with the exception of FDA-approved or OTC Monograph validation batches. Validation batches shall be noted specifically in an application and shall be considered product development material that will be taken into account once a product is FDA-approved for commercial sale. No inventory shall be granted for these efforts, nor shall replacement quota be considered for destroyed material issued under this quota subcategory.

(d) Quota for Replacement is a type of individual manufacturing quota or procurement quota that is granted to a registrant after the registrant disposes of material that was initially intended for commercial sale, but for some reason was unable to be marketed. This quota is separate and shall not count against a registrant's other issued quota. Replacement quota will be granted on a case by case basis. The merits of the request shall be determined by the registrant's justification. Replacement quota is intended to replace material from the current quota year and shall not be used to replace disposed samples, analytical samples, product development material or inventory acquired under previous quota years.

(e) Quota for Packaging/Repackaging and Labeling/Relabeling is quota for the amount of material moved to a registrant to undergo packaging and labeling activities. This quota is limited to that activity *only* and only for the packaging/repackaging and labeling/relabeling noted in the application; it shall not be used or substituted for commercial production or the packaging of a different product.

§ 1315.11 [Amended]

■ 13. Amend § 1315.11 by removing "May" and adding in its place "September" in the first sentence of paragraph (c).

§ 1315.21 [Amended]

■ 14. Amend § 1315.21 by removing "July" and adding in its place "December" in the first sentence.

- 15. Amend § 1315.22 by revising the first sentence of the introductory text to read as follows:

§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical and shall state separately for each subcategory, as defined in 21 CFR 1315.07, each quantity of such chemical. * * *

* * * * *

§ 1315.23 [Amended]

- 16. Amend § 1315.23 by removing “March” and adding in its place “July” in the first sentence of paragraph (c).
- 17. Revise § 1315.24 to read as follows:

§ 1315.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1315.23, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) For current manufacturers, 30 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 30 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) For the purpose of determining procurement quotas pursuant to § 1315.32, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) For current manufacturers, 30 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 30 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(c) During each calendar year, each registered manufacturer shall be allowed to maintain an inventory of a chemical not exceeding 45 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 45 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 40 percent of his estimated net

disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph (c) to continue manufacturing and to accumulate an inventory in excess of 45 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(d) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to him under an individual manufacturing quota, and his inventory of that chemical is less than 20 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 30 percent of the estimated net disposal for that year.

■ 18. Amend § 1315.27 by revising the first sentence to read as follows:

§ 1315.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to § 1315.23 may at any time abandon his right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. * * *

- 19. Amend § 1315.32 by:
- a. Revising the first sentence in paragraph (a);
- b. Removing “July” and adding in its place “December” in the introductory text of paragraph (f);
- c. Removing “manufacturer or importer” and adding in its place “registrant” in paragraph (h).

The revision reads as follows:

§ 1315.32 Obtaining a procurement quota.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24 of this chapter, and who desires to use during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing (including repackaging or relabeling), must apply on DEA Form 250 for a procurement quota for the chemical and shall state separately for each subcategory, as defined in 21 CFR 1315.07, each quantity of such chemical. * * *

* * * * *

§ 1315.34 [Amended]

- 20. Amend § 1315.34 by removing “July” and adding in its place “December” in paragraph (f).

Dated: September 28, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019-21989 Filed 10-22-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2019-0846]

RIN 1625-AA00

Safety Zone for Fireworks Display; Spa Creek, Annapolis, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of Spa Creek. This action is necessary to provide for the safety of life on these navigable waters of Spa Creek in Annapolis, MD, on December 31, 2019, during a fireworks display. This proposed rulemaking would prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 22, 2019.

ADDRESSES: You may submit comments identified by docket number USCG-2019-0846 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the

SUPPLEMENTARY INFORMATION section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ron Houck, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410-576-2674, email Ronald.L.Houck@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations