OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

15 CFR Part 2004

RIN 0350–AA13

Technical Amendment: Freedom of Information Act Policies and Procedures

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Adoption of interim rule as final.

SUMMARY: This final rule adopts, without change, an interim final rule with a request for comments published in the **Federal Register** on July 25, 2023, that made a minor technical change to the USTR Freedom of Information Act (FOIA) regulation.

DATES: Effective October 2, 2023.

FOR FURTHER INFORMATION CONTACT: Janice Kaye or Monique Ricker at *FOIA@ustr.eop.gov* or 202–395–3150.

SUPPLEMENTARY INFORMATION:

I. Technical Change

On July 25, 2023, USTR published an interim final rule that made a technical change to § 2004.6 of the USTR FOIA regulation to align it with the statute and Office of Information Policy guidance about the compelling circumstances under which an agency must grant expedited processing. *See* 88 FR 47772. Although the interim final rule was effective upon publication, USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the interim final rule without any changes.

II. Regulatory Flexibility Act

USTR considered the impact of this rule and determined that it will not have a significant economic impact on a substantial number of small business entities because it applies only to USTR's internal operations and legal obligations. 5 U.S.C. 605(b).

III. Paperwork Reduction Act

The final rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

IV. Administrative Procedure Act (APA)

On July 25, 2023, USTR published an interim final rule (88 FR 47772) and determined that there was a basis under the Administrative Procedure Act for issuing the interim final rule with immediate effect. USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the provisions of the interim final rule as a final rule with no changes.

List of Subjects in 15 CFR Part 2004

Administrative practice and procedure, Courts, Disclosure, Exemptions, Freedom of information, Government employees, Privacy, Records, Subpoenas, Testimony.

PART 2004—DISCLOSURE OF RECORDS AND INFORMATION

■ Accordingly, the interim final rule published in the **Federal Register** on July 25, 2023, at 88 FR 47772, amending 15 CFR part 2004, is adopted as a final rule without change.

Janice Kaye,

Chief FOIA Officer, Office of the United States Trade Representative.

[FR Doc. 2023–18866 Filed 8–30–23; 8:45 am]

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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: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this final rule to manage the quotas for controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, held by DEA-registered manufacturers. This final rule will 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. This final rule will also amend 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.

DATES: This final rule is effective November 29, 2023.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of the Drug Enforcement Administration (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). 21 U.S.C. 871(b) and 958(f). Subchapter I includes provisions which require the Administrator to establish the aggregate production quota for each basic class of controlled substance listed in schedules I and II and the assessment of annual needs for the ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States each calendar year to provide for the estimated medical, 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 listed in schedules I and II and ephedrine, pseudoephedrine, and phenylpropanolamine pursuant to stipulated conditions: limit or reduce individual production quotas for each registered manufacturer,[1] and fix individual manufacturing quotas for registrants.[2]

On October 24, 2018, Congress revised the CSA through the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities (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.

[1] 21 U.S.C. 826(b).

[2] 21 U.S.C. 826(d).

I. Executive Summary

A. Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on October 23, 2019, which provided an opportunity for comments to be submitted. 84 FR 56712. The comment period closed on December 23, 2019. DEA invited comments from the public on all of the topics covered in the NPRM; however, DEA cannot change the implementation of amendments from the SUPPORT Act.

B. Summary of the Purposes and Provisions of the Rule

1. Types of Quota

In the NPRM, DEA proposed the addition of new sections to introduce and define the types of quotas and proposed an update to the procedure for abandoning quota. The types of quotas are as follows:

- Aggregate production quota (APQ) (for controlled substances);
- Assessment of Annual Needs (AAN) (for list I chemicals); [3]
- Individual Manufacturing Quota (for controlled substances and list I chemicals);
- Procurement Quota (for controlled substances and list I chemicals); and
- Import Quota (for list I chemicals).

Through this final rule, DEA will add these new sections to the regulations that will define the types of quotas for controlled substances in schedules I and II and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Also, DEA will change the regulations to stay up to date with modern technology by 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 the NPRM, DEA introduced the SUPPORT Act [4] and informed the public of the new legislation as it applies to DEA. With this final rule, DEA is updating the current regulations to comply with this new law. The SUPPORT Act now gives the Administrator, by way of delegation from the Attorney General, the authority to establish the APQ, individual manufacturing quotas, and procurement quotas in terms of pharmaceutical dosage-form prepared from or containing a controlled substance. The SUPPORT Act also changed the deadline for DEA 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, DEA must consult with the Department of Health and Human Services (HHS) on rates of overdose deaths, rates of abuse, and the impacts on overall public health related to the covered controlled substances. DEA may also take into consideration other sources of information deemed 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

DEA proposed to change the regulations to require certification of procurement quota in the NPRM. This final rule changes the regulations to provide that both manufacturers and distributors selling to a manufacturer will be required to obtain certification of the buyer's quota when an order is placed. This is implemented by changing the words ''importer,'' ''manufacturer,'' and ''bulk manufacturer'' to ''registrant.''

4. Inventory Allowances

In the NPRM, DEA proposed reductions to the acceptable inventory allowance, the amount of inventory at which quota would be suspended, and when DEA would grant a request for additional quota. DEA also proposed the establishment of inventory allowances for procurement quota for controlled substances. Due to comments and concerns received from the NPRM, DEA will be implementing different provisions in this final rule. Instead of the proposed amendments, DEA will:

- Decrease the inventory allowance issued by DEA for individual manufacturing quotas from 50 percent to 40 percent;
- Establish an inventory allowance issued by DEA for all procurement quotas, except liquid injectable products, at 35 percent, instead of the proposed 30 percent;
- Establish an inventory allowance issued by DEA for liquid injectable dosage-form procurement quotas at 50 percent, instead of the proposed 30 percent;
- Suspend individual manufacturing quota issued by DEA if a registrant's inventory exceeds 55 percent (reduced from 65 percent) of the registrant's estimated net disposal;
- Suspend procurement quota issued by DEA, except that for liquid injectable dosage-forms, if a registrant's inventory exceeds 50 percent of the registrant's estimated net disposal;
- Suspend liquid injectable dosage-form procurement quota issued by DEA if a registrant's inventory exceeds 65 percent of the registrant's estimated net disposal;
- Review request to determine if request for additional individual manufacturing quota by registrant should be granted when inventory is less than 30 percent (reduced from 40 percent) of the registrant's estimated net disposal;
- Review request to determine if request for additional procurement quota, except for liquid injectable dosage-forms, by registrant should be granted when inventory is less than 25 percent of the registrant's estimated net disposal;

and

- Review for request to determine if request for additional procurement quota for liquid injectable dosage-forms by registrant should be granted when inventory is less than 40 percent of the registrant's estimated net disposal.

5. Subcategories for Quotas

DEA proposed 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

In the NPRM, DEA proposed changes to 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. This final rule will implement the following new deadlines:

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

[3] 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.

[4] The SUPPORT for Patients and Communities Act, Public Law 115–271.

II. Discussion of Comments

DEA received 258 comments. Many comments addressed multiple topics of the NPRM. Commenters also addressed the changes made to the CSA by the SUPPORT Act, which Congress put into effect.

A. Defining Types of Quota and Filing To Abandon Quota

Issue: DEA received nine comments regarding the definitions and types of quotas and three comments regarding the updates for the process of abandoning quota. Comments received from several organizations stated that they support DEA's changes to its regulations introducing and defining the types of quota. One company justified its support stating that DEA's change serves to educate and inform those not familiar with the quota process.

While one pharmaceutical company had no objections to the definitions of the types of quotas, they stated that DEA should consider creating a distinct sixth type of quota: procurement quota utilized to import concentrate of poppy straw (CPS) or raw opium that should remain independent of any inventory restraints. This company further suggested that the 30 percent inventory range would be too restrictive and would risk supply disruption from one year to the next as it believes a higher inventory range is necessary both to create a buffer in the first quarter of a new year and to avoid disruption in the event of delivery delays involving United States Customs and Border Protection.

Many commenters also fully supported the formalization of the quota abandonments with the UN Reporting and Quota Section in the online Quota Management System. One commenter explained its support by stating that these changes will allow for automation of the abandonment/surrender process. One pharmaceutical company recommended DEA take advantage of the opportunity provided by modifying the quota regulations to include the same provision in the section for procurement quota. This same company believes this will better reflect current practice as both manufacturing and procurement quota utilize the same mechanism for surrendering unnecessary quota.

DEA Response: DEA is committed to taking into consideration any changes in market dynamics that may require allocation of individual manufacturer's quotas or revisions to the APQ. DEA is also committed to ensuring that quotas are set in a way as to grant manufacturers the ability to provide controlled substances to meet the demands of the legitimate medical, scientific, and export needs of the United States. It has been DEA's long-standing intent to improve the process of setting the annual quota while ensuring an adequate supply of controlled substances is available for legitimate needs.

A sixth category of procurement quota for the acquisition of CPS or raw opium imported in compliance with DEA regulations for the purpose of removing restraints on inventory allowances whose aims are to ensure availability is unnecessary. First, there are a very small number of entities (<10) registered in the United States to procure narcotic raw materials (NRMs) for processing into schedule II controlled substances and these companies have a long history of obtaining the NRM necessary to meeting the estimated needs of the United States.

In addition, there are inventory allowances built into multiple quotas that DEA grants to those who produce active pharmaceutical ingredients (APIs) derived from NRM. Prior to implementing this rule, DEA granted a 50 percent inventory allowance to registered bulk manufacturers that procure NRM for the API they produce each year, pursuant to a DEA issued manufacturing quota. That total quantity (*i.e.,* 150 percent of estimated net disposals minus any existing inventory on hand) is then utilized to calculate the amount of procurement quota that the bulk manufacturer requires to make the API for which a manufacturing quota was granted. In those instances, DEA assesses the amount of NRM necessary to produce the above-mentioned API and then calculates an inventory allowance on the amount of NRM required. Both inventory allowances ensure that there are adequate amounts in the drug supply to meet legitimate needs. Finally, while appropriate safeguards are currently in place, the potential for diversion still exists for NRM from excessive stockpiling of NRM due to changes in legitimate need of the end products which may reduce the need to manufacture.

In addition, DEA appreciates the comments received in support of the process to formalize quota abandonments. Formalizing the procedure to abandon quota is simply a codification of existing DEA practice. While this formalization will have no economic costs or benefits, DEA believes there are benefits to accurately codifying existing practices. As such, this final rule will enhance efficiency and improve the process to abandon the right to manufacture all or any part of both individual manufacturing and procurement quotas.

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

DEA received nine comments about the changes imposed by the SUPPORT Act. As stated in the NPRM, these updates to DEA's regulations are being implemented to comply with the amendments made to the CSA by the SUPPORT Act. While DEA does not have the authority to change what has been established by Congress, DEA will still discuss the comments below.

The Establishment of Quotas in Terms of Pharmaceutical Dosage-Forms

Issue: By way of the SUPPORT Act, DEA's regulations were changed to allow quotas to be established in terms of pharmaceutical dosage-forms. In the NPRM, DEA explained that the discretionary authority granted to DEA to establish APQ, procurement, and individual manufacturing quotas in terms of pharmaceutical dosage-forms would not be used at this moment. The comments received addressed DEA's decision to delay the use of this discretionary authority, with some disagreeing with DEA's decision not to use the authority at this moment. Some suggested that DEA note the distinction between manufacturing injectables (which are given to in-patients) versus oral solid dosage-forms. These commenters opined that setting the quotas in terms of pharmaceutical dosage-forms will help address nationwide shortages of injectables.

DEA Response: In the matter of DEA's decision not to use the discretionary authority at this present time, DEA emphasizes that the SUPPORT Act states that DEA (by delegation from the Attorney General) *may* establish the quotas in terms of pharmaceutical dosage-forms prepared from or containing the controlled substance when it is determined that these such establishments will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. This is not an express requirement to grant quotas in that manner, however it does grant the authority to do so. If DEA were to exercise its discretionary authority, it would be implemented at the procurement quota level, which would have a more direct impact on the availability of specific dosage-forms for legitimate medical need. During the analysis and review process for individual procurement quotas, DEA examines in detail the supporting documentation provided by dosage-form manufacturers to distinguish the type of

product to be manufactured. This includes the type of formulation (solid, oral liquid, or liquid injectable) and dosage strengths, which become part of the factors considered in estimating an appropriate procurement quota accordingly.

Currently, all liquid injectable products receive 50 percent inventory allowance. DEA will continue issuing the inventory allowance for these dosage-forms at the same percentage because there are significantly fewer dosage-form manufacturers of injectable products. DEA is aware that quality or production problems related to sterility issues for injectable products have led to higher likelihood of recalls of such products. DEA believes that these products, when administered in controlled clinical and hospital settings, decrease the likelihood of diversion due to higher levels of oversight. Furthermore, the ongoing Coronavirus Disease of 2019 (COVID–19) public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, has made it necessary for DEA to consider both the potential for diversion, as well as the anticipated increase in demand for injectable products used to treat patients suffering from COVID–19. Due to COVID–19, DEA had to issue an adjustment to the established APQ for 2020 [5] for selected controlled substances involved in manufacturing injectable drug products for COVID–19 treatment. The adjustment of APQ allowed DEA to adjust the individual procurement quotas and related inventory allowances for injectable products. While DEA declines to establish APQ in terms of pharmaceutical dosage-forms at this time, DEA has decided to implement a separate inventory allowance for liquid injectable dosage-forms. This will be discussed later in the document.

Deadline To Fix Individual Manufacturing Quotas

Issue: DEA also received a comment from an individual regarding the date change for fixing the individual manufacturing quota. The commenter asked, ''how and why did DEA have Congress change the date to December?''

DEA Response: The SUPPORT Act revised the CSA by issuing a mandatory change to the date by which DEA must fix individual manufacturing quotas to ''on or before December 1.'' Because Congress issued this change, DEA must follow this law and implement the new date into DEA's regulations.

Estimation of Diversion

Issue: DEA received comments that were in support of DEA providing explanations for the increase in quotas but there was concern with the reliability of the data available for abuse (manufactured products vs. illicit substances). Commenters suggested DEA consider a broader range of data when calculating diversion by considering sources that are already available, pushing for even better data sources for future years, and adopting a uniform method of accounting for diversion. They stated that DEA should exhaust other means of curtailing illegitimate sales, abuse, and diversion before looking to quota as a prevention tool. Companies suggested that DEA differentiate among specific dosage-forms and target the dosage-forms that are subject to abuse to encourage the use of dosage-forms that are less prone to diversion. They stated that there needs to be an objective evaluation considering the exclusion of injectable dosage-forms from quota reductions. Commenters also suggested that DEA account for over-prescribing as a part of the diversion analysis by considering data and best practices of healthcare providers and by collecting information from the Prescription Drug Takeback Programs and similar sources. Further, they suggested that DEA use the medical professionals' ''best practices'' to help account for overprescribing at the physician level and incorporate data collection into the Prescription Drug Takeback Program to account for overprescribing at the patient level.

DEA Response: The Food and Drug Administration (FDA) is responsible for approving drug products and can require a manufacturer to submit a Risk Evaluation and Mitigation Strategy (commonly referred to by the industry as a REMS), which is a risk management plan that uses tools beyond the prescribing information to ensure that the benefits of certain drugs outweigh their risks. Certain REMS may include strategies to prevent, monitor, and manage specific risks resulting from inappropriate diversion and abuse of products. The information provided from a REMS informs DEA of potential abuse liability issues that may lead to diversion. If a manufacturer believes that its product is potentially being diverted or abused within the supply chain based on customer orders received that raise suspicion, it is responsible for notifying DEA by sending a report to the agency through DEA's Suspicious Orders Reporting System (SORS). *See* 21 U.S.C. 802(57), 21 CFR 1301.74(b). Once notified, DEA will alert the field office regarding the situation. The diverted amount will then become a factor when processing the quota for the current year and an adjustment to the amount of quota granted will be made indicating the diverted amount. DEA also acquires data from HHS, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and the States to determine reliable rates of overdose deaths, abuse, and overall public health impact as a factor of diversion to make appropriate quota reductions for each of the covered controlled substances. DEA conducts diversion analysis for the five covered controlled substances and the remaining drugs not considered a ''covered controlled substance'' by the SUPPORT Act.

C. Procurement Quota Certification

Issue: DEA received three comments from industry expressing concern about DEA's change to the regulations to ensure that both manufacturers and distributors selling to a manufacturer are required to obtain certification of a buyer's quota for the request of schedule I and II controlled substances, as well as list I chemicals when the buyer is a manufacturer.

One pharmaceutical company felt that the proposed changes seemed too broad. This company did not question the requirement to provide a certificate of quota when purchasing from a distributor or a manufacturer. However, the company stated that the specific wording of the proposed regulation may be overly broad. According to the company, as worded, the proposed regulation would require a certificate for orders from any registrant. The company believed this wording could be construed to apply to reference standards from analytical sites or complaint samples and certificates should not be required when manufacturers order from pharmacists, health care practitioners, or analytical laboratories.

DEA Response: By requiring that any manufacturing registrant provide a certification of quota before receiving any quantity of a schedule I or II controlled substance or list I chemical,

[5] DEA published *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020* in the **Federal Register**, 84 FR 66014, on December 2, 2019. In response to COVID–19, DEA published *Adjustments to Aggregate Production Quotas for Certain Schedule II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine and Pseudoephedrine for 2020, in Response to the Coronavirus Disease 2019 Public Health Emergency* in the **Federal Register**, 85 FR on April 10, 2020, to address any potential shortages that may occur during the public health emergency.

DEA is better able to maintain the closed distribution system and provide a more accurate calculation of the APQ for the United States per 21 CFR 1303.12(f). 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 and to maintain a closed distribution system for schedule I and II controlled substances and list I chemicals, DEA requires any registrant to whom a procurement quota has been issued to follow the laws and regulations of the CSA and Code of Federal Regulations (CFR). One method of doing this is to require all registrants sending material to a manufacturer to verify proof of quota through certification, which ensures that purchases do not exceed the procurement quota set by DEA.

D. Inventory Allowances

There were 23 in-scope comments that discussed the proposed reductions of inventory allowances. Many of the comments discussed each reduction separately. Furthermore, many of the comments from companies asked DEA to clarify which registrants the various reductions would be applicable to, due to the current placement of the regulations in the CFR. In general, commenters objected because of the economic impact to their business and the inability to ensure adequate supply. Commenters contend that DEA should not use a one-size fits all method for inventory and limiting additional quota because it will create a constant state of backorder and market shortage. A commenter proposed a grace period of at least one year before making the reductions effective.

Reduction and Establishment of New Inventory Allowances for Individual Manufacturing Quotas and Procurement Quotas From 50 Percent to 30 Percent

Issue: Commenters objected to the reduction/establishment of inventory allowance stating that the lower amount of inventory allowance combined with the new date for individual manufacturing and procurement quotas may cause a shortage. A commenter stated that DEA's data on theft and loss at the manufacturing level show that the security of the products exceeds the security at the retail level. Commenters asked DEA to name studies showing that increased inventory at manufacturing facilities correlates to an increase in diversion or abuse. Further, many commenters allege that the proposed changes will create incentives that may increase opportunities for diversion and conveyed that DEA should assess whether reducing quotas would create shortages and jeopardize patient care. Commenters also emphasized that DEA needs to evaluate carefully the legitimate supply chain's full throughput time to bring medicines to market, so that patient care is not jeopardized.

Many commenters conveyed that the proposed 30 percent inventory allowance for procurement quota is overly restrictive and such a reduction would cause inefficiencies and shortages. Furthermore, it was commonly said that the reduction would hinder the ability to provide consistent care to patients, and it may result in potential shortages in hospitals and clinics and severely impact those patients managing an opioid dependence. They mentioned that there was already a shortage in acute care facilities.

Commenters suggested that DEA should give further consideration to the potential for supply disruptions that would result from decreasing the inventory allowance for API bulk manufacturers from 50 percent to 30 percent. It risks imposing significant costs and inefficiencies on the production of authorized bulk drug substances without corresponding benefits.

Commenters also stated that DEA's claim that the reductions will not increase the likelihood of shortages because there has been an increase in the number of manufacturers is too broad. Manufacturers of approved drug products can only use the approved suppliers that they named in their FDA-approved applications. Typically, manufacturers of approved drug products only have one or two suppliers that they can use. Commenters also said that DEA misstated data when claiming that the proposed reduction should not affect manufacturers. Three manufacturers supply over 90 percent of the API for codeine, hydrocodone, oxycodone, and morphine; therefore, there are fewer API producers in 2019 than 2007. API from one of the three primary manufacturers is not interchangeable across dosage-form manufacturers without FDA approval. In respect to procurement quotas, commenters alleged that the reduction to 30 percent would leave no margin for recovery. They also stated that the reduction to 30 percent will result in unnecessary restraints on API manufacturers.

Multiple commenters want DEA to keep the existing allowances of 50 percent for bulk manufacturers and state DEA should consider possible alternatives to reduce the additional cost burdens and risks of shortages and diversion. Commenters frequently claimed that DEA did not provide data to support its claim that the reduction for individual manufacturing quota inventory allowances would reduce the potential for diversion, especially because commenters believe that the material is not desirable at the bulk manufacturing level. They also mentioned that the reductions will substantially increase the cost of bulk manufacturing, will increase the risk of shortages of API supplies, and may increase the risk of diversion. In respect to bulk and dosage-form manufacturers, commenters assert the reduction could be harmful to patients and will potentially lead to market shortages of injectable medicines needed for critical medical care. Commenters also alleged that constricting inventories at pharmaceutical manufacturers or in institutional settings will have little impact on curbing diversion. Many commenters conveyed the want for DEA to publicly provide data that validates and supports the need for any reductions in inventory allowances.

Commenters asked for clarification on whether the 30 percent inventory allowance would be applicable to dosage-form manufacturers, due to its placement in the CFR. They suggested that if DEA applies the inventory allowance to dosage-form manufacturers, then it only be reduced for domestic consumption and not for exports. They also suggested that dosage-form manufacturers be allowed to calculate their allowance using the estimate of the current year's sales and bulk manufacturers calculate their allowance using the average of the preceding calendar year and the current calendar year. Several commenters mentioned that year-end inventory is not indicative of how much inventory they require throughout the year because a manufacturer's inventories are lowest at year-end as they have sold down their stock and await the granting of quota for the next calendar year. Commenters opined that the reduction of inventory from 50 to 30 percent is counter intuitive because more quota is needed due to the additional waste that would be caused from the increased number of manufacturing campaigns that would be required. Furthermore, they alleged that DEA will experience an increase in the amount of quota requests due to this reduction.

A few commenters worried that the reductions may not have a significant effect on a provider's decision to prescribe. They explained that if DEA

limits production but providers continue to prescribe at the same rate, the issue will not have been addressed. Instead, costs may rise as supply decreases due to the reduction in production. One organization recommended that DEA pay greater attention to evidence-based research on appropriate prescribing and provide greater education for physicians and patients based on this research.

DEA Response: DEA has been working to prevent and to decrease diversion for years. DEA uses Composite Risk Management [6] to assess the risk of diversion at all levels of the supply chain. While diversion at the manufacturing level may be low, DEA emphasizes that there is still the potential for diversion to occur at that level. When setting quotas for the year, DEA assesses whether they would cause a shortage or jeopardize patient care. Also, DEA uses several sources of data to evaluate legitimate supply chains, such as Automated Reports and Consolidated Ordering System (ARCOS), IQVIA, and manufacturers' own data. The quotas granted are a composite of estimated requirements for legitimate medical, scientific, and export needs, manufacturing yields, and inventory allowance to begin to meet the next year's legitimate needs while reducing the risk of diversion.

While there may not be published studies showing that an increase in inventory at manufacturing facilities correlates to an increase in diversion or abuse, a fundamental principle governing policy discussions and DEA rulemaking, especially during the height of an opioid epidemic, is that DEA must strike a balance between ensuring an adequate and uninterrupted supply of controlled substances while preventing an oversupply which increases the risk of diversion. DEA does have internal information that it takes into consideration when granting individual quotas at that time. Review of internal actions of enforcement measures taken over the years have shown thefts at the manufacturing level and the public health impact in the surrounding communities as a result of those thefts. There have been occurrences of thefts of bulk API and thefts of finished dosage-forms from manufacturers' production facilities, and these products were sold into the community. Overproduction of API and finished dosage-forms can lead to high inventories and questionable high pressure marketing practices. DEA notes that manufacturers cannot sell more than their granted quotas plus previous year inventories but that high inventories could allow small thefts to go unnoticed from production facilities.

DEA understands the worries of commenters regarding the reduction of inventory allowances possibly jeopardizing patient care; however, DEA wants to stress that the management of patient care is not controlled by way of quotas. While DEA is aware of the opioid crisis, the issuance of quotas and accompanying inventory allowances are not directly involved with the management and care of patients. The issuance of quotas does not regulate the physician's practice of medicine. Therefore, inventory allowance reductions would not hinder a physician's ability to provide consistent care to patients, as voiced by commenters. DEA does not regulate a provider's prescription methods so long as there is a legitimate medical need. While the inventory allowance reductions apply to what manufacturers hold in inventory to begin dispositions for the next calendar year, they can utilize the inventory in the event that there is a shortage or there is an issue in the supply chain during manufacturing to prevent disruption to the legitimate supply chain. DEA does not control the way a company conducts business, as business decisions on production and supply chain management are done on the company level. DEA notes that it is HHS' area of responsibility to provide Evidence Based Medicine as guidance to providers and the public.

While there are a few commenters who have shared the concern that DEA's reduction of inventory will not have much of an effect on overprescribing, DEA believes that this is one of many factors being implemented at the federal level that will have an impact on decreasing overdoses due to prescription medications. DEA also notes that there has been a decline in the prescribing of schedule II opioid prescriptions since 2016 as many of those other factors have been implemented at Federal and state levels. As shown by IQVIA and demonstrated by a review of CMS' data, prescribing rates for opioids have decreased 44 percent since 2016 without a significant increase in price.[7]

While commenters opined that DEA is being too broad in stating that the increase in manufacturers will offset the chances of a shortage, DEA did not generalize or understate the concept of there being enough dosage-form manufacturers so as not to increase the chances of shortages. Most dosage-form companies may have one main API supplier to ensure a continuous supply of product to meet patient need and mitigate the impact of potential shortage of the product. However, many dosage-form manufacturers have named a second supplier in FDA-approved applications and can request API from either supplier to meet legitimate patient need. While a secondary supplier is not required for New Drug Application or Abbreviated New Drug Application approval, DEA has noted that most requests for product development quota include a second supplier of API. DEA reviewed FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (hereinafter ''Orange Book'') to determine the number of approved products and then matched those products to DEA registered manufacturers. In the event that there is an increase in a company's risk of shortage of supplies, the applicant may file for additional quota at any time during the calendar year. During that time, the application, along with its supporting documents, will be reviewed and if needed, an adjustment to the quota will be granted. Currently, DEA has already been applying the reduced inventory allowance of 30 percent to fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone.

DEA has decided to reduce the individual manufacturing inventory allowance for all controlled substances and list I chemicals to 40 percent and the procurement inventory allowance for controlled substances and list I chemicals to 35 percent, with the exception of liquid injectable dosage-forms. For liquid injectable dosage-forms, the procurement quota inventory allowance will be set at 50 percent. The inventory allowance requires that manufacturers maintain their inventory allowance based on estimated net disposals for the calendar year. It is based on what the manufacturer estimates their disposal to be and not the actual disposal at a specific point in time. DEA requires year-end reporting that demonstrates the manufacturer ended the year with the correct inventory allowance percentage. The inventory allowance does not affect the amount of a net-disposition quota granted to a manufacturer. DEA grants the quota necessary to be able to continue to meet legitimate patient needs based on the historical and

[6] For purposes of this document, Composite Risk Management is a decision making process used to mitigate risk associated with all hazardous equipment or impact to the mission.

[7] The Centers for Medicare & Medicaid Services, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.html,* accessed 6/15/2020.

estimated future data including changes in market share and FDA guidance. DEA grants an inventory allowance to the manufacturer to begin disposition for the next year; however, this may also be used to meet the unanticipated market changes in the current year. API and/or finished dosage-forms in reserve are usually held for unanticipated market changes, manufacturing issues, and to begin the next year. As such, DEA's lowering of the inventory allowance as written in the regulations should not affect a manufacturer's sales. While diversion may not occur with high frequency at the manufacturing level, it occurs and can impact public health in the surrounding community. Since 2004, DEA has sought to address risk of diversion at the apex of the distribution system (*i.e.,* manufacturing level). Granting higher inventory based on sales provides more incentive to push more material further downstream as no entities want to maintain higher levels of stocks than what they deem necessary due to storage and monetary constraints, the fact is that profit is only generated through sales of the product and not production. DEA previously demonstrated that bulk manufacturers were only holding 39 percent inventory. It is for these reasons, and the fact that historically manufacturers have not held 50 percent inventory levels, that a lower inventory at the manufacturer level should be implemented. Also, the lower inventory allowances can potentially reduce diversion throughout the supply chain.

DEA notes that bulk manufacturers have not always utilized all of their granted quota to manufacture API and have consistently held less than 50 percent inventory. The year-end sales and inventory provides information on how a registrant is doing in the market and provides a starting point when assessing requests for revisions to current quotas. If a bulk manufacturer's sales to customers are more robust than anticipated, inventories will be low and DEA will grant a quota adjustment to ensure that the customers can receive material up to their individually granted procurement quota. If inventories are high, it indicates that the company has not sold as much API to their customers as they forecasted, and therefore the higher inventory allowance is unnecessary.

Over the last decade, DEA has implemented a 30 percent inventory allowance for opioid related procurement quotas. This inventory level has not caused issues due to quota being set at the legitimate patient level. DEA notes that over the last four years, after reviewing the applicants' year-end reports and other data reporting sites, dosage-form manufacturers have reported higher than average inventories of opioids as prescriptions for opioids have declined significantly due to the implementation of CDC guidelines and DEA enforcement activities. The data show that manufacturers only acquired 72.7 percent of fentanyl, 73.9 percent of hydrocodone, 56.7 percent of hydromorphone, 79.3 percent of oxycodone, and 73 percent of oxymorphone from the quotas granted to them by DEA. As prescription rates have fallen, the data show that the material has not sold, but has been moved to their inventory, thereby significantly increasing inventory levels above that which are medically necessary on an annual basis. DEA has found that over the past years, inventory levels have averaged 72 percent for fentanyl, 36.9 percent for hydrocodone, 57 percent for hydromorphone, 36.3 percent for oxycodone, and 61.0 percent for oxymorphone, while companies have met legitimate medical needs. The inventory levels for fentanyl, hydromorphone, and oxymorphone include product development efforts as manufacturers seek FDA approval of abuse-deterrent formulations. DEA has considered the comments from manufacturers and will set the inventory allowance for procurement quotas at 35 percent for all dosage-forms, except liquid injectable dosage-forms. Liquid injectable dosage-forms will receive a 50 percent inventory allowance for procurement quotas.

To determine the amount for the procurement quota inventory allowance, DEA has reviewed the Orange Book and internal quota applications. These reviews led DEA to determine that, generally, there are more dosage-form manufacturers than bulk manufacturers, and as such, an individual dosage-form manufacturer does not need as great of an inventory as a bulk manufacturer. Therefore, the procurement quota inventory allowance should be lower than the manufacturing quota inventory allowance. DEA has considered new data from FDA on new approved drug applications and internal quota applications that showed that manufacturers are producing or seeking to produce more extended-release and/or abuse-deterrent dosage-form products that require additional manufacturing time compared to immediate-release drug products. Therefore, DEA has determined that a procurement quota inventory allowance of 35 percent provides the necessary manufacturing lead time to prevent shortages or gaps in the supply chain. DEA believes this increase in inventory allowance from the proposed amount will provide the necessary time for all manufacturers to complete their manufacturing activities and place their products in the supply chain for legitimate need.

However, DEA will not be reducing the inventory allowance for procurement quotas of the liquid injectable dosage-forms. After further review of comments, DEA acknowledges that for injectable products, there are significant manufacturing issues when manufacturers fail to comply with FDA's Current Good Manufacturing Practice (cGMP) regulations. Additionally, DEA has realized that the lower number of manufacturers, coupled with the higher likelihood of recalls due to cGMP violations, requires the higher inventory allowance for dosage-form manufacturers of injectable products. In light of COVID–19, DEA also acknowledges that declining to reduce inventory allowances for these liquid injectable dosage-forms ensures that manufacturers are able to address and endure potential circumstances of nationwide shortages. The liquid injectable dosage-form procurement quotas will be set at 50 percent.

DEA read the comments regarding the limited number of bulk manufacturers supplying the market. DEA and international drug control treaty obligations control the number of bulk manufacturers who supply the dosage-form manufacturers. While the number of bulk manufacturers may fluctuate, over the past 10 years there have been 10 bulk manufacturers that have supplied the opioid market, with three of them supplying the majority of the requirements. DEA analyzed the data and determined that the bulk manufacturers did not utilize the entire quota granted to them each year. On average, the companies manufactured only 85.2 percent of the fentanyl, 61.7 percent of the hydrocodone, 79.1 percent of the hydromorphone, 78.3 percent of the oxycodone, and 69 percent of the oxymorphone quota granted by DEA. These bulk manufacturers have maintained an average inventory of 39 percent and have continually met the legitimate medical need before and during the opioid crisis. DEA has noted that dosage-form manufacturers are now validating a second API supplier as a precautionary measure. As dosage-form manufacturers continue to seek FDA approval for new drug products containing controlled substances, DEA continues to grant product development quotas to allow for qualification of two suppliers and grants quota to bulk

manufacturers to support this qualification effort.

DEA notes that the proposed regulations for procurement quota were added to the only regulation in the CFR for inventory allowance, which is located under the subheading of ''Individual Manufacturing Quotas.'' To lessen the chance of causing confusion to registrants, DEA has chosen to move the procurement quota inventory allowance regulations. As such, DEA will create new regulations to address the inventory allowance amounts for procurement quotas.

Reduction of Amount at Which Quota Would Be Suspended to 45 Percent

Issue: Many commenters explained that the reduction of the level at which quota will be suspended would require manufacturers to run smaller campaigns. They argue that this will increase the number of campaigns required to produce the same amount of product in a given year. Commenters also noted that the proposed reduced suspension amount would interfere with product supply. Commenters stated that the reduction in the suspension threshold would increase substantially the cost of bulk manufacturing and would increase the risk of shortages of API supplies and may increase the risk of diversion. They also conveyed that reducing the trigger for suspending bulk API manufacturing quota would decrease significantly the efficiency and increase the costs of bulk API manufacturers.

Commenters asked for clarification on whether the quota suspension will apply to dosage-form manufacturers and suggested that DEA clarify that it is not applicable to bulk manufacturers. They suggested that DEA apply the suspension threshold at year-end so that the inventory level is only above the trigger level briefly. Commenters conveyed that this would ensure that the suspension does not interrupt timely and efficient processing of bulk API. As an alternative option, commenters suggested that DEA clarify the definition of inventory so that it does not include material of a basic class that is not yet in finished form suitable or intended for sale or provide a more effective procedure for issuing exceptions to the quota suspension threshold.

Commenters explained that lowering the inventory ceiling to 45 percent would disrupt manufacturing operations and cause significant cost increases because this will require smaller, more frequent campaigns. They argue that these would generally decrease efficiency and potentially increase the amount of product wasted during the required cleaning of equipment between each additional campaign. Additionally, there may also be an increase in the generation of hazardous waste because of these additional campaigns. One commenter specifically stated that the reduction is too restrictive for lower volume APIs. Also, the reduction may potentially short the finished dosage-form markets by greatly impacting lead-times to get the material to customers, and it would force customers to wait an extra four to five months.

It was suggested that DEA evaluate the data throughout the year and not just the year-end data. Furthermore, DEA received suggestions that the ceiling should be set at 55 percent instead, so that drug shortages do not occur. Some commenters suggested the reduction in allowances should only apply to dosage-form manufacturers by lowering the inventory allowance for those manufacturers to 40 percent and that DEA specify that this does not apply to bulk API manufacturers.

DEA Response: DEA has been working to prevent and detect diversion for years. DEA grants the quota to companies, and they can use the quota for various purposes within the scope of their requested business activity. The companies and DEA calculate inventory allowance suspension is calculated based on the companies' estimated net-disposal for the calendar year. If the companies' dispositions are robust as estimated, the company will likely not meet the suspension percentage. If the companies' dispositions are not meeting the company's estimations as the calendar year progresses, the company will likely meet the suspension percentage and need to discontinue manufacturing until net disposition volume increases to the extent that the estimated inventory is below the inventory allowance suspension percentage. Companies can and do apply for quota revisions at any time during the calendar year. DEA grants quota to meet estimated legitimate patient need and provide an inventory allowance based for the next calendar year based on net dispositions. A company requesting quota in excess of their estimated market portion necessary to meet legitimate medical need and relevant inventory allowance, as determined by the company's supporting documentation, IQVIA data and FDA guidance, which are among the list of factors [8] DEA considers, will not receive the requested quota; however, the quota granted will be sufficient to meet legitimate need and inventory allowance. DEA has noted instances where (1) bulk manufacturers have not utilized all of their granted quota to manufacture API and have consistently held less than 50 percent in inventory; and (2) dosage-form manufacturers have requested additional quota while not distributing finished dosage-forms from their inventory to the market to cause an artificial drug shortage.

DEA wants to clarify that this final rule will be applicable to both bulk manufacturers and dosage-form manufacturers. The amount at which quota will be suspended will differ for individual manufacturing quota and procurement quota. In reviewing FDA's Orange Book by controlled substance, it is apparent the ratio of dosage-form manufacturers to bulk manufacturers is heavily weighted on dosage-form manufacturers many of whom make generic drug products that are therapeutically equivalent to other drug products for treating patients. Therefore, the dosage-form manufacturers' quota suspension level will be lower.

While DEA understands the concerns brought forth by the registrants, DEA will continue to grant quota based on legitimate need. The reduction of the suspension of quota remains based on estimated dispositions for the calendar year. This suspension does not interfere in normal campaign batches unless a company's net dispositions decrease markedly from the company's own estimated dispositions provided to DEA at the time of their quota application. A manufacturer may complete their campaigns for the calendar year based on estimated net dispositions. If dispositions are not as robust as the company predicted, then any unused quota will be suspended until dispositions are estimated to leave the company with the appropriate inventory levels at the end of the year. If the company is in the middle of a campaign batch when they realize they will exceed their estimated inventory allowance, the company can apply and request with good cause to complete the batch before suspending manufacturing activities until sales/dispositions bring the estimated inventory level to the correct percentage. *See* 1303.24(b). DEA does not control the way a company conducts business, as business decisions on production and supply chain management are done on the company level.

However, as this relates to finished dosage form manufacturers, a company who requests quota revisions because of poor business decisions, such as manufacturing unnecessary dosage-forms or strength based on estimated legitimate need for the substance,

[8] 21 CFR 1303.23 and 1315.23.

provides DEA an opportunity to grant quota based on specific FDA approved dosage-forms as authorized by the SUPPORT Act. For example, at the beginning of the COVID–19 pandemic, hospitals declared drug shortages of specific treatment drugs. DEA estimated that it granted sufficient quota to manufacturers for COVID–19 treatment drugs. DEA received additional detailed inventory information from the dosage-form manufacturers and determined that the manufacturers did not have the correct dosage forms and strengths available for hospitals to utilize immediately. Therefore, DEA granted additional quota specifically to meet the dosage forms and strengths hospitals required to treat COVID–19 patients.

Reduction of Amount at Which Requests of Additional Quota Would Be Granted to 20 Percent

Issue: Commenters requested clarification as to whether the 20 percent rule will apply to dosage-form manufacturers who use procurement quota due to its proposed placement within the CFR and because historically, DEA has said it does not apply. Many commenters opined that waiting until 20 percent to grant additional quota is too low of a threshold and would lead to supply disruption if applied to dosage-form manufacturers. The lower amount also would not allow manufacturers to be ''flexible to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications.'' Commenters went on to explain that 20 percent equals 10 weeks of inventory but production lead times are typically greater than 10 weeks. According to these commenters, waiting until there is less than 10 weeks of inventory will lead to market shortages and disrupt patient care.

The commenters went on to state that the time that it takes DEA to review quota applications is longer than six to eight weeks and granting more quota at the 20 percent mark would possibly mean depleting stock before DEA finishes reviewing. In particular, Teva stated that 15 of 36 (42 percent) of Teva's 2019 quota adjustment applications took nine weeks or longer for DEA to respond, and seven of 36 applications (19 percent) took 13–15 weeks for response. Response times of 10 or more weeks are unacceptable under normal circumstances and will exacerbate out of stock issues with reduced inventory allowances. All of this attributes to the increased potential for shortages and delays of medicine.

DEA Response: When establishing quota, DEA takes into account the current and previous year's sales and uses historical data to justify the need. DEA is not mandating that manufacturers need to have an inventory of less than 30 percent (for individual manufacturing quota) or 25 percent (for procurement quota) before applying for additional quota. A registrant may file for additional quota at any time during the calendar year. During that time, DEA will review the application and, if needed, will grant an adjustment to the quota. Registrants already apply for quota adjustments per their needs, and this will not change the current application process.

DEA acknowledges that quota processing times can vary throughout the year with some outliers. A quota processing time analysis was conducted for quota requests processed in 2019. The analysis showed a quota processing time range of four to eight weeks. When initial quotas were not factored into the calculation, the average time to process quotas was approximately 37 calendar days (estimate typical provided to registrants is four to six weeks). However, between October and December, when concomitant processing of initial and revised quota applications occur, it took an average of 57 calendar days (estimate provided to registrants is six to eight weeks). Quota processing delays can be caused by various circumstances such as, but not limited to, incomplete, poorly written, and mislabeled applications; pages of extraneous information; and extremely busy times of the year; however, inventory has historically been adequate to cover these delays and other situations.

Additionally, as previously stated, DEA has found that a portion of the procurement quota granted for some substances has not been utilized; therefore, formally establishing an inventory allowance five percent higher than that which had already been implemented should not cause more quota applications to be submitted or subsequent delays in processing. In fact, DEA showed that manufacturers have not been selling the material they have procured against their quota and instead have been adding it to their inventory to await changes in patient need.

DEA's actions in response to COVID–19 prove that even with lower inventory levels, DEA is able to be flexible to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications, despite the concerns of commenters. During the COVID–19 pandemic, DEA, FDA, other federal agencies, private partnerships, and others in the pharmaceutical industry—specifically the injectable dosage-form manufacturers—were in continuous dialogue regarding the availability of controlled substances to be used in the treatment of ventilator patients. Despite the injectable dosage-form manufacturers having almost a full year's worth of inventory, based on previous year's sales, plus current year quota on hand, hospitals reported shortages almost immediately as soon as the treatment protocols were determined. DEA soon determined that despite the sheer quantity of available inventory at the dosage-form manufacturing level, the specific formulations hospitals required were not available. In order for DEA to respond to hospitals reporting shortages of injectable products for treatment of ventilator patients during the COVID–19 pandemic, DEA and the injectable manufacturers entered into continuous dialogue to meet hospitals' demand for injectable products. With proper supporting documentation, DEA was able to process their quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. This manufacturing time further shows that manufacturers also have the flexibility to address those situations raised by the commenters.

The COVID–19 pandemic demonstrated that the issue was not the availability of large inventories on hand, but the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded at the time of the crisis. While the inventory allowance for injectable products was not at issue, discussions with FDA and manufacturers during COVID–19 regarding cGMP issues allowed DEA to realize the importance of maintaining a separate inventory allowance for these types of products as mentioned in comments received regarding injectables.

E. Subcategories for Quotas

Issue: DEA received seven comments concerning the formalization of the current practice of use-specific subcategories for individual manufacturing and procurement quotas. One company was concerned that the

specificity may create an administrative burden on manufacturers who may need more product for one category versus another. This commenter also suggested that DEA allow registrants to transfer product between categories based on notice to DEA rather than requiring a formal reallocation of quota. Another organization emphasized that it did not object to the proposed addition of use-specific subcategories for individual manufacturing and procurement quotas and the use of subcategories by registrants. It recommends that DEA establish a new procurement quota or subcategory for CPS and opium.

An association representing manufacturers and distributors of over-the-counter medicines, dietary supplements, and consumer medical devices in the United States noted that although the subcategories for types of quotas seem workable, it would reduce flexibility. This association stated that subcategories could create inefficiencies or shortages in the supply chain if, for instance, a manufacturing batch required rework and thus required a change in which use-specific subcategory was used. The association further noted that introduction of new line extension of a medicine with a list I chemical can result in in-year shifts in the amount of material expected with little notice as development, validation or revalidation, or scale-up occur, with different sub-category quota impacts.

One commenter was concerned with how DEA defines replacement quota and whether replacement quota will be subtracted from the APQ. This same commenter questioned whether DEA intends to exceed the APQ by the issuance of additional quota to replace quota that was previously granted within the same calendar year. Additionally, the commenter suggested that DEA explain how replacement quota is factored into the APQ. As such, this commenter believes that granting replacement quota on a case-by-case can appear to be unfair when faced with identical circumstances submitted by two different manufacturers.

Another commenter requested that DEA provide clarification on whether DEA-registered manufacturers are materially impacted by the creation of new sub-categories for suppliers that will need to register for procurement quotas and would there be any additional impact to quota management and certification procedures for repackagers.

DEA Response: DEA is committed to ensuring that quotas are set in such a way as to grant manufacturers the ability to provide controlled substances to meet the demand of the legitimate medical, scientific, industrial, and research needs of the United States. DEA is required to understand what is available for legitimate patient need versus what is available for product development to calculate properly the APQ and individual quotas. Additionally, as the number of manufacturers continues to increase and industry practices and specializations change, the ability to track methodically movements of material between registrants at all stages of manufacturing becomes more critical. The specificity of quota is important. DEA is responsible for many reports that require the denotation of quantities by quota type, and it improves the efficiency of the application and reporting process for DEA-registered manufacturers. If categories are combined, there would be no way to calculate efficiently quota that was used for commercial sales, product development, packaging, etc. This would drastically inflate the quantity of commercial sales quota, as packaging/repackaging and labeling/relabeling quota, among other categories, could not be separated from commercial sales quota.

Replacement quota is intended to replace material that does not meet good manufacturing practice standards slated to meet patient needs during the current quota year and is not a means to replace disposed samples, analytical samples, product development material, and expired 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 in the supply chain, or unusable material received from a bulk manufacturer. Replacement quota is granted on a case-by-case basis. The specifics of the registrant's justification and situation determines the merit of the request.

HHS contemplates legitimate patient needs and DEA then estimates the APQ necessary to meet that need. While DEA may have granted an initial quota, changes instituted by HHS and/or market needs may demonstrate that the original quota is now higher than necessary to meet market demand. For example in November 2010, FDA asked the manufacturers of propoxyphene drug products to voluntarily withdraw their drug products due to cardiotoxicity issues. In response, DEA denied all quotas for 2011 to dosage-form manufacturers and bulk manufacturers who supplied the domestic market, and it granted substantially reduced quotas to allow manufacturers to meet the market demand of foreign countries and reference standards only. In this example, manufacturers providing just notice could exceed both agencies' estimations for legitimate need allowing for the possibility for misuse and abuse. To obtain quota, a manufacturer must submit a request to DEA for the quantity they wish to manufacture. 21 CFR 1303.12 and 130.22. DEA in turn performs a quota analysis based on the information submitted and provides a determination based on legitimate need.

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 APQ for the United States by preventing double counting of quota. They have been in place informally for well over a decade with no complaints from the registrants who have found the system beneficial in separating their product development and packaging efforts from their commercial manufacturing efforts when requesting adjustments to their quotas. Furthermore, packaging and repackaging are manufacturing activities as defined in the CSA and CFR and already require quota.

F. New Deadlines for the Establishment of Quotas

Issue: DEA received eight comments from the public regarding the deadline changes. Many comments were either silent on the new deadlines or either expressly stated that they had no objection for the deadline changes, with some going as far as to say they agree and understand the need to change the dates. Some desired clarification on how DEA will reconcile new deadlines for the supply chain where inconsistences have been noted. For instance, it was stated that extending the deadlines would potentially bring about supply disruptions when there are long lead times. There is also concern that changing the deadline to issue quota adjustments would represent a significant change because DEA normally issues them any time during the year, within six to eight weeks of a request. Pushing the procurement quota date to December 1 would make the manufacturing process harder with the reductions because DEA must issue procurement quota before it approves an import permit.

Response: DEA is changing the deadline for issuing initial quotas to December 1 as required in the SUPPORT Act. This new deadline will not affect the supply chain because the quota issued cannot be utilized until January 1 of the next calendar year. Initial quota applications are due to DEA by April 1 and May 1 of the preceding year to be considered in the APQ estimates which must be published before quotas are allotted. The December 1 deadline takes into account the considerable amount of information that must be collected from various sources, analyzed, and reviewed by multiple agencies prior to establishing the quota. Under the current regulations, DEA has less than two months to accomplish this task and it has proven unattainable as the controlled substance manufacturing business has grown larger and more complex. Manufacturers will still be able to apply for quota adjustments at any time throughout the calendar year. Registrants seeking an import permit need to take into account any possible delays when applying for them.

G. Letter From the States Attorneys General

Types of Quota

Issue: DEA received a letter from the Attorneys General of the States of West Virginia, Arkansas, Florida, Kentucky, Missouri, and Nebraska (hereinafter ''letter from State Attorneys General'') concerning the process for setting annual production quotas for controlled substances.

The States applauded the significant improvements DEA has made in reducing opioid production quotas over the past several years. The States stated that DEA failed to tailor the quota-setting process to legitimate medical need, and urged DEA to consider additional sources to set quotas. They further commented that there is a lack of transparency in setting quotas. The States believe that DEA needs to explain the logic behind the different approaches to set quotas.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, scientific, and export needs of the United States. DEA sets aggregate production quotas in a manner to ensure that all prescriptions that are authorized for legitimate medical purposes can be filled. For purposes of setting quotas, it should be noted that, as a result of new laws and regulations, DEA considers a number of factors, including, but not limited to, the extent of any diversion of the controlled substance in the class; relevant information obtained from HHS including FDA, CDC, CMS; and relevant information obtained from the States.[9]

SUPPORT Act

Issue: As previously stated, DEA received a letter from six State Attorneys General. West Virginia, along with five other states, urged DEA to expand the sources of data used to determine the amount of diversion that occurs. They mentioned that the SUPPORT Act and the ''Controlled Substances Quotas'' final rule (83 FR 32784) require the determination of the extent of diversion, but stated that they believe DEA takes different approaches in fulfilling this requirement. The commenters stated that DEA should estimate the diversion of *all* controlled substances the same way that DEA estimates the diversion of *covered* controlled substances. Furthermore, they want DEA to explain the logic of taking two separate approaches, as they feel that even though the wording of the two reforms slightly varies, DEA's approach should be the same.

As for the type of data DEA uses, the States suggest that DEA use national and state databases in the analysis. Specifically, they recommended three steps that DEA should take to incorporate information that is currently available: (1) Improve ARCOS and the SORS to allow greater insight into prescribing; (2) look at other national databases that track drug abuse patterns, poisonings, emergency room visits, and treatment patients; and (3) consider state databases that track drug overdoses and hospital visits.

DEA Response: As stated above, in its efforts to estimate the amount of diversion, DEA acquires data from other Federal agencies. While DEA currently utilizes multiple internal and external data sources, DEA remains open to additional sources of reliable and relevant data. Some of the sources the States suggested that DEA use are not reliable and precise and lack the required granular specificity within the data needed to estimate diversion. The data does not examine each controlled substance individually (*i.e.,* as a basic class and the quantity ingested), but groups them together chemically, making it difficult to determine which basic class was involved and to what extent its aggregate production quotas should be lowered. For example, patients that overdose from hydrocodone, oxycodone, or hydromorphone are grouped together under opioid-related overdose. DEA is unable to determine the basic class that led to the overdose from this information. Additionally, DEA cannot determine from the data if the patient overdosed on an illicit opioid or a legally marketed opioid product. For purposes of calculating the extent of diversion for each basic class of controlled substance, DEA would benefit more from the drug overdose and mortality data if it precisely identified the controlled substance(s) believed to be the cause of overdose or death and if it included the quantity of the substance ingested.

Modifications to the SORS and ARCOS reporting requirements are beyond the scope of this document. DEA did request state specific data on overdoses, death rates, and prescription data in August 2018 for consideration in setting the 2019 APQ. Only eight states provided data, none of which are represented in the comment letter; however, the data provided was not broken down by individual controlled substances, which would allow DEA to consider in determining the extent of diversion or estimating diversion.

Over-Prescribing

Issue: As previously mentioned, DEA received a comment that was co-signed by six State Attorneys General, including West Virginia. The State Attorneys General conveyed that DEA should account for over-prescribing when analyzing diversion. The commenters contend that only relying on theft and seizure records does not give a complete view of diversion. Furthermore, they suggested using the ''best practices'' of medical professionals to help account for overprescribing at the physician level. These commenters stated that medical professionals are now crafting ''best practices'' for opioid prescribing, which the states believe can aid DEA in determining correct quantities of what is ''medically necessary'' for opioids. The letter also suggests that DEA expand the National Take Back Programs to capture more data on overprescribing rates.

DEA Response: For validly dispensed controlled substances, DEA relies on physicians to use their best judgment on how much to prescribe. DEA does not establish best practices for physicians, nor does it control how much of a prescription a patient ends up consuming. DEA has previously stated that ''studies have found, with respect to a variety of medical procedures, that physicians prescribe more controlled substances for post-operative pain than the patients utilize. However, . . . DEA has concluded that while the referenced studies are concerning, they are

[9] 21 U.S.C. 826(a); 21 CFR 1303.11.

insufficient to support a determination as to the level of overprescribing that occurs across the range of the medical procedures that are performed each year on a national basis.'' [10] More recently, DEA has found that physicians are already prescribing at lower rates because of healthcare guidance.

As previously stated, there has been a decline in schedule II opioid prescriptions since 2014. Currently, there is no reliable method for quantifying the amount of prescription medications turned in to the Take-Back program. DEA found one study from 2015 that attempted to quantify the drugs received at one Take-Back location titled, ''Analysis of Medications Returned During a Medication Take-Back Event.'' However, DEA believes that this study is not useful because the methods drastically affect/limit the quantity of each substance that could be included in the analysis. To be included in the study, the medication had to have the following identifiers: drug name, strength, amount remaining, amount prescribed, generic or brand, and source (local pharmacy, mail-order pharmacy, or sample). The study also excluded medications unavailable in the United States, pet medications, medications in containers without a legible label, containers with remaining medication amounts larger than the amount dispensed, and medications not in tablet or capsule formulations. The study authors were able to demonstrate an average overprescribing rate for all medication types of 66 percent based on the total number of pills dispensed (obtained from labels) and the total number of pills remaining in the containers; however, substance specific information is not available because the medications (controlled and non-controlled) were grouped. The study does not mention the proportion of medicine excluded from the study or an estimate of diversion of particular substances. The study assumed that over prescribing was the cause of the remaining number of tablets in the bottle based on the written prescription. It also assumed that the remainder in the bottle was legitimate; however, neither of these assumptions may be the case. The bottle may have contained the remainder of multiple prescriptions of the same drug product dispensed over time and brought to the drug Take-Back event in a single container. This single study cannot be extrapolated to the national level for use in estimating diversion or overprescribing.

H. Out of Scope

DEA received 194 comments are that are being considered out of scope in their entirety or partially. These comments were very general and mentioned personal medical issues, treatments, medication costs, and drug shortages. Included in these general out of scope comments were assertions that illicit drug use is the problem and that doctors are not treating patients due to fear of punishment from DEA.

DEA remains committed to ensuring that there is an adequate and uninterrupted supply of control substances to meet the legitimate medical, scientific, and export needs of the United States. DEA does not tell manufacturers how to manage their quota within the use-specific categories. For example, if a manufacturer holds an FDA-approved application for several different strengths of a dosage-form drug product, DEA will not dictate which strengths it should manufacture. Furthermore, as previously stated, DEA does not plan to set APQ in terms of pharmaceutical dosage-form. As such, the FDA-approved dosage-forms and strengths that a manufacturer produces are solely based on the manufacturers' decision. In the event of shortages of specific dosage-forms and/or strengths of a dosage-form, DEA has and will continue to implement actions based on quota to prevent or alleviate a drug shortage; however, DEA notes that the injectable shortage is not a quota issue, but instead due to manufacturers not complying with FDA's cGMP requirements. In fact, DEA has granted quota to manufacturers seeking to comply with FDA requirements. If DEA receives reliable information of a manufacturer refusing to manufacture a dosage-form or strength to alleviate a drug product shortage, DEA will implement its authority under the SUPPORT Act to issue the manufacturer's quota in terms of dosage-form and/or strength to ensure that manufacturers produce certain dosage-forms to assist in alleviating the drug shortage.

III. Provisions Implemented in the Final Rule

A. Types of Quota

DEA is adding sections 21 CFR 1303.03, 1303.17, 1315.06, and 1315.37, and revising 1303.27 and 1315.27 to introduce and define the types of quotas in the current quota system and to clarify and update the method to abandon both individual manufacturing and procurement quotas. Section 21 CFR 1303.03 will define the three types of quota for schedule I and II controlled substances: APQ, individual manufacturing quotas, and procurement quotas. Section 21 CFR 1315.06 will define the four types of quotas available for list I chemicals: AAN, individual manufacturing quotas, procurement quotas, and import quotas.

To strengthen the quota management process, DEA has turned to managing many aspects of the quota system online. With this final rule, DEA will update 21 CFR 1303.27 and 1315.27 to require manufacturers submit a quota application to the UN Reporting and Quota Section in the online Quota Management System instead of submitting to the Drug and Chemical Evaluation Section a written notice to abandon any or all parts of the individual manufacturing quotas for schedule I and II controlled substances and list I chemicals.

Sections 1303.17 and 1315.37 will clarify that a manufacturer must also abandon procurement quota for schedule I and II controlled substances and list I chemicals using the online Quota Management System. Current regulations only refer to the abandonment of individual manufacturing quota. To further clarify the CFR, DEA will separate the current subsection within the controlled substance quota regulations entitled ''Aggregate Production and Procurement Quotas'' and will make a separate subsection for ''Procurement Quotas.'' In accordance with the creation of this new subsection, DEA will move 21 CFR 1303.12 to 1303.15 and reserve 1303.12 for future use. These additions and changes are also required due to the procurement quota inventory allowances that are being finalized with this rule.

B. SUPPORT Act

As previously discussed in the NPRM, as well as above in Section II, DEA will be implementing in its regulations the amendments to the CSA made by the SUPPORT Act. These amendments include the authority to establish APQ, individual manufacturing quotas, and procurement quotas in terms of pharmaceutical dosage-forms, if it is determined that it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, which will be added to DEA's regulations at 21 CFR 1303.11(a), 1303.12(a) and 1303.21(a). DEA will also be revising 21 CFR 1303.21(a) and 1315.21 to change the date to on or before December 1 by which individual manufacturing quotas must be fixed.

[10] *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2019.* 85 FR 67348 at 67350. December 28, 2018.

DEA will be adding a new regulation regarding the requirement to estimate the amount of diversion of the five covered controlled substances in the United States when establishing quotas for these controlled substances and make appropriate reductions will be added to 21 CFR 1303.05. Furthermore, this regulation will codify the requirements of the SUPPORT Act regarding information to be considered when estimating diversion. The SUPPORT Act requires consultation with the Secretary of HHS in any year that the approved APQ for a covered controlled substance is higher than that of the previous year and an explanation from DEA in the APQ final order 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 21 U.S.C. 826(i)(2)(A). These requirements will also be included in 1303.05, along with the definition of a covered controlled substance.

C. Procurement Quota

Sections 1303.12(f) and 1315.32(h) currently require certificates of quota only when purchasing from a manufacturer. Currently, 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). When the CSA and DEA's regulations were first promulgated, 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 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.

This final rule revises 21 CFR 1303.12(f) and 1315.32(h) by ensuring 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. By requiring that all manufacturers and distributors receive a certification of quota before providing any quantity of controlled substance or list I chemical to a DEA registered manufacturer, DEA is better able to maintain the closed distribution system.

D. Inventory Allowance

DEA is revising 21 CFR 1303.24 and 1315.24 to reduce the overall inventory held by DEA-registered bulk and dosage-form manufacturers. In response to the comments received, DEA will create a new regulation to address the procurement quota changes. DEA had proposed to place the changes for procurement quotas in 21 CFR 1303.24 and 1315.24; however, it was pointed out that the proposed placements fall under the ''Individual Manufacturing Quota'' subsections. As such, DEA will create two new regulations, 21 CFR 1303.16 and 1315.31 and will place them within the appropriate procurement quota subsections.

DEA also acknowledges the concerns conveyed in the comments regarding the proposed percentages being too restrictive. In response to these concerns, DEA conducted further analyses on dosage-form manufacturer inventory data. As previously stated, the data showed that manufacturers only acquired 72.7 percent of fentanyl, 73.9 percent of hydrocodone, 56.7 percent of hydromorphone, 79.3 percent of oxycodone, and 73 percent of oxymorphone from the quotas granted to them by DEA. As prescription rates have fallen, DEA has issued lower quotas to match the estimated fallen rates. The data show that even with the reduced quotas, the material has not sold, but has been placed into inventory, thereby significantly increasing inventory levels above that which is medically necessary on an annual basis. DEA has found that over the past years, inventory levels have averaged 72 percent for fentanyl, 36.9 percent for hydrocodone, 57 percent for hydromorphone, 36.3 percent for oxycodone, and 61 percent for oxymorphone, while still meeting legitimate medical needs. The inventory levels for fentanyl, hydromorphone, and oxymorphone include product development efforts as manufacturers seek FDA approval of abuse-deterrent formulations. This data suggests that the current allowance of 30 percent was not too restrictive and has allowed manufacturers to acquire the quota they need for commercial sales. However, in light of the need for preparedness for any contingencies, DEA will establish the procurement quota inventory allowance at 35 percent.

DEA is also taking the time to clarify what changes will apply to bulk form manufacturers and dosage-form manufacturers. Bulk manufacturers receive individual manufacturing quotas and dosage-form manufacturers receive procurement quota. DEA acknowledges the concerns of manufacturers, but for reasons stated above, a lower inventory allowance for individual manufacturing quota needs to be implemented. As such, DEA has reviewed historical data from the companies and determined that 50 percent (six months) of inventory allowance is no longer necessary given the changes in prescribing guidelines to meet legitimate medical need and will be reducing individual manufacturing quota inventory allowances to 40 percent instead. The reduction to 40 percent allows for just under five months of inventory and takes into account the latest prescribing practices of the most prescribed substances as well as decreasing the likelihood of diversion of stocks. It still allows manufacturers the flexibility to accommodate market changes, FDA regulations, and unforeseen circumstances. As previously discussed for procurement quotas, there are more dosage-form manufacturers than bulk manufacturers; therefore, a lower inventory allowance for procurement quota is warranted. For procurement quotas, DEA will establish (for controlled substances) and will reduce (for list I chemicals) inventory allowances to 35 percent (instead of 30 percent), except in the circumstances of liquid injectable dosage-forms. Liquid injectable dosage-forms (injectable products, vials, solution bags, but not tablets, capsules, suppositories, patches, films, and oral solutions) will continue to receive a 50 percent inventory allowance due to DEA's acknowledgement that there are less dosage-form manufacturers for these liquids, as addressed above. Instead of suspending all quota when a registrant's inventory exceeds the proposed amount of 45 percent, DEA will be finalizing three different suspension amounts. The amount at which quota will be suspended for manufacturing quota is when the inventory reaches 55 percent and will remain suspended until the amount is lower than 50 percent. For all dosage-forms, except liquid injectable dosage-forms, individual procurement quota will be suspended at 50 percent and will be reinstated when the amount is less than 45 percent. As applied to liquid injectable dosage-forms,

individual procurement quota will be suspended at 65 percent and will remain in suspension until the inventory amount is lower than 60 percent. Last, instead of DEA granting requests of additional quota if inventory is less than the proposed 20 percent, DEA again will be finalizing three different amounts based on type of quota. DEA may increase the amount of individual manufacturing quota once the inventory is less than 30 percent. For individual procurement quota, the amount of quota may be increased when the inventory is less than 25 percent; however, individual procurement quota for liquid injectable dosage-forms may be increased when the inventory is less than 40 percent.

The final changes are as follows:

- 21 CFR 1303.16(a)—establishes an inventory allowance issued by DEA for procurement quotas of 35 percent for all dosage-forms of schedules I and II controlled substances, except liquid injectable dosage-forms, which will receive an inventory allowance of 50 percent;
- 21 CFR 1303.16(b) and (c)—suspends procurement quota issued by DEA if inventory exceeds 50 percent for all dosage-forms of schedules I and II controlled substances, except liquid injectable dosage-forms, which will be suspended if inventory exceeds 65 percent;
- 21 CFR 1303.16(d) and (e)—may grant request for additional procurement quota by registrant if inventory is less than 25 percent for all dosage-forms of the registrant's estimated net disposal for schedules I and II controlled substances, except liquid injectable dosage-forms, which may be granted if inventory is less than 40 percent;
- 21 CFR 1303.24(a)—decreases the inventory allowance issued by DEA for individual manufacturing quotas from 50 to 40 percent for schedules I and II controlled substances;
- 21 CFR 1303.24(b)—suspends individual manufacturing quota issued by DEA if inventory exceeds 55 percent of the registrant's estimated net disposal for schedules I and II controlled substances;
- 21 CFR 1303.24(c)—may grant request for additional individual manufacturing quota by registrant if inventory is less than 30 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 40 percent for the list I chemicals;
- 21 CFR 1315.24(b)—suspends individual manufacturing quotas issued by DEA if inventory exceeds 55 percent of the registrant's estimated net disposal for the list I chemicals;
- 21 CFR 1315.24(c)—may grant request for additional individual manufacturing quotas by registrant if inventory is less than 30 percent of the registrant's estimated net disposal for the list I chemicals;
- 21 CFR 1315.31(a)—decreases the inventory allowance issued by DEA for procurement quotas from 50 to 35 percent for all dosage-forms of the list I chemicals, except liquid injectable dosage-forms, where an inventory allowance of 50 percent will be created;
- 21 CFR 1315.31(b) and (c)—suspends procurement quotas issued by DEA if inventory exceeds 50 percent for all dosage-forms of the registrant's estimated net disposal for the list I chemicals except liquid injectable dosage-forms, which will be suspended if inventory exceeds 65 percent; and
- 21 CFR 1315.31(d) and (e)—may grant request for additional procurement quotas by registrant if inventory is less than 25 percent for all dosage-forms of the registrant's estimated net disposal for the list I chemicals, except liquid injectable dosage-forms, which may be granted if inventory is less than 40 percent.

E. Subcategories

DEA is formalizing the addition of use-specific subcategories by adding 21 CFR 1303.04 and 1315.07. As a practical matter, DEA acknowledges that these subcategories are already in use through voluntary and cooperative efforts of DEA registrants. This final rule will codify DEA's current utilization of subcategories while facilitating the issuance of individual manufacturing and procurement quotas.

Additionally, the specification of subcategories for manufacturing and procurement quotas provides benefits to the registrant by allowing for a more detailed level of communication with DEA as to why a registrant requires specific controlled substances and list I chemicals and how the registrant will utilize those substances.

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

F. Deadlines

DEA collects various data to administer the quota system and moving the deadlines will allow more time for processing the numerous applications that DEA receives and for responding to applications for quota, as there are more registrants now than there were when the regulations were first promulgated. The new deadlines will also allow DEA more time to obtain additional relevant data from multiple agencies. The changes are as follows:

- Establishment of the APQ and the AAN (21 CFR 1303.11(c) and 1315.11(c)): change from May 1 to September 1;
- Deadline to issue procurement quota (21 CFR 1303.12(c) and 1315.32(f)): change from July 1 to December 1;
- Deadline to issue import quota for list I chemicals (21 CFR 1315.34(f)): change from July 1 to December 1; and
- Deadline to adjust individual manufacturing quota (21 CFR 1303.23(c) and 1315.23(c)): change from March 1 to July 1.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule has been developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 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). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action'' requiring review by the Office of Management and Budget (OMB) as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, 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 final rule is not economically significant, it is a significant regulatory action under E.O.

12866, section 3(f) subjecting it to review by OMB. DEA analyzed the economic impact of each provision of this final rule, including any changes made from the proposed rule, and estimated the annual cost to be $26.4 million. Certain provisions are estimated to have benefits; however, DEA does not have a basis to estimate those benefits due to many unknowns. Because of this, the benefits of this 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, reductions to inventory allowances, and additional considerations for revisions to the APQ. 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 DEA. The formal definition of quota types will have no economic impact on registrants or DEA, and formalizing the procedure to abandon quota is simply a codification of DEA's current procedure. While these provisions will have no quantifiable impact, DEA believes there is at least a minimal benefit to codifying existing practices accurately. Because these provisions codify existing practice, current registrants are, in most cases, already complying and will not change their behavior. Errors and misunderstandings on the part of registrants do happen, but are uncommon. Nevertheless, these provisions of the final rule are expected to enhance clarity, certainty, and efficiency.

Conforming Revisions Related to the SUPPORT Act

As indicated above, the SUPPORT Act gives DEA discretionary authority to establish quotas in terms of pharmaceutical dosage-form. At the present time, 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 best to allocate those kilograms to different FDA-approved dosage-forms. While it is impossible to know all the circumstances in which this authority might be utilized in the future, it is 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. 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, DEA is likely to use this authority sparingly, and only adjust quotas for manufacturers producing the dosage-form, DEA anticipates that this provision of the proposed rule will have minimal impact.

The SUPPORT Act also requires 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. 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, although in the past DEA has relied on its own internal data in the process of determining the APQ. DEA's view is that considering additional reliable information gathered from outside the agency to estimate the amount of diversion will result in minimal additional time or cost.

The SUPPORT Act updates also extend DEA's deadline to fix individual manufacturing quotas for schedules I and II controlled substances from October to December, and they 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 DEA currently does not meet the October deadline and has not met that deadline since before 1996. This extension will align the regulations with reality for registrants and 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 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 to minimize public harm. DEA would use dosage-form quotas 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 eliminates regulatory uncertainty for manufacturers. Regulations that realistically reflect current DEA and industry practice will benefit the planning processes of current and future market participants.

Procurement Quota Certification

The final rule will 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 certify quota before a sale.[11]

To estimate the cost of this provision, 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,[12] the type of registrant employee that would be tasked with certifying quota, 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 [13] by

[11] 21 CFR 1303.12(f) and 1315.32(h).

[12] For the purposes of this analysis, DEA used the median hourly wage rate of $32.63 for 13–1041 Compliance Officers. Bureau of Labor Statistics, Occupational Employment and Wages, May 2017, *https://www.bls.gov/oes/2017/may/oes131041.htm.*

[13] The loaded hourly rate for 13–1041 Compliance Officers is $46.99 ($32.63 × 1.44). Bureau of Labor Statistics, Employer Costs for

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0.25 and applying that to the estimated 3,000 certification letters per year yields a combined annual 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

In response to public comments regarding the proposed inventory allowance reductions put forth in the NPRM, DEA is modifying the reductions that will become effective upon publication of this final rule, while also establishing new procurement quota inventory allowances for dosage forms. Comments received from manufacturers stressed that the proposed changes to the inventory allowance would increase production costs, product waste, and inefficiencies. Specifically, manufacturers stated that the proposed reductions would require smaller, more frequent manufacturing campaigns in order to produce the same amount of finished product in a given year, and that DEA's ability to respond to requests for quota adjustments throughout the year is not sufficient if market demand fluctuates. Additionally, commenters expressed concern that reducing inventory allowances for certain liquid injectable dosage-forms may cause a significant disruption in the supply of these life-saving drugs given the relatively limited number of manufacturers. As a result, DEA is adjusting the inventory allowance reductions in this final rule to minimize, to the extent possible, any supply disruptions or increases in manufacturing production costs. DEA is also clarifying which inventory allowances apply to individual manufacturing quota and which apply to procurement quota by establishing a procurement quota inventory allowance in 21 CFR 1303.16(a). While there may not be published studies showing that smaller inventories reduce diversion, DEA must 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 also preventing an oversupply which increases the risk of diversion. DEA believes that these final inventory allowance reductions will help achieve its goal of reducing the risk of diversion at the manufacturer level.

Many of the comments received from manufacturers stated generally that the proposed inventory allowance reductions would increase the cost of API production, but only one commenter provided a detailed estimate for how much their costs are likely to increase in a given year. This commenter estimates that their incremental production costs would rise by approximately $600,000 per year, primarily due to the reduced inventory allowance necessitating an additional manufacturing campaign for their largest volume API products, decreasing efficiency and potentially increasing the amount of product wasted during the required cleaning of equipment between each additional campaign. While DEA recognizes this single cost estimate as legitimate, it is unlikely that production costs are uniform across manufacturers and depend largely on variables unique to each firm. However, given the absence of detailed monetary cost estimates from other commenters, and the fact that the required inputs to calculating an individual firm's manufacturing costs are proprietary and unknown to DEA, using this commenter's estimate as the basis for estimating the impact of this provision of the final rule is the most reasonable option available to DEA.

With this final rule, DEA will be reducing individual manufacturing quota inventory allowances to 40 percent (instead of the proposed 30 percent) and will be establishing (for controlled substances) and reducing (for list I chemicals) procurement quota inventory allowances for all dosage-forms (except liquid injectable dosage-forms) to 35 percent. Procurement quota inventory allowances for liquid injectable dosage-forms are being formally established at 50 percent, resulting in no change from the pre-rule baseline. The threshold at which individual manufacturing quota will be suspended is reached when inventories exceed 55 percent of estimated net disposal (instead of the proposed 45 percent) and will remain suspended until inventory falls below 50 percent. However, DEA will suspend individual procurement quota at 50 percent, and will reinstate it when inventories fall below 45 percent. DEA will suspend procurement quota for liquid injectable dosage-forms when inventories rise above 65 percent, and will reinstate it when inventories fall below 60 percent. Finally, DEA may increase the amount of individual manufacturing quota once the inventory is less than 30 percent (instead of the proposed 20 percent). For individual procurement quota, the amount of quota may be increased when the inventory is less than 25 percent or when inventories are less than 40 percent for liquid injectable dosage-forms.

Because the comments received from manufacturers focused primarily on their estimation of the increase in time and cost of manufacturing API products, DEA believes it is reasonable to assume that the costs imposed by this provision stem primarily from the inventory allowance reduction for individual manufacturing quotas, and this cost is borne by bulk manufacturers. There are currently 44 bulk manufacturers registered with DEA. Based on the only detailed monetary cost estimate received, DEA assumes that each of these registrants will incur an average annual cost of $600,000, equating to $26.4 million in total annual costs as a result of this provision of the final rule.

It is important to note that the estimated total annual costs from reducing inventory allowances could be higher than actual costs. The incremental cost increase of $600,000 presented by the commenter and being used in this analysis as representative of the average annual costs for each bulk manufacturer was based on the proposed individual manufacturing quota inventory allowance reduction from 50 percent to 30 percent, with suspension of quota at 45 percent. As stated above, based on public comments, DEA is choosing to implement a smaller reduction to inventory allowances with this final rule, settling on an individual manufacturing quota inventory allowance of 40 percent, with suspension of quota occurring if inventories rise above 55 percent. Additionally, the commenter that provided the monetary cost estimate is a large manufacturer; therefore, applying their estimated costs across all 44 bulk manufacturers, which includes many small manufacturers, likely overstates the total annual cost. Because of this, it may be the case that the average incremental costs incurred by bulk manufacturers are less than $600,000, especially if the revised inventory allowances prevent the need for some manufacturers to add production campaigns for certain products. However, DEA has no way of knowing if this is indeed the case; therefore, DEA assumes that an average annual cost estimate of $600,000 incurred by bulk manufacturers as a result of this provision is reasonably accurate.

Inventory allowances are a factor in DEA's determination of a registrant's quota for the coming year and provides inventory for sales at the beginning of a new quota year before quota is received. Registrants may also exceed their

Employee Compensation—December 2018, *https://www.bls.gov/news.release/archives/ecec_12142018.pdf.*

inventory allowance during the year. If at any time during the year, the inventory of a basic class held by a manufacturer exceeds 55 percent (or 50 percent for procurement quota of dosage-forms) of estimated net disposal, the quota for that class is automatically suspended and would remain suspended until inventory is less than 50 percent (or 45 percent for procurement quota of dosage-forms) of the estimated net disposal. Practically speaking, the changes to inventory allowances equate to a reduction from the current half of a year's sales supply (50 percent) allowed to be held as inventory to nearly five months (40 percent) for individual manufacturing and over four months (35 percent) for dosage-form manufacturing. Additionally, the 55 percent maximum inventory during the year would give manufacturers the flexibility to have over six months of sales supply inventoried to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year. For dosage-form manufacturers, the maximum inventory of 50 percent provides exactly six months of sales supply. The inventory allowance for liquid injectable dosage-forms remains unchanged; thus, there is no impact on these products.

While DEA acknowledges that reducing inventory allowances will increase costs for bulk manufacturers, DEA concludes that these reductions are not likely to result in supply disruptions. Registrants routinely request adjustments to their quota throughout the year due to fluctuations in market conditions, and this is a normal part of a manufacturer's business operations. 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), DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota. Additionally, in response to the ongoing COVID–19 pandemic, DEA and manufacturers of injectable products for treatment of ventilator patients have entered into continuous dialogue to meet surging hospital demand. During this time, DEA was able to process manufacturer quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that would require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. The COVID–19 pandemic has demonstrated that the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded in times of crisis is more important than the availability of large inventories on hand.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the final rule is a codification of existing voluntary and cooperative efforts between registrants and DEA that have been in place since 2001 and facilitates a more accurate calculation of APQ 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 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 management of quota, and it will have no economic impact on registrants or DEA.

New Deadlines for Establishing Quotas

The final rule will modify the deadlines for establishing and publishing the APQ, AAN, import quotas, procurement quotas, manufacturing quotas, and any adjustments to manufacturing quotas. Due to the expansion of the market and the increase in the number of bulk and dosage-form manufacturers since that deadline was implemented almost 50 years ago, DEA frequently misses the current 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. Congress mandated quotas for importers of list I chemicals in 2007.[14] Applications for import and procurement quota are due April 1, giving DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that DEA has historically missed these deadlines since it must take adequate time to provide a thorough and careful assessment of each application, both 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 practices of DEA and industry.

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, impose enforcement responsibilities on any State, or 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), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that this final rule will not 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. 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) and 13563 (Improving Regulation and Regulatory Review)'' section above, this rule has six key components as described below.

Defining Types of Quota and Filing To Abandon Quota

This provision codifies existing DEA practices and will result in no economic

[14] Combat Methamphetamine Epidemic Act of 2005, Public Law 109–177.

impact on registrants or 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 provision will have no costs.

Conforming Revisions Related to the SUPPORT Act

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

Additionally, the SUPPORT Act defines the phrase ''covered controlled substance'' to include fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. It requires 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 United States that is determined to be reliable. DEA has considered the amount of diversion when establishing quotas when data has been available and 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 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 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 DEA.

Procurement Quota Certification

The final rule will 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.[15] 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 certify quota before a sale.[16]

To estimate the cost of this provision, 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, DEA estimated the labor cost of quota certification to distributors to be $11,747 and $23,494 to manufacturers, resulting in a combined annual labor cost of $35,241.

Reduction of Inventory Allowances

This final rule will reduce the inventory allowance for manufacturers of controlled substances and list I chemicals from 50 percent to 40 percent of the registrant's estimated net disposal, and it will establish a procurement quota inventory allowance for dosage-forms and list I chemicals at 35 percent of the registrant's estimated net disposal. Procurement quota inventory allowances for liquid injectable dosage-forms are also being formally established at 50 percent, resulting in no change. Inventory allowances are a factor in DEA's determination of a registrant's quota for the coming year and provide inventory for sales at the beginning of a new quota year before quota is received. Registrants may exceed their inventory allowance during the year. If at any time during the year the inventory of a basic class held by a manufacturer exceeds 55 percent (or 50 percent for procurement quota for dosage-forms) of estimated net disposal, the quota for that class is automatically suspended and would remain suspended until inventory is less than 50 percent (45 percent for procurement quota dosage-forms) of the estimated net disposal. Practically speaking, the changes to inventory allowances equate to a reduction from the current half of a year's sales supply (50 percent) allowed to be held as inventory to nearly five months (40 percent) for individual manufacturing and over four months (35 percent) for dosage-form manufacturing. Additionally, the 55 percent maximum inventory during the year gives manufacturers the flexibility to have over six months of sales supply inventoried to account for any unplanned fluctuations in demand or timing in orders for their product throughout the year. For dosage-form manufacturers, the maximum inventory of 50 percent provides exactly six months of sales supply. The inventory allowance for liquid injectable dosage-forms remains unchanged at 65 percent; thus, there is no impact on these products.

Because the comments received from manufacturers on this provision of the proposed rule focused primarily on their estimation of the increase in time and cost of manufacturing API products, DEA believes it is reasonable to assume that any costs imposed by this provision stem primarily from the inventory allowance reduction for individual manufacturing quotas, and this cost is borne by bulk manufacturers. The only commenter to provide a detailed monetary cost estimate for DEA to consider stated that its incremental production costs would rise by approximately $600,000 per year primarily due to the reduced inventory allowance necessitating an additional manufacturing campaign for their largest volume API products. While DEA recognizes this single cost estimate as legitimate, it is unlikely that production costs are uniform across manufacturers and depend largely on variables unique to each firm. However, given the absence of detailed monetary cost estimates from other commenters and the fact that the required inputs to calculating an individual firm's manufacturing costs are proprietary and unknown to DEA, using this commenter's estimate as the basis for estimating the impact of this provision of the final rule is the most reasonable option available to DEA.

There are currently 44 bulk manufacturers registered with DEA. DEA assumes that each of these registrants will incur an average annual cost of $600,000, equating to $26.4 million in total annual costs because of this provision of the final rule.

While DEA acknowledges that reducing inventory allowances will increase costs for bulk manufacturers, DEA concludes that these reductions are not likely to result in supply disruptions. 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. DEA quickly responds to these requests within six to eight weeks, ensuring legitimate business is not

[15] 21 CFR 1303.12(f) and 1315.32(h).

[16] *Id.*

disrupted, and it will continue to do so once this rule is promulgated. For example, in 2017 (the last year in which data are available), DEA processed 1,752 initial quota applications and 2,299 requests for adjustment to quota. Additionally, in response to the ongoing COVID–19 pandemic, DEA and manufacturers of injectable products for treatment of ventilator patients entered into continuous dialogue to meet surging hospital demand. During this time, DEA was able to process manufacturer quota requests in less than five business days, demonstrating DEA's flexibility to address situations such as shortages, natural disasters, epidemics, medical demand, and other scenarios that could require an increase in production of critical medications. Also, in these dialogues, injectable manufacturers stated that the manufacturing times from acceptance of API to release of the drug product took approximately 30 to 42 days. The COVID–19 pandemic has demonstrated that the flexibility to grant and utilize quotas to produce the formulations and dosage strengths demanded in times of crisis is more important than the availability of large inventories on hand.

Formalization of Subcategories for Manufacturing Quotas and Procurement Quotas

This provision of the final rule is a codification of existing voluntary and cooperative efforts between registrants and DEA that have been in place since 2001 and allows a more accurate calculation of APQ 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 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 management of quota and will have no economic impact on registrants or DEA.

New Deadlines for Establishing Quotas

The final rule would modify the deadlines for establishing and publishing the APQ, AAN, and procurement and manufacturing quotas, and any adjustments to manufacturing quotas. 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, DEA frequently misses 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 deadline of July 1. Applications for import and procurement quota are due April 1, giving DEA only 30 days before the May 1 deadline for publication of the APQ and AAN. Given that DEA has historically missed these deadlines since it must take adequate time to provide a thorough and careful assessment of each application, both 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 DEA and industry.

Summary

In summary, only the procurement quota certification requirement and reduction to inventory allowances impose costs. The certification requirement results in a $23,494 annual cost to all manufacturers and an $11,747 annual cost to all distributors for a combined annual cost of $35,241. The reduction to inventory allowances imposes an estimated annual cost of $600,000 on each of the 44 bulk manufacturers registered with DEA, equating to $26.4 million in total annual costs.

Description and Estimate of the Number of Small Entities

This rule has the potential to affect entities registered with 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,[17] distributors, and importers,[18] there are the following number of firms: [19]

- 404 'Medicinal and Botanical Manufacturing' (325411)
- 957 'Pharmaceutical Preparation Manufacturing' (325412)
- 6,739 '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 three industries are 1,000 employees for Medicinal and Botanical Manufacturing, 1,250 employees for Pharmaceutical Preparation Manufacturing, and 250 employees for Drugs and Druggists' Sundries Merchant Wholesalers.[20]

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

- 377 (93.3 percent of total) 'Medicinal and Botanical Manufacturing' (325411);
- 885 (92.5 percent of total) 'Pharmaceutical Preparation Manufacturing' (325412); and
- 6,475 (96.1 percent of total) 'Drugs and Druggists' Sundries Merchant Wholesalers' (424210).

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

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[17] DEA believes 'Pharmaceutical Preparation Manufacturing' (325412) includes 503B outsourcing facilities.

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

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

[20] SBA ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective August 19, 2019.''

Detailed Analysis of Percentage of Entities That Are Small Entities by Industry.

NAICS Description	Firm Size by Average Employees	Firms	Establish-ments	SBA Size Standard	Small Entities	% Small Entities
325411-Medicinal and Botanical Manufacturing	Total	404	439	1,000	377	93.3
	<500	367	376	1,000	367	100
	500-749	4	6	1,000	4	100
	750-999	6	8	1,000	6	100
	1,000-1,499	6	6	1,000	0	0
	1,500-1,999	1	1	1,000	0	0
	2,000-2,499	3	4	1,000	0	0
	2,500-4,999	3	10	1,000	0	0
	5,000+	14	26	1,000	0	0
325412-Pharmaceutical Preparation Manufacturing	Total	957	1,208	1,250	885	92.5
	<500	850	870	1,250	850	100
	500-749	20	31	1,250	20	100
	750-999	10	17	1,250	10	100
	1,000-1,499	10	20	1,250	5	50
	1,500-1,999	8	9	1,250	0	0
	2,000-2,499	4	10	1,250	0	0
	2,500-4,999	19	68	1,250	0	0
	5,000+	36	183	1,250	0	0
424210-Drugs and Druggists' Sundries Merchant Wholesalers	Total	6,739	9,964	250	6,475	96.1
	<100	6,304	6,436	250	6,304	100
	100-149	104	133	250	104	100
	150-199	43	52	250	43	100
	200-299	48	76	250	24	50
	300-399	29	47	250	0	0
	400-499	16	85	250	0	0
	500-749	34	59	250	0	0
	750-999	17	81	250	0	0
	1,000-1,499	15	80	250	0	0
	1,500-1,999	13	28	250	0	0
	2,000-2,499	16	58	250	0	0
	2,500-4,999	32	118	250	0	0
	5,000+	68	2,711	250	0	0

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Because DEA registrants frequently hold more than one registration for separate locations, one entity may hold many registrations. DEA estimates the number of affected entities by multiplying the number of DEA registrations in each business activity by its ''firm-to-establishment'' ratio 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.[21] DEA analyzed how each provision of the proposed rule will affect DEA registrants, including how many entities each provision will affect, and found that at least one provision of this proposed rule will affect 561 DEA registered entities. A summary of this analysis is detailed in the table below:

[21] For example, the firm-to-establishment ratio for NAICS 325412 is obtained by dividing the 957 total firms in the industry by the 1,208 total establishments in the industry, yielding a ratio of .79.

Summary of DEA Registered Entities Affected by Provision of Proposed Rule

Activity	DEA Registr-ants	Provisions						Affected Entities*
		Inventory Allowance	APQ and AAN Dates	Subcateg-ories	SUPPORT Act	Definit-ions	Quota Cert	
Manufacturer CS, Bulk	44	Yes	Yes	Yes	Yes	Yes	No	40
Manufacturer List I, Bulk		Yes	Yes	Yes	Yes	Yes	No	
Manufacturer CS, Dosage	417	Yes	Yes	Yes	Yes	Yes	Yes	329
Manufacturer List I, Dosage		Yes	Yes	Yes	Yes	Yes	Yes	
Importer List I	35	No	Yes	No	No	Yes	No	24
Distributor CS	143	No	No	No	No	Yes	Yes	97
Distributor List I	104	No	No	No	No	Yes	Yes	71
Total								**561**

*Firm-to-establishment ratios of .92 for bulk manufacturers (NAICS 352411), .79 for dosage-form manufacturers (NAICS 352412), and .68 for distributors and importers (NAICS 424210) 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 to estimate the number of affected small entities. DEA estimates that of the 561 affected entities 525 are small entities: 161 distributors, 304 dosage-form manufacturers, 37 bulk manufacturers, and 23 importers. In summary, the percentages of small entities affected are as follows:

- 9.8 percent 'Medicinal and Botanical Manufacturing' (325411);
- 34.4 percent 'Pharmaceutical Preparation Manufacturing' (325412); and
- 2.8 percent '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	Estimated Number of Affected Small Entities	Percentage of Small Entities Affected
325411	Medicinal and Botanical Manufacturing	1,000	377	37	9.8
325412	Pharmaceutical Preparation Manufacturing	1,250	885	304	34.4
424210	Drugs and Druggists' Sundries Merchant Wholesalers	250	6,475	184*	2.8
Total			**7,737**	**525**	**N/A**

*161 distributors and 23 importers

As described above, the quota certification provision of this final rule is estimated to cost a total of $23,494 to manufacturers annually and a total of $11,747 to distributors annually, or an average cost of $70 ($23,494/334) per affected manufacturer and $71 ($11,747/166) per distributor. Additionally, the reduction to inventory allowances are estimated to impose costs of $600,000 annually on the 44 affected bulk manufacturers that are registered with DEA, 37 of which are small entities. DEA generally uses 30 percent as a ''substantial'' number of affected small entities. The analysis reveals that a non-substantial percentage of small distributor entities (2.8 percent) and

small bulk manufacturer entities (9.8 percent) will be affected while a substantial percentage of small dosage-form manufacturing entities (34.3 percent) will be affected by this rule. DEA generally considers impacts that are greater than three percent of yearly revenue to be a ''significant economic impact'' on an entity. DEA compared the compliance cost of $70 and $71 to the average annual receipts of dosage-form manufacturers and distributors/imports, respectively, for each size range.[22] Additionally, DEA compared the estimated $600,000 per-entity cost attributed to reducing inventory allowances to the average annual receipts of bulk manufacturers for each size range. For even the smallest of entities, the costs calculated above are much less than three percent of yearly revenue and are not significant. The table below summarizes the analysis.

Summary of Analysis.

NAICS Code	NAICS Description	Small Entity Threshold/ SBA Size Standard	Estimated Number of Small Entities	Estimated Number of Affected Small Entities	Percentage of Small Entities Affected	Economic Impact of Compliance
352411	Medicinal and Botanical Manufacturing	1,000	377	37	9.8 (Not Substantial)	Not Significant
325412	Pharmaceutical Preparation Manufacturing	1,250	885	304	38.6 (Substantial)	Not Significant
424210	Drugs and Druggists' Sundries Merchant Wholesalers	250	6,475	184*	2.8 (Not Substantial)	Not Significant

*161 distributors and 23 importers

DEA examined the economic impact of this final rule for each affected industry for various size ranges. Based on the analysis above, and because of these facts, DEA believes this rule 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 million or more (adjusted annually 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 revises existing information collections 1117–0006, 1117–0008, and 1117–0047 and creates one new information collection. DEA is amending 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. A person is not required to respond to a collection of information unless it displays a valid OMB control number. DEA has submitted these collection requests to the 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.

DEA is formally implementing 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. DEA will be adding 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 will continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these controlled substances and list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

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.

DEA is formally implementing the use of subcategories to facilitate the issuance of procurement quotas and provide a more accurate calculation of the aggregate production quotas for the

[22] 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.

United States. DEA is adding 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 will 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 will continue to receive manufacturing and procurement quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these controlled substances and list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

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.

DEA will be formally implementing 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. DEA is adding 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 will be requested using the same application and format registrants are accustomed to using in an online form. Importers of list I chemicals will continue to receive import quotas appropriate to their manufacturing and inventory requirements, and DEA will retain greater control over the amount of these list I chemicals produced, thereby reducing the amount of inventories at risk of diversion.

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: 1117–0055.

DEA Form Number: N/A.

This final rule will 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 will 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. 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 this final rule, this recordkeeping requirement will apply to certifications included with orders for schedules I and II controlled substances or list I chemicals to all registrants, including distributors.

DEA estimates that distributors fill an average of 3,000 orders to manufacturers per year, which under this final 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. For the purposes of this final rule, 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).

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

No comments were received on any of the information collections being modified in connection with this final rule. Any comments related this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB49/Docket No. DEA–455.

Congressional Review Act

This 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 million 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, DEA is amending 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 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 (FDA), 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. 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 the 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. Revise the undesignated center heading ''Aggregate Production and Procurement Quotas'' to read as ''Aggregate Production Quotas''.

■ 4. Amend § 1303.11 by:

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

■ b. Removing the date ''May 1'' in the first sentence of paragraph (c) and adding in its place ''September 1''; and

■ c. Adding paragraph (d).

The revisions to 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.

■ 5. Add an undesignated center heading before § 1303.15 to read as follows:

* * * * *

Procurement Quotas

* * * * *

§ 1303.12 [Redesignated as § 1303.15]

■ 6. Redesignate § 1303.12 as § 1303.15 and add and reserve a new § 1303.12.

■ 7. Amend newly redesignated 1303.15 § by:

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

■ b. Revising the first sentence in paragraph (b);

■ c. Removing ''July'' in paragraph (c) introductory text and adding in its place ''December''; and

■ d. In paragraph (f), removing the words ''manufacturer'' and ''bulk manufacturer'' and adding in their place ''registrant'', and removing ''Manufacturers'' and adding in its place ''A registrant''.

The revision to read as follows:

§ 1303.15 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 they determine 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. * * *

* * * * *

■ 8. Add § 1303.16 to read as follows:

§ 1303.16 Inventory allowance for procurement quotas.

(a) For the purpose of determining procurement quotas pursuant to § 1303.15, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:

(1) Except as provided in paragraph (a)(3) of this section, for current manufacturers, 35 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) Except as provided in paragraph (a)(4) of this section, for new manufacturers, 35 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(3) For current liquid injectable dosage-form manufacturers, 50 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(4) For new liquid injectable dosage-form manufacturers, 50 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 50 percent of his estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 50 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until his inventory is less than 45 percent of their 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 to continue manufacturing and to accumulate an inventory in excess of 50 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) For liquid injectable dosage-forms, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 65 percent of their estimated net disposal of that class for that year during each calendar year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until their inventory is less than 60 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 to continue manufacturing and to accumulate an inventory in excess of 65 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(d) Except as provided in paragraph (e) of this section, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to him under an individual procurement quota, and their inventory of that class is less than 25 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 35 percent of the estimated net disposal for that year.

(e) For liquid injectable dosage-forms, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to them under an individual procurement quota, and their inventory of that class is less than 40 percent of their estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

■ 9. Add § 1303.17 to read as follows:

§ 1303.17 Abandonment of procurement quota.

Any manufacturer assigned a procurement quota for any basic class of controlled substance listed in schedule I or II pursuant to § 1303.12 may at any time abandon their 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. The Administrator may, in their discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

■ 10. In § 1303.21 amend paragraph (a) by removing the date ''July 1'' in the first sentence and adding in its place ''December 1'' and adding a new second sentence to read 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 they determine it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. * * *

* * * * *

■ 10. 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 § 1303.04, each quantity of such class. * * *

* * * * *

§ 1303.23 Procedure for applying for individual manufacturing quotas.

■ 11. In § 1303.23, amend paragraph (c) by removing the date ''March 1'' in the first sentence and adding in its place ''July 1''.

■ 12. Revise § 1303.24 to read as follows:

§ 1303.24 Inventory allowance for individual manufacturing quotas.

(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, 40 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 40 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year, each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 55 percent of their estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 55 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until their inventory is less than 50 percent of their 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 to continue manufacturing and to accumulate an inventory in excess of 55 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to them under an individual manufacturing quota, and their inventory of that class is less than 30 percent of their 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 40 percent of the estimated net disposal for that year.

■ 13. Amend § 1303.27 by revising the section heading and the first sentence to read as follows:

§ 1303.27 Abandonment of quota for Individual Manufacturing 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 their 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

■ 14. The authority citation for part 1315 continues to read as follows:

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

■ 15. 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.

■ 16. 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 Assessment of annual needs.

■ 17. In § 1315.11, amend paragraph (c) by removing the date ''May 1'' in the first sentence and adding in its place the date ''September 1''.

§ 1315.21 Individual manufacturing quotas.

■ 18. Amend § 1315.21 by removing the date ''July 1'' in the first sentence and adding in its place the date ''December 1''.

■ 19. 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 § 1315.07, each quantity of such chemical. * * *

* * * * *

§ 1315.23 Procedure for fixing individual manufacturing quotas.

■ 20. In § 1315.23, amend paragraph (c) by removing the date ''March 1'' in the first sentence and adding in its place the date ''July 1''.

■ 21. Revise § 1315.24 to read as follows:

§ 1315.24 Inventory allowance for individual manufacturing quotas.

(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, 40 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 40 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year, each registered manufacturer receiving a manufacturing quota shall be allowed to maintain an inventory of a chemical not exceeding 55 percent of their 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 55 percent of their estimated net disposal, their quota for that chemical is automatically suspended and shall remain suspended until their inventory is less than 50 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 to continue manufacturing and to accumulate an inventory in excess of 55 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to them under an individual manufacturing quota, and their inventory of that chemical is less than 30 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 40 percent of the estimated net disposal for that year.

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

§ 1315.27 Abandonment of individual manufacturing quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to § 1315.23 may at any time abandon their 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. * * *

■ 23. Add § 1315.31 to read as follows:

§ 1315.31 Inventory allowance for procurement quotas.

(a) 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) Except as provided in paragraph (a)(3) of this section, for current manufacturers, 35 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) Except as provided in paragraph (a)(4) of this section, for new manufacturers, 35 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(3) For current liquid injectable dosage-form manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(4) For new liquid injectable dosage-form manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a chemical not exceeding 50 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 50 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 45 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 to continue manufacturing and to accumulate an inventory in excess of 50 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) For liquid-injectable dosage-forms, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a chemical not exceeding 65 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 65 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 60 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 to continue manufacturing and to accumulate an inventory in excess of 65 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 procured the entire quantity of a chemical allocated to him under an individual procurement quota, and his inventory of that chemical is less than 25 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 35 percent of the estimated net disposal for that year.

(e) For liquid-injectable dosage-forms, if, during a calendar year, a registrant has procured the entire quantity of a chemical allocated to him under an individual procurement quota, and his inventory of that chemical is less than 40 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 50 percent of the estimated net disposal for that year.

■ 24. Amend § 1315.32 by:

■ a. Revising the first sentence in paragraph (a);

■ b. Removing the date ''July 1'' in the introductory text of paragraph (f) and adding in its place the date ''December 1'';

■ c. Removing ''manufacturer or importer'' in paragraph (h) and adding in its place ''registrant''.

The revision to read 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 Obtaining an import quota.

■ 25. In § 1315.34 amend paragraph (f) by removing the date ''July 1'' and adding, in its place, the date ''December 1''.

■ 26. Add § 1315.37 to read as follows:

§ 1315.37 Abandonment of procurement quota.

Any manufacturer assigned a procurement 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. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Signing Authority

This document of the Drug Enforcement Administration was signed on August 28, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–18885 Filed 8–30–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2023–OS–0076]

RIN 0790–AL68

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense, Department of Defense (DoD).

ACTION: Technical amendment.

SUMMARY: The DoD is amending this part to correct an error in the Privacy Act exemption rule associated with the Privacy Act system of records DoD–0007, ''Defense Reasonable Accommodation and Assistive Technology Records.''

DATES: The rule will be effective on August 31, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, *OSD.DPCLTD@mail.mil,* (703) 571–0070.

SUPPLEMENTARY INFORMATION: The Privacy Act permits Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including the provisions providing individuals with a right to request access to and amendment of their own records and accountings of disclosures of such records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process to provide public notice and an opportunity to comment on the exemption.

DoD is amending 32 CFR 310.13(e)(6) to correct an error in the Privacy Act exemption rule associated with the Privacy Act system of records notice DoD–0007, ''Defense Reasonable Accommodation and Assistive Technology Records.'' Section 310.13(e)(6) erroneously claims an exemption for this system of records from 5 U.S.C. 552a(c)(4), which generally requires the agency maintaining the system of records to inform recipients with whom it has shared a record if later the record was corrected or disputed pursuant to the requirements of the Privacy Act. DoD's inclusion of subsection 552a(c)(4) was an error and DoD is removing it from the exemption rule as well as the DoD–0007 system of records notice, which is being modified in a notice published concurrently in today's issue of the **Federal Register**.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action under these Executive Orders.

Congressional Review Act (5 U.S.C. 804(2))

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. DoD will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal**