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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1303 and 1315

[Docket No. DEA-1278]

RIN 1117-AB86

Revision of Applications for Manufacturing and Procurement Quotas

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to revise existing regulations relating to the management of quotas for schedule I and II controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, to be utilized by DEA-registered manufacturers. This rule is being proposed to: restructure DEA's manufacturing and procurement quota regulations for more clarity and consistency; clarify which use-specific subcategories for quotas should be used for controlled substances that will be sold domestically and controlled substances that will be exported; and revise the applications for individual manufacturing and procurement quota. The changes are necessary to increase visibility into the controlled substance supply chain by providing DEA with more detailed information allowing the agency to react more precisely in preventing drug shortages; and to ensure that enough of the schedule I and II controlled substances and three list I chemicals can be manufactured to meet estimated scientific, medical, lawful export, and inventory needs. This rule also contains revisions to use gender neutral language and other non-substantive revisions.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

- Electronically at *https://www.regulations.gov.* Follow the "Submit a comment" instructions. If you are reading this document on federalregister.gov, you may use the green "SUBMIT A PUBLIC COMMENT" button beneath this rulemaking's title to submit a comment to the regulations.gov docket.
- You may mail written comments to the following address: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. Mailed comments must be received by the close of the comment period.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on *https://www.regulations.gov* to view public comments.

FOR FURTHER INFORMATION CONTACT: Heather Achbach, Regulatory Drafting & Policy Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make all comments available for public inspection online at *http://www.regulations.gov*. Such information includes personal or business identifiers (such as name, address, state or federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below,

will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked "CONTAINS CONFIDENTIAL INFORMATION" and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked "TO BE PUBLICLY POSTED" and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *http://www.regulations.gov* for public inspection.

For easy reference, an electronic copy of this document and supplemental information to this notice of proposed rulemaking are available at *http://www.regulations.gov*.

Legal Authority

DEA implements and enforces the Controlled Substances Act (CSA) which authorizes the Administrator of the DEA (by delegation from the Attorney General) to promulgate rules and regulations that the Administrator deems necessary and appropriate for the efficient execution of the Administrator's functions. 21 U.S.C. 871(b). The CSA also requires the Administrator to establish the aggregate production quota (APQ) for each basic class of controlled substance listed in schedules I and II and the assessment of annual needs (AAN) for three list I chemicals annually. The APQ and AAN represent the total quantity to be manufactured in the United States (U.S.) each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the U.S., the lawful export requirements, and the establishment and maintenance of reserve stocks. 21 U.S.C. 826(a). The Administrator also is required to fix manufacturing quotas for registered manufacturers of the same controlled substances. In fixing

those quotas, the Administrator is required to consider, among other things, the manufacturer's current rate of disposal, the manufacturer's production cycle, and the manufacturer's inventory position. 21 U.S.C. 826(c).

Background

In the August 2023 final rule "Management of Quotas for Controlled Substances and List I Chemicals,"[1] DEA revised its regulations to align with the Agency's business practices and to reduce the potential for diversion. That rule also moved a section of DEA's regulations to aid in clarifying the procurement quota regulations. DEA acknowledges the need for further clarification and now aims to add more organization to the procurement and individual manufacturing quota section of DEA's regulations.

Purpose

While the CSA requires DEA to consider production cycles in establishing quotas, DEA currently has limited insight into manufacturers' intended production calendars for the quota year. At present, DEA obtains production cycle information irregularly from individual manufacturers. Furthermore, while manufacturers currently note on quota applications the amounts requested for domestic products as opposed to products for export, DEA's quota subcategories do not formally account for that distinction. The absence of a formalized process for collecting this data makes it more difficult for DEA to assess midyear whether quotas remain adequate to meet estimated domestic needs. This restricts DEA's ability to help prevent drug shortages by adjusting quota allotments based on manufacturers' production timelines. Thus, this rule aims to implement two of the four steps to increase manufacturer transparency and receive better data regarding drug production cycles mentioned by the Agency in a November 2023 letter to manufacturers: (1) requiring drug manufacturers to submit their anticipated production timelines for medications to DEA as a part of their application for quota; and (2)

[1] 88 FR 60117, August 31, 2023.

specifying whether a manufacturer's quota allotment is for the production of products for the domestic market or export market.[2]

Through this Notice of Proposed Rulemaking (NPRM), DEA proposes to require additional information to be submitted during the application process for individual manufacturing quotas and procurement quotas for controlled substances in schedules I and II and the list I chemicals. In addition, DEA proposes to revise existing subcategories and add additional subcategories to both the regulations and the relevant quota applications. These changes would assist DEA in complying with its statutory responsibilities in reviewing applications for individual manufacturing quota and procurement quota. The provisions being proposed in this rule will help DEA anticipate shortages in drugs containing these controlled substances or manufactured using these listed chemicals and will reduce related potential burdens on patients by allowing DEA to adjust quotas more quickly. The structural changes will provide a cohesive organization of the quota sections of the regulations.

Subcategories

DEA formalized use-specific subcategories for individual manufacturing and procurement quotas. These subcategories allow DEA to avoid "double counting" legitimate needs as the material moves from registrant to registrant, preventing an artificial increase in the APQ.[3] The current use-specific subcategories are:

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

[2] Letter issued by the Administrator, November 1, 2023, Quota-Shortages Letter.pdf (dea.gov) https://www.dea.gov/sites/default/files/2023-11/Quota-Shortages%20Letter.pdf.
[3] "Management of Quotas for Controlled Substances and List I Chemicals," 88 FR 60117, August 31, 2023.

The use-specific subcategories help DEA achieve its key objective for the quota system which is to track how much of a schedule I or II controlled substance or list I chemical is available, ensuring that there is sufficient material to provide for the estimated medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA now seeks to clearly delineate the amount of quota needed to meet domestic needs and the amount needed for lawful exports.

Individual Manufacturing Quota and Procurement Quota

An individual manufacturing quota is the maximum quantity of a schedule I or II controlled substance or list I chemical a bulk manufacturer is authorized to manufacture in a calendar year.[4] The sum of all individual manufacturing quotas issued to bulk manufacturers for a particular basic class of controlled substance in schedule I or II or list I chemical must be less than or equal to the established APQ for that basic class or AAN for that chemical, as established under 21 CFR 1303.11 and 1315.11. A bulk manufacturer may request, at any time during the calendar year to which it applies, an adjustment in its quota for a schedule I or II controlled substance or list I chemical.[5] DEA's determinations of individual manufacturing quota amounts are informed by the relevant procurement quotas. Only DEA-registered bulk manufacturers may apply for, and be issued, individual manufacturing quotas.

A procurement quota, in contrast, establishes the maximum quantity of a schedule I or II controlled substance or list I chemical a registrant is authorized to acquire in a calendar year for the purpose of further manufacturing, which may include manufacturing bulk controlled substances into dosage-forms, converting a controlled substance into another schedule I or II controlled substance (with corresponding individual manufacturing quota for that new drug code), packaging, repackaging, labeling, and/or relabeling.[6] The manufacturer must apply[7] for a

[4] 21 CFR 1303.21 and 1315.21.
[5] 21 CFR 1303.25(a), 1315.25(a).
[6] 21 U.S.C. § 802(15); 21 CFR 1303.03(c) and 1315.30(b).
[7] 21 CFR 1303.15(b) and 1315.32(a).

procurement quota using DEA Form 250. Finished dosage-form manufacturers, packagers, and labelers may apply for procurement quota only.

In establishing manufacturing and procurement quotas, DEA is required by the CSA to consider the manufacturer's production cycle. 21 U.S.C. 826(c). Historically and to date, DEA has received little data about such production cycles. Even as manufacturing practices have evolved, supply chains have become significantly more efficient, and manufacturers have improved the data they use to create sales forecasts, DEA has continued to receive the same types of data about manufacturers' production cycles that DEA received in decades past. The lack of more detailed information has made it difficult for DEA to have accurate and timely visibility into the controlled substance supply chain, preventing the agency from reacting with greater precision in preventing drug shortages. To increase manufacturing transparency and receive better data to inform DEA's quota determinations under the CSA, DEA now seeks to require drug manufacturers to submit additional information about their anticipated production cycles at the time of application for quota. To achieve this, DEA is proposing to require bulk manufacturers to provide certain information when applying for individual manufacturing quota under proposed 21 CFR 1303.22(c) for controlled substances and proposed 21 CFR 1315.22(c) for listed chemicals. DEA likewise is proposing to require non-bulk manufacturers to submit additional information when applying for procurement quota under proposed 21 CFR 1303.14(b) for controlled substances and proposed 21 CFR 1315.32(b) for listed chemicals.

Discussion of Proposed Changes

Restructuring Regulations for Procurement Quota

Under DEA's "Management of Quota for Controlled Substances and List I Chemicals" rulemaking,[8] DEA relocated 21 CFR 1303.12 to 21 CFR 1303.15 but left all the phases of the procurement quota application and determination process together in that section. In contrast, in

[8] 88 FR 60117, August 31, 2023.

21 CFR 1303.21 through 1303.27, DEA uses separate sections and subsections for each phase in the individual manufacturing quota process.

For controlled substances, DEA proposes to discuss the process of applying for and granting procurement quotas in three sections: 21 CFR 1303.13, 1303.14, and 1303.15. To do so, DEA would move existing text. This reconfiguration of text would add significant clarity and would more closely mirror the organization of the regulations relating to individual manufacturing quotas for controlled substances. DEA would move the current 21 CFR 1303.13, relating to adjustments of APQs, to the reserved 21 CFR 1303.12; move the current Procurement Quotas heading to before 1303.13; move the current 1303.15(a) to 1303.13; move 1303.15(b) and (e) to a new section 1303.14 and break the current 1303.15(b) into six paragraphs; move the current 1303.15(c) and (f) up to 1303.15(a) and (b), respectively; move the current 1303.15(d) to 21 CFR 1303.17; and move the current text of 1303.17 relating to abandonment of procurement quotas to a new 21 CFR 1303.18.

For the listed chemicals, DEA proposes creating five new sections for the procurement quota process. DEA would be moving paragraphs (f), (h), and (i) of 21 CFR 1315.32 to 21 CFR 1315.35(a), (b), and (c), respectively. In addition, DEA proposes to move 1315.32(g) to 21 CFR 1315.37. Last for the restructuring, DEA would move the current 21 CFR 1315.37 to 21 CFR 1315.38. DEA also would make appropriate changes to the cross-references within these sections. These changes would allow for the listed chemical procurement quota regulations to align with, as best as possible, the procurement quota regulations for controlled substances.

DEA is also proposing changes to current practices by requiring DEA Form 250 and DEA Form 189 to be completed in the online Quota Management System. DEA is proposing corresponding changes to eliminate cross-references to the Table of DEA Mailing Addresses in 21 CFR 1321.01 that currently appear (for example in 21 CFR 1303.15, 1303.22, 1315.22, and 1315.32) and to eliminate the option of obtaining copies of the application forms from DEA (as currently provided in 21 CFR 1303.22, 1315.22, and 1315.32).

In moving the current text of 21 CFR 1303.15(a) to the new 1303.13, DEA is proposing a minor non-substantive change to more clearly reflect that DEA's reference to the manufacturing of "dosage forms or other substances" is merely an illustrative example of the types of manufacturing that may be undertaken with, and that require, a procurement quota. Procurement quota has always been required for the acquisition of any schedule I or II controlled substance for the purpose of any manufacturing after its initial bulk manufacture.[9] In addition, DEA is proposing other minor non-substantive revisions including using gender neutral language and ensuring the word "schedules" is lowercase.

Procurement Quota Application

DEA proposes to require non-bulk manufacturers to provide additional information when applying for procurement quota under 21 CFR 1303.14(b) for controlled substances and under 21 CFR 1315.32(b) for listed chemicals. Manufacturers would be required to provide this additional information on the DEA Form 250. The specified information would give DEA more insight into the manufacturer's production cycle for that controlled substance. As noted above, the CSA requires DEA to consider the manufacturer's production cycle in establishing quotas. This information will provide DEA with a better understanding of when the finished drug product will be estimated to enter the domestic market or be exported. This will better allow DEA to assess midyear whether quotas remain adequate to meet the estimated needs in the United States and for lawful export requirements. That is, with additional insight into the products that have yet to reach the market—information that DEA currently lacks–DEA can more comprehensively consider whether quotas need to be increased in order to meet the CSA's directives. DEA also can utilize this information to help prevent relevant drug shortages by adjusting quota allotments based on manufacturers' timelines.

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[9] "The procurement quota form DEA 250 is required for dosage form manufacturers, compound pharmacies, labelers/re-labelers, and packagers/re-packagers." Quota Manual, https://www.deadiversion.usdoj.gov/quotas/quotas_userguide.pdf. "Manufacturers of Schedule I and II controlled substances" and "[m]anufacturers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine" must apply for quota, with no limitation with respect to the type of manufacturer. https://www.deadiversion.usdoj.gov/quotas/quota-apps.html.

For each basic class or chemical (as applicable) desired to be procured or used, the application would be required to include the following information:

1. The length of time it will take to receive the controlled substance or active pharmaceutical ingredient (API) after receiving the quota letter from DEA pursuant to 21 CFR 1303.15 or 1315.35;
2. The supplier of the basic class or chemical, if obtaining it from another registrant;
3. The length of time it will take to begin the production cycle after receiving the controlled substance or chemical;
4. The estimated length of time it will take to perform the production cycle; and
5. The length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after production is complete.

Individual Manufacturing Quota Application

DEA similarly is proposing to require additional information from bulk manufacturers when applying for individual manufacturing quota under 21 CFR 1303.22(c) for the relevant controlled substances and under 21 CFR 1315.22(c) for the relevant listed chemicals. The requested additional information would be added to DEA Form 189 and would require the manufacturer to be more transparent with DEA regarding the production timeline. The information gained would provide insight into the processing timeline in much the same way as it would for procurement quota. Obtaining this information at the time of application allows DEA to more quickly respond to any problems that arise during the year and helps prevent possible drug shortages due to lack of available API.

For each basic class or chemical (as applicable), the application would be required to include the following information:

1. The desired individual manufacturing quota;
2. The length of time it will take to start the production cycle after receiving the quota letter from DEA pursuant to 21 CFR 1303.21 or 1315.21;

3. The length of time it will take to perform the production cycle;
4. The length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after production is complete; and
5. Any additional factors which the applicant finds relevant to the fixing of the individual manufacturing quota, including the trend of (and recent changes in) the applicant's and the national rates of net disposal, the applicant's production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

Use-Specific Subcategories for Domestic Use and Exportation

As noted above, DEA currently has limited insight into how much quota will be utilized to manufacture API and finished products for export as opposed to domestic use. Currently, the use-specific subcategories of quota for commercial sale, product development, and packaging/repackaging and labeling/relabeling do not distinguish between quota utilized in the production of API or finished drug products to be consumed domestically versus quota utilized in the production of items to be exported.

To obtain this important data, DEA proposes to bifurcate these subcategories. For example, "Quota for Commercial Sale" would be separated into two further subcategories: "Quota for Domestic Commercial Sale," which would apply to quota used to manufacture API or finished drug products that will remain in the U.S., and "Quota for Commercial Manufacturing for Export," which would apply to quota used to manufacture API or finished drug products for lawful export purposes. Similarly, "Product Development" would be separated further into "Quota for Domestic Product Development," which would apply to quota used in the development of finished drug products that will remain in the U.S., and "Quota for Product Development for Export," which would apply to quota that will be used for the development of

finished drug products for lawful export purposes. Finally, "Packaging/Repackaging and Labeling/Relabeling" would be separated further into "Quota for Packaging/Labeling Domestic," which would apply to quota used in the packaging/repackaging and labeling/relabeling of API and/or finished products that will remain in the U.S., and "Quota for Packaging/Labeling for Export," which would apply to quota that will be used in the packaging/repackaging and labeling/relabeling of API and/or finished products for lawful export purposes.

Specifically, DEA would add two further subcategories to the current subcategory Quota for Commercial Sale in 21 CFR 1303.04(a) and 1315.07(a). The first further subcategory would be (1) "Quota for Domestic Commercial Sale" to specify that this subcategory applies when the quota being requested will be used for controlled substances (or list I chemicals) that will be manufactured and distributed within the U.S. The "Quota for Commercial Manufacturing for Export" category would be subcategory (2) and would be used by a manufacturer if they will export the item that they are manufacturing. That subcategory also would be used if the manufacturer knows the item being manufactured will be exported after some later manufacturing step performed by another registered manufacturer. If the bulk and dosage form manufacturers do not know whether the finished product will be exported, but the manufacturer who is assigned to package/repackage or label/relabel the finished product does know, the last manufacturer in the supply chain will apply for "Quota for Packaging/Labeling for Export" quota to reflect this information. However, registrants would be required to provide correct and detailed information about the next destination of the product.

Similarly, DEA would add two further subcategories to the current subcategory Quota for Product Development in 21 CFR 1303.04(c) and 1315.07(c). The first further subcategory would be (1) "Quota for Domestic Product Development" for quota used in the development of finished drug products that will remain in the U.S. The "Quota for Product Development for Export" category would be subcategory (2) and would apply to quota that will be used for the development of finished drug products where the approval and distribution will occur outside the

U.S. DEA likewise would add two further subcategories to the current subcategory "Quota for packaging/repackaging and labeling/relabeling" in 21 CFR 1303.04(e) and 1315.07(e). The first further subcategory would be (1) "Quota for Packaging/Labeling Domestic" and the "Quota for Packaging/Labeling for Export" category would be subcategory (2) in the section.

These further subcategories would allow DEA to better track material that is being utilized under the current "Quota for Commercial Sale," "Quota for Product Development," and "Quota for Packaging/Repackaging and Labeling/Relabeling" subcategories. This would allow DEA to better execute its responsibility to establish quotas to account for both the needs within the United States and for lawful export requirements. This additional data also would allow DEA to better anticipate how much of a drug is available for legitimate domestic patient, industrial, scientific and research needs as opposed to the needs of foreign markets.

DEA has decided that the existing subcategories for quotas for transfer and replacement do not need to be revised to distinguish their application between domestic use and export use. The amount necessary for domestic use and export use is already accounted for in the quota for commercial sale applications; therefore, bifurcating these two categories would be redundant.

The domestic/export distinction would be applicable for controlled substances and list I chemicals requiring a quota for manufacturing purposes as defined in the CSA. While DEA is currently focused on the manufacturing of drug products containing schedule II controlled substances, for example medications used in the treatment of pain or attention deficit/hyperactivity disorder as these medications are important in healthcare, they need to be manufactured and consumed responsibly. The aggregate production quotas for controlled substances are affected by both legitimate domestic medical needs and exportation to meet global requirements and therefore the submission of separate detailed data will enhance DEA's visibility into production and the supply chain.

In proposing these changes, DEA also proposes minor clarifying changes in 21 CFR 1303.04(a) and (c) and 1315.07(c). Those sections currently refer specifically to approval of

drug products by the U.S. Food and Drug Administration (FDA). DEA understands that manufacturers in the U.S. may manufacture products that are authorized for marketing in countries other than the U.S. To avoid any potential confusion, DEA is proposing to expand the existing references to FDA approval to also include approval or authorization by equivalent foreign regulatory bodies. DEA views this as merely clarifying DEA's intent without effecting any substantive change. Similarly, DEA proposes to revise the text of 21 CFR 1303.04(a) and 1315.07(a), relating to quota for commercial sale, to reflect that both apply to bulk API that is produced by a registrant, in addition to API that is acquired by a registrant. These changes clarify the manner in which the text applies to individual manufacturing quotas. As these provisions have always applied to individual manufacturing quotas, DEA does not view these changes as substantive.

Regulatory Analysis

Executive Orders 12866, 13563, and 14192 (Regulatory Review)

DEA has determined that this rulemaking is not a "significant regulatory action" under section 3(f) of Executive Order (E.O.) 12866, Regulatory Planning and Review. Accordingly, this proposed rule has not been submitted to the Office of Management and Budget (OMB) for review. This proposed rule has been drafted and reviewed in accordance with E.O. 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation; E.O. 13563, "Improving Regulation and Regulatory Review," section 1(b), General Principles of Regulation; and E.O. 14192, "Unleashing Prosperity Through Deregulation."

DEA proposes to revise existing regulations that manage the quotas for controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, held by DEA-registered manufacturers. This rule is being proposed to: restructure DEA's procurement quota regulations for more clarity and consistency, clarify which subcategories for quotas should be used for controlled substances that will be sold domestically and controlled substances that will be exported, and revise the applications for individual manufacturing and

procurement quota. The changes are necessary to ensure clarity, provide DEA with adequate information about manufacturing to help the agency foresee and prevent both shortages and oversupply, and to ensure enough of the schedule I and II controlled substances and three list I chemicals can be manufactured to meet estimated scientific, medical, lawful export, and inventory needs. Additionally, DEA proposes to codify current practices by requiring DEA Form 250 and DEA Form 189 to be completed online. This NPRM has been determined not to be a significant regulatory action under E.O. 12866 with an estimated annual cost of $50,496. This rule is not subject to E.O. 14192 because it is not a significant regulatory action under section 3(f) of E.O. 12866.

This NPRM contains three types of changes. First, DEA proposes to require non-bulk manufacturers to submit additional information online on the DEA Form 250 to give DEA more insight into their procurement process and their production cycle. Second, DEA proposes to require bulk manufacturers to submit additional information online on the DEA Form 189 to give DEA more insight into their production cycle. Third, DEA proposes to revise the use-specific subcategories for procurement and individual manufacturing quotas for controlled substances and listed chemicals to help in the administration of these quotas. DEA would add new further subcategories to DEA's regulations in 21 CFR 1303.04 for controlled substances and 21 CFR 1315.07 for listed chemicals. The revised subcategories would allow for the continued tracking of material being moved at all stages of manufacturing so that DEA is able to anticipate how much of a drug is available in the U.S. DEA has examined the benefits and costs of each provision of this proposed rule and are as follows.

Benefits

This NPRM would expand upon previously implemented regulations by requiring additional information from registrants applying for individual manufacturing quotas and procurement quotas for controlled substances in schedules I and II and the list I chemicals. In addition, DEA would revise the subcategories in its regulations and the relevant applications.

The changes proposed in this NPRM would enable DEA to receive better data on the manufacturer's anticipated drug production cycles at the time the manufacturer applies for individual manufacturing quota or procurement quota. The provisions being proposed in this notice of proposed rulemaking will help DEA anticipate shortages and reduce burdens on patients by allowing DEA to adjust more quickly. Finally, codifying the current practice for completing DEA Form 250 and DEA Form 189 online provides clarity and alignment between practice and regulations.

Impact on Non-Bulk manufacturer

As discussed above, DEA proposes to require additional information from non-bulk manufacturers when applying for procurement quota under 21 CFR 1303.14(b) for controlled substances and under 21 CFR 1315.32(b) for listed chemicals. The information would be added to DEA Form 250 and would require the manufacturer to give DEA more insight into their production cycle timeline, including the timeline for procurement of materials. Based on the estimated time to complete the current application, DEA estimates an additional 20 minutes will be needed to provide the additional information and minimal additional time to complete the new use-specific subcategory for procurement quotas.

Impact on Bulk manufacturer

As discussed above, DEA is proposing to require additional information from bulk manufacturers when applying for individual manufacturing quota under 21 CFR 1303.22(c) for controlled substances and under 21 CFR 1315.22(c) for listed chemicals. For each basic class or chemical (as applicable) desired to be synthesized or extracted, the applicant would be required to include the additional information. The information would be added to DEA Form 189 and would require the manufacturer to be more transparent with DEA regarding the production timeline. DEA estimates an additional 20 minutes will be needed to provide the additional information and minimal additional time to complete the new use-specific subcategory for

individual manufacturing quotas. The current practices are used as baseline for the purposes of this analysis.

Costs

DEA estimates, under the proposed rule, there is a cost associated with the estimated additional 20 minutes to complete DEA Form 189 and 250.

The U.S. Bureau of Labor Statistics (BLS) data indicates that the median hourly wage for a purchasing manager is $63.15.[10] According to the BLS Employer Costs for Employee Compensation (ECEC), for private industry workers, average total benefits is 29.4 percent and wages and salaries is 70.6 percent of total compensation. The total benefits of 29.4 percent equate to a 41.6 (29.4 /70.6) percent load on wages and salaries.[11] Adding the 41.6 percent load on the median salary, the loaded median hourly wage for a purchasing manager is $89.42 ($63.15 x 1.416). Based on the estimated additional 20 minutes (0.33 hours) to complete both DEA Forms 189 and 250, the estimated cost to a purchasing manager is $29.81.

Number of Affected Persons

DEA estimated the number of affected persons based on the total number of DEA Forms 189 and 250 received in 2022. In 2022, DEA received 875 DEA Forms 189 from 40 bulk manufacturers and 2,514 DEA Forms 250 from 291 non-bulk manufacturers and six bulk manufacturers. Table 1 summarizes the total number of affected registrants.

Table 1: Number of affected registrants

Business Activity	**Affected Registrants**
Bulk Manufacturer	40
Non-Bulk Manufacturer	291
Total	**331**

[10]BLS, Occupational Employment and Wage Statistics, May 2022 National Occupational Employment and Wage Estimates, 11-3061 Purchasing Managers, https://www.bls.gov/oes/current/oes_nat.htm. (Accessed 11/15/2023.)
[11]BLS, Employer costs for employee compensation – June 2023 https://www.bls.gov/news.release/pdf/ecec.pdf. (Accessed 11/15/2023.)

Applying the estimated cost of $29.81 per application to the 875 and 2,514 (6 from bulk and 2,508 from non-bulk manufacturers) Forms 189 and 250 received, DEA estimates the total cost of this proposed rule is $101,026: $26,084 (875 x $29.81) for DEA Form 189 by bulk manufacturers, $179 (6 x $29.81) for DEA Form 250 by bulk manufacturers, and $74,763 (2,508 x $29.81) for DEA Form 250 by non-bulk manufacturers. Table 2 summarizes the total cost burden of both DEA Form 189 and 250 applications.

Table 2: Total cost burden

Business Activity	DEA Form 189 ($)	DEA Form 250 ($)	Total ($)
Bulk Manufacturers	26,084	179	26,263
Non-Bulk Manufacturers	-	74,763	74,763
Total cost burden	**26,084**	**74,763**	**101,026**

*Numbers are rounded as shown.

As described earlier, the proposed change to require DEA Form 250 and DEA Form 180 to be completed online codifies current practices. All such forms are already submitted to DEA online and meet the requirements of the proposed change. Therefore, there is no cost associated with this proposed change.

Executive Order 12988, Civil Justice Reform

The provisions of this regulation meet the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have direct effects on one or more Indian tribes, on the relationship between the Federal

Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Executive Order 14267, Reducing Anti-Competitive Regulatory Barriers

The proposed rule does not reduce competition, entrepreneurship, and innovation.

Executive Order 14294, Overcriminalization of Federal Regulations

Executive Order 14294 specifies that all notices of proposed rulemaking (NPRMs) and final rules published in the Federal Register, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the mens rea requirement for each element of the offense. This NPRM does not involve a criminal regulatory offense and thus E.O. 14294 does not apply.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), has reviewed this proposed rule and by approving it, certifies that it will not, if promulgated, have a significant economic impact on a substantial number of small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that this rule will not have a significant impact on a substantial number of small entities. For the 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.

DEA is proposing to expand upon existing regulations by requiring additional information be provided during the application process for individual manufacturing quotas and procurement quotas for controlled substances in schedules I and II and the three list I chemicals. In addition, DEA proposes to revise its subcategories in its regulations and the relevant applications for controlled substance and list I chemical quotas. Finally, DEA is proposing to require DEA Form 250 and DEA Form 189 to be completed online. The proposed change

codifies current practices as all such forms are already submitted to DEA online and meet the requirements of the proposed change. Therefore, there is no cost associated with this proposed change.

The provisions being proposed in this rule will help DEA execute its functions as defined in 21 U.S.C. 826, will help DEA anticipate and prevent shortages, and will help reduce burdens on patients by allowing DEA to adjust more quickly. The structural changes will provide a cohesive organization of the quota sections.

This proposed rule would, if implemented, affect bulk manufacturers and non-bulk manufacturers who apply for individual manufacturing quota and procurement quota. Based on a review of the North American Industry Classification System (NAICS) codes for the best representation of affected industries, DEA estimates that the proposed rule primarily affects the following industries:[12]

- 325411-Medicinal and Botanical Manufacturing.
- 325412-Pharmaceutical preparation Manufacturing.

Small Business Administration (SBA) size standards for 325411- Medicinal and Botanical Manufacturing, 325412- Pharmaceutical preparation Manufacturing are 1,000 and 1,250 employees, respectively.[13]

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides economic data by enterprise size and industry. SUSB data contains the number of firms for various employment or revenue size ranges for each industry. Specifically, SUSB data contains the number of firms by size ranges for each NAICS code. For the purposes of this analysis, the term "firm" as defined in the SUSB data is used interchangeably with "entity" as defined in the RFA. Comparing the size ranges to the SBA size standards, DEA estimated the

[12] Executive Office of the President, Office of Management and Budget. "North American Industry Classification System, United States, 2017." https://www.census.gov/naics/. (Accessed 11/15/2023.)
[13] SBA, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective August 19, 2019."

number of entities in each affected industry, number of small entities in each affected industry, and number of affected small entities. For NAICS code 325411, there are 667 firms of which 635 are small firms. For NAICS code 325412, there are 1,154 firms, of which 1,080 are small firms.[14]

Table 3: Number of small entities

NAICS	NAICS Description	Enterprise Size	Firms	SBA Size Standard (number of employees)	Small Firms
325411	Medicinal and Botanical Manufacturing	<500 employees	626	1,000	626
		500-749 employees	9		9
		1,000-1,499 employees	3		-
		2,000-2,499 employees	3		-
		2,500-4,999 employees	10		-
		5,000+ employees	12		-
		Total	**667***		**635**
325412	Pharmaceutical Preparation Manufacturing	<500 employees	1,041	1,300	1,041
		500-749 employees	22		22
		750-999 employees	10		10
		1,000-1,499 employees	11		7
		1,500-1,999 employees	10		-
		2,000-2,499 employees	5		-
		2,500-4,999 employees	16		-
		5,000+ employees	39		-
		Total	**1,154**		**1,080**

Source: 2020 SUSB Annual Data Tables by Establishment Industry, 2017, Data by Enterprise Receipt Size, U.S., 6-digit NAICS. (Accessed 11/20/2023)
*Sum of the line items do not equal the "Total" in the original.

DEA calculated the percent of firms that are small firms for each industry, then applied these percentages to the number of affected entities to estimate the number of affected small entities. Based on the analysis above 95.2 percent (635/667) and 93.6 percent (1,080/1,154) of entities in 325411 and 325412 are small firms, respectively. Based on this analysis, DEA estimates 308 small entities would be affected by this proposed rule, 38 (40 x 0.952) in the

[14] SUSB, 2020 SUSB Annual Data Tables by Establishment Industry, 2020, Data by Enterprise Receipt Size, U.S. 2020 SUSB Annual Data Tables by Establishment Industry (census.gov). (Accessed 11/15/2023)

325411-Medicinal and Botanical Manufacturing industry and 272 (291 x 0.936) in the 325412-Pharmaceutical preparation manufacturing industry.

In summary, this proposed rule is estimated to affect 38 of 635 small entities in the 325411-Medicinal and Botanical Manufacturing industry and 272 of 1,080 small entities in the 325412- Pharmaceutical preparation manufacturing industry. Therefore, this proposed rule will not affect a substantial number of small entities. Table 4 summarizes the number of firms, small firms, and affected small entities for each affected NAICS code.

Table 4: Small firms, affected entities, and affected small firms

NAICS Code	Firms	Small firms	Affected Entities	Affected entities %	Affected small entities
325411	663	635	40	95.8%	38
325412	1,154	1,080	291	93.6%	272

DEA also estimated the impact on small entities by comparing the average cost of the rule to annual receipts on a 'per entity' basis. The estimated average cost of this proposed rule is $652 ($26,084/40) and $257 ($74,763/291) for entities in 325411 and 325412, respectively. Table 5 summarizes the average cost per entity.

Table 5: Average cost per entity

	Bulk Manufacturer	Non-bulk Manufacturer
Total cost burden	$ 26,084	$ 74,763
Number of entities	40	291
Cost per entity	$ 652	$ 257

From 2017 SUSB data, the most recent year with receipts data, the average annual receipts are lowest for the smallest of small entities, with "<5 employees," with average annual revenues of $689,768 and $1,183,789 per entity, respectively.[15] The average annual costs of $652 and $257 are 0.095 percent ($652/$689,768) and 0.022 percent ($257/$1,183,789) for industries in 325411 and 325412, respectively. If the impact is not significant for the smallest of

[15] SUSB, The Number of Firms and Establishments, Employment, Annual Payroll, and Receipts by State, Industry, and Enterprise Employment Size: 2017, https://www2.census.gov/programs-surveys/susb/tables/2017/us_state_naics_detailedsizes_2017.xlsx. (Accessed 11/20/2023.)

small entities, the impact is not significant for the larger small entities. Table 6 summarizes the impact on the smallest of small entities.

Table 6: Impact on smallest of small entities

NAICS Code	Enterprise Size	Firms	Receipts ($1,000)	Average Annual Receipts ($)	Average Cost per Entity ($)	Average Cost of Average Annual Receipt (Percent)
325411	<5 employees	142	97,947	689,768	652	0.095
325412	<5 employees	331	391,834	1,183,789	257	0.022

Source: SUSB, The Number of Firms and Establishments, Employment, Annual Payroll, and Receipts by State, Industry, and Enterprise Employment Size: 2017, https://www2.census.gov/programs-surveys/susb/tables/2017/us_state_naics_detailedsizes_2017.xlsx. (Accessed 11/20/2023.)

As discussed above, this proposed rule would affect 38 of 635 small entities in NAICS 325411 and 272 of 1,080 entities in NAICS 325412. Additionally, the economic impact of the proposed rule, as compared to estimated annual receipts, is 0.095 and 0.022 percent for NAICS 325411 and 325412, respectively. Therefore, DEA estimates the proposed rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

This proposed rule would modify existing collections of information under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. DEA has identified the following collections of information related to this proposed rule: 1117-006 and 1117-0008. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain*.

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 proposes modifying this application by requiring bulk manufacturers to submit additional information on the form when applying for individual manufacturing quota for controlled substances and listed chemicals. While the current form is online, DEA is proposing to eliminate the paper form making the form online only. The applicant would also be required to provide the following:

(1) the desired individual manufacturing quota;

(2) the length of time it will take to start the production cycle after receiving the quota letter from DEA pursuant to 21 CFR 1303.21 and 1315.21;

(3) the length of time it will take to complete the production cycle;

(4) the length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after production is complete; and

(5) any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

DEA is also proposing to bifurcate the current subcategories found on the form for "Quota for Commercial Sale," "Quota for Product Development," and "Quota for packaging/repackaging and labeling/relabeling." DEA proposes that "Quota for Commercial Sale" would be separated into two further subcategories: "Quota for Domestic Commercial Sale," for quota to be used for controlled substances and ephedrine, pseudoephedrine, and

phenylpropanolamine products and bulk API acquired by outsourcing facilities, manufacturers, etc. that will be manufactured and distributed within the U.S., and "Quota for Commercial Manufacturing for Export," which would apply to quota used to manufacture controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine products and bulk API acquired by outsourcing facilities, manufacturers, etc. for lawful export purposes. Similarly, "Product Development" would be separated further into "Quota for Domestic Product Development," and "Quota for Product Development for Export." Finally, "Quota for packaging/repackaging and labeling/relabeling" would be separated further into "Quota for Packaging/Labeling Domestic," and "Quota for Packaging/Labeling for Export." Like the other subcategories, these subcategories would be requested on the existing online form.

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

- Number of respondents: 40
- Frequency of response: 21.88 annually (as needed, calculated value)
- Number of responses: 875
- Burden per response: 50 min
- Total annual hour burden: 729 hours

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 proposes modifying this application by requiring non-bulk manufacturers to submit additional information on the form when applying for procurement quota for controlled substances and listed chemicals. While the current form is online, DEA is proposing to eliminate the paper form making the form online only. Applicants would be required to also provide the

following for each basic class or chemical (as applicable) desired to be procured or used for the next calendar year:

(1) the length of time it will take to receive the controlled substance or active pharmaceutical ingredient after receiving the quota letter from DEA pursuant to 21 CFR 1303.15 and 1315.35;

(2) the supplier of the basic class or chemical, if obtaining it from another registrant;

(3) the length of time it will take to start production after receiving the controlled substance or chemical;

(4) the estimated length of time it will take to perform the production cycle; and

(5) the length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after production is complete.

DEA is also proposing to bifurcate the current subcategories found on the form for "Quota for Commercial Sale," "Quota for Product Development," and "Quota for packaging/repackaging and labeling/relabeling." DEA proposes that "Quota for Commercial Sale" would be separated into two further subcategories: "Quota for Domestic Commercial Sale," for quota to be used for controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine that will be manufactured and distributed within the U.S., and "Quota for Commercial Manufacturing for Export," which would apply to quota used to manufacture controlled substances and the three listed chemicals for lawful export purposes. Similarly, "Product Development" would be separated further into "Quota for Domestic Product Development," and "Quota for Product Development for Export." Finally, "Quota for packaging/repackaging and labeling/relabeling" would be separated further into "Quota for Packaging/Labeling Domestic," and "Quota for Packaging/Labeling for Export." Like the other subcategories, these subcategories would be requested on the existing online form.

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

- Number of respondents: 291
- Frequency of response: 8.64 annually (as needed, calculated value)
- Number of responses: 2,514
- Burden per response: 50 min
- Total annual hour burden: 2,095 hours

B. Request for Comments Regarding the Proposed Collections of Information

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

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

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB86/Docket No. DEA-1278. All comments must be submitted to OMB on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The

final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

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 stated in the preamble, DEA proposes to amend 21 CFR parts 1303 and 1315 as follows:

PART 1303—QUOTAS

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

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

2. Revise § 1303.04 to read as follows:

§ 1303.04 Subcategories of manufacturing and procurement quotas.

* * * * *

(a) ***Quota for commercial sale.*** This subcategory is divided into Quota for Domestic Commercial Sale and Quota for Commercial Manufacturing for Export. This is a quota for the amount of bulk active pharmaceutical ingredients (API) initially produced or acquired by a registrant for the manufacture of drug products approved by the U.S. Food and Drug Administration or an equivalent foreign regulatory body, and bulk API acquired by outsourcing

facilities, manufacturers, etc. This type of quota may only be used to support commercial manufacturing efforts and may not be used to support other manufacturing efforts.

(1) **Quota for domestic commercial sale.** This quota category is used to capture bulk API produced by a bulk manufacturer or moving from a bulk manufacturer to other registered manufacturers to support commercial manufacturing for the domestic market. This type of quota may only be used to support commercial manufacturing efforts for the domestic market and may not be used to support the manufacture of products for export or other manufacturing efforts.

(2) **Quota for commercial manufacturing for export.** This is a quota for the amount of bulk active pharmaceutical ingredients initially produced by the bulk manufacturer or acquired by a registrant that will be manufactured domestically to be exported to another country. This type of quota may only be used to support commercial manufacturing for export activities for the foreign market and may not be used to support the manufacture of products for domestic use or other manufacturing efforts. Such quotas are limited to the purpose of exportation.

* * * * *

(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 validation batches post-approval by the country's drug regulatory agency. 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 approved by the country's drug regulatory agency 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. This subcategory is further divided into Quota for Domestic Product Development and Quota for Product Development for Export.

(1) **Quota for domestic product development**. This will apply to quota used toward the development of finished drug products that will remain in the U.S.

(2) **Quota for product development for export.** This will apply to quota that will be used toward the development of finished drug products where the approval and distribution will occur outside the U.S.

* * * * *

(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 controlled substances as they undergo packaging/labeling activities; however, packaging/repackaging and labeling/relabeling quotas shall not be counted against the aggregate production quotas. This subcategory is further divided into Quota for Packaging/Labeling Domestic and Quota for Packaging/Labeling for Export, which also apply to repackaging and relabeling.

(1) **Quota for packaging/labeling domestic.** This would apply to quota used in the packaging/repackaging and labeling/relabeling of API and/or finished products that will remain in the U.S.

(2) **Quota for packaging/labeling for export.** This would apply to quota that will be used in the packaging/repackaging and labeling/relabeling of API and/or finished products for lawful export purposes.

3. Redesignate § 1303.13 as § 1303.12 and reserve the new § 1303.13.

4. Move the undesignated center heading before § 1303.15 to before § 1303.13.

5. Amend newly reserved § 1303.13 by revising and republishing to read as follows:

§ 1303.13 Procurement quotas.

In order to determine the estimated needs for, and to insure an adequate and uninterrupted supply of, basic classes of controlled substances listed in schedules I and II (except raw opium being imported by the registrant pursuant to an import permit) the Administrator shall issue procurement quotas authorizing persons to procure and use quantities of each basic class of such substances for the purpose of manufacturing, including manufacturing such class into dosage forms or into other substances. 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.

6. Add § 1303.14 to read as follows:

§ 1303.14 Applications for procurement quotas.

(a) 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 in the online Quota Management System 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 desired. A separate application must be made for each basic class desired to be procured or used, by filing an application electronically in the online Quota Management System. DEA Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied.

(b) For each basic class desired to be procured or used for the next calendar year, the applicant must provide the following information:

(1) each purpose for which the basic class is desired, the quantity desired for that purpose during the next calendar year, and the quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years;

(2) whether the applicant intends to manufacture the basic class themselves or obtain it from another registrant and, if obtaining it from another registrant, the supplier's name;

(3) the length of time it will take to receive the controlled substance after receiving the quota letter from DEA pursuant to § 1303.15;

(4) the length of time it will take to start production after receiving the controlled substance;

(5) the estimated length of time that it will take to perform their portion of the production cycle; and

(6) for quota categories other than product development and transfer, the length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after the current registrant's production activity is complete.

(c) If the purpose is to manufacture the basic class into dosage form, the applicant shall state the official name, common or usual name, chemical name, or brand name of that form.

(d) If the purpose is to manufacture another substance, the applicant shall state the official name, common or usual name, chemical name, or brand name of the substance, and, if a controlled substance listed in any schedule, the schedule number and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the substance.

(e) If the purpose is to manufacture another basic class of controlled substance listed in schedule I or II, the applicant shall also state the quantity of the other basic class which

the applicant has applied to manufacture pursuant to § 1303.22 and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class.

(f) The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.

(g) The following persons need not obtain a procurement quota:

(1) Any person who is registered to manufacture a basic class of controlled substance listed in schedule I or II and who uses all of the quantity they manufactured in the manufacture of a substance not controlled under the Act;

(2) Any person who is registered or authorized to conduct chemical analysis with controlled substances (for controlled substances to be used in such analysis only); and

(3) Any person who is registered to conduct research with a basic class of controlled substance listed in schedule I or II and who is authorized to manufacture a quantity of such class pursuant to § 1301.13 of this chapter.

7. Revise and republish § 1303.15 to read as follows:

§ 1303.15 Procedure for issuing and certifying available procurement quota.

(a) The Administrator shall, on or before December 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing them to procure and use:

(1) All quantities of such class necessary to manufacture all quantities of other basic classes of controlled substances listed in Schedules I and II which the applicant is authorized to manufacture pursuant to § 1303.23; and

(2) Such other quantities of such class as the applicant has applied to procure and use and are consistent with their past use, estimated needs, and the total quantity of such class that will be produced.

(b) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of a basic class of controlled substances listed in schedules I or II during the current calendar year, shall, at or before the time of giving an order to another manufacturer requiring the distribution of a quantity of such basic class, certify in writing to such other registrant that the quantity of such basic class ordered does not exceed the person's unused and available procurement quota of such basic class for the current calendar year. The written certification shall be executed by the same individual who signed the DEA Form 222 transmitting the order. A registrant shall not fill an order from persons required to apply for a procurement quota under § 1303.14 unless the order is accompanied by a certification as required under this section. The certification required by this section shall contain the following: The date of the certification; the name and address of the registrant to whom the certification is directed; a reference to the number of the DEA Form 222 to which the certification applies; the name of the person giving the order to which the certification applies; the name of the basic class specified in the DEA Form 222 to which the certification applies; the appropriate schedule within which is listed the basic class specified in the DEA Form 222 to which the certification applies; a statement that the quantity (expressed in grams) of the basic class specified in the DEA Form 222 to which the certification applies does not exceed the unused and available procurement quota of such basic class, issued to the person giving the order, for the current calendar year; and the signature of the individual who signed the DEA Form 222 to which the certification applies.

8. Revise and republish § 1303.17 to read as follows:

§ 1303.17 Adjusting procurement quotas.

Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. Such application shall be filed electronically with the UN Reporting and Quota

Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. The Administrator shall increase or decrease the procurement quota of such person if and to the extent that the Administrator finds, after considering the factors enumerated in § 1303.15(a) and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

9. Add § 1303.18 to read as follows:

§ 1303.18 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 § 1303.15 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. Revise and republish § 1303.22 to read as follows:

§ 1303.22 Procedure for applying for individual manufacturing quotas.

(a) 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 in the online Quota Management System 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 desired. A separate application must be made for each basic class desired to be manufactured by filing an application electronically in the online Quota Management System. DEA Form 189 shall be filed on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied.

(b) For the basic class desired to be manufactured the applicant must provide the following information for each of the current and preceding 2 calendar years:

(1) The authorized individual manufacturing quota, if any;

(2) The actual or estimated quantity manufactured;

(3) The actual or estimated net disposal;

(4) The actual or estimated inventory allowance pursuant to § 1303.24; and

(5) The actual or estimated inventory as of December 31.

(c) For each basic class desired to be manufactured for the next calendar year, the applicant must provide the following information:

(1) the desired individual manufacturing quota;

(2) the length of time it will take to start production after receiving the quota letter from DEA pursuant to § 1303.21;

(3) the length of time it will take to perform their portion of the production cycle;

(4) the length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after the current registrant's production activity is complete; and

(5) Any additional factors which the applicant finds relevant to the fixing of the individual manufacturing quota, including any of the following:

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

* * * * *

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

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

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

12. Revise § 1315.07 to read as follows:

§ 1315.07 Subcategories of manufacturing and procurement quotas.

* * * * *

(a) ***Quota for commercial sale.*** This subcategory is divided into Quota for Domestic Commercial Sale and Quota for Commercial Manufacturing for Export. This quota is for the amount of bulk active pharmaceutical ingredients (API) initially produced or 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.

(1) **Quota for domestic commercial sale.** This quota category is used to capture bulk API produced by a bulk manufacturer or moving from a bulk manufacturer to other registered manufacturers to support commercial manufacturing for the domestic market. This type of quota may only be used to support commercial manufacturing efforts for the domestic market and may not be used to support the manufacture of products for export or other manufacturing efforts.

(2) **Quota for commercial manufacturing for export.** This is a quota for the amount of bulk API initially produced by the bulk manufacturer or acquired by a registrant that will be manufactured domestically to be exported to another country. This type of quota may only be used to support commercial manufacturing for export activities for the foreign market and may not be used to support the manufacture of products for domestic use or other manufacturing efforts. Such quotas are limited to the purpose of exportation.

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(c) ***Quota for product development.*** This 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 validation batches following approval by the country's drug regulatory agency or authorization through compliance with an FDA OTC monograph (or its equivalent in that country). 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 approved or otherwise authorized by the country's drug regulatory agency 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. This subcategory is further divided into Quota for Domestic Product Development and Quota for Product Development for Export.

(1) **Quota for domestic product development**. This will apply to quota used toward the development of finished drug products that will remain in the U.S.

(2) **Quota for product development for export.** This will apply to quota that will be used toward the development of finished drug products where the approval and distribution will occur outside the U.S.

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(e) Quota for packaging/repackaging and labeling/relabeling. This 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. This subcategory is further divided into Quota for Packaging/Labeling Domestic and Quota for Packaging/Labeling for Export, which also apply to repackaging and relabeling.

(1) **Quota for packaging/labeling domestic.** This would apply to quota used in the packaging/repackaging and labeling/relabeling of API and/or finished products that will remain in the U.S.

(2) **Quota for packaging/labeling for export.** This would apply to quota that will be used in the packaging/repackaging and labeling/relabeling of API and/or finished products for lawful export purposes.

13. Revise and republish § 1315.22 to read as follows:

§ 1315.22 Procedure for applying for individual manufacturing quotas.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply in the online Quota Management System on DEA Form 189 for a manufacturing quota for the quantity of the chemical desired and shall state separately for each subcategory, as defined in § 1315.07, each quantity of such chemical. A separate application must be made for each chemical desired to be manufactured by filing an application electronically in the online Quota Management System. DEA Form 189 must be filed on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied.

(b) For each chemical desired to be manufactured the applicant must provide the following information for each of the current and preceding 2 calendar years,:

(1) The authorized individual manufacturing quota, if any;

(2) The actual or estimated quantity manufactured;

(3) The actual or estimated net disposal;

(4) The actual or estimated inventory allowance pursuant to § 1315.24; and

(5) The actual or estimated inventory as of December 31.

(c) For each chemical desired to be manufactured for the next calendar year, the applicant must provide the following information:

(1) the desired individual manufacturing quota;

(2) the length of time that it will take to start production after receiving the quota letter from DEA pursuant to § 1315.21;

(3) the length of time it will take to perform their portion of the production cycle;

(4) the length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after the current registrant's production activity is complete; and

(5) Any additional factors that the applicant finds relevant to the fixing of the individual manufacturing quota, including any of the following:

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

14. Amend § 1315.32 by revising and republishing paragraphs 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 in the online Quota Management

System 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. A separate application must be made for each chemical desired to be procured or used by filing an application electronically in the online Quota Management System. DEA Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied.

(b) The applicant must state separately all of the following:

(1) Each purpose for which the chemical is desired;

(2) The quantity desired for each purpose during the next calendar year;

(3) The length of time applicant expects it will take to receive the active pharmaceutical ingredient after receiving the quota letter from DEA pursuant to § 1315.35;

(4) The supplier of the chemical;

(5) The length of time it will take to start production after receiving the chemical;

(6) The estimated length of time it will take to perform their portion of the production cycle;

(7) The length of time it will take for the applicant to ship the finished goods to the next registrant in the supply chain after the current registrant's production activity is complete;

(8) The quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years;

(9) If the purpose is to manufacture the chemical into dosage form, the applicant must state the official name, common or usual name, chemical name, or brand name of that form. If the dosage form produced is a controlled substance listed in any schedule, the applicant must also state the schedule number and National Drug Code Number, of the substance; and

(10) If the purpose is to manufacture another chemical, the applicant must state the official name, common or usual name, chemical name, or brand name of the substance and the DEA Chemical Code Number, as set forth in part 1310 of this chapter.

15. Add § 1315.35 to read as follows:

§ 1315.35 Issuing and certifying available procurement quota.

(a) The Administrator shall, on or before December 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing them to procure and use:

(1) All quantities of the chemical necessary to manufacture products that the applicant is authorized to manufacture pursuant to § 1315.23; and

（2）Such other quantities of the chemical as the applicant has applied to procure and use and are consistent with their past use, estimated needs, and the total quantity of the chemical that will be produced.

(b) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of ephedrine, pseudoephedrine, or phenylpropanolamine during the current calendar year, must, at or before the time of placing an order with another registrant requiring the distribution of a quantity of the chemical, certify in writing to the other registrant that the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine ordered does not exceed the person's unused and available procurement quota of the chemical for the current calendar year. The written certification must be executed by a person authorized to sign the registration application pursuant to § 1301.13 or § 1309.32(g) of this chapter or by a person granted power of attorney under § 1315.33 to sign the certifications. A copy of such certification must be retained by the person procuring the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine for two years from the date of the certification. Registrants must not fill an order from

persons required to apply for a procurement quota under § 1315.32 unless the order is accompanied by a certification as required under this section.

(c) The certification required by paragraph (b) of this section must contain all of the following:

(1) The date of the certification.

(2) The name and address of the registrant to whom the certification is directed.

(3) A reference to the purchase order number to which the certification applies.

(4) The name of the person giving the order to which the certification applies.

(5) The name of the chemical to which the certification applies.

(6) A statement that the quantity (expressed in grams) of the chemical to which the certification applies does not exceed the unused and available procurement quota of the chemical, issued to the person giving the order, for the current calendar year.

（7）The signature of the individual authorized to sign a certification as provided in paragraph (b) of this section.

16. Revise and republish § 1315.37 to read as follows:

§ 1315.37 Adjustment of procurement quota.

Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the UN Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that the Administrator finds, after considering the factors enumerated in § 1315.35(a) and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

17. Add § 1315.38 to read as follows:

§ 1315.38 Abandonment of procurement quota.

Any manufacturer assigned a procurement quota for a chemical pursuant to § 1315.35 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 the amount among the other manufacturers in proportion to their respective quotas.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on May 15, 2026, by DEA Administrator Terrance C. Cole. 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.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[FR Doc. 2026-10128 Filed: 5/19/2026 8:45 am; Publication Date: 5/20/2026]