Title 21 —Food and Drugs
Chapter II —Drug Enforcement Administration, Department of Justice

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

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Subpart A—General Information

§ 1315.01 Scope.

This part specifies procedures governing the establishment of an assessment of annual needs, procurement and manufacturing quotas pursuant to section 306 of the Act (21 U.S.C. 826), and import quotas pursuant to section 1002 of the Act (21 U.S.C. 952) for ephedrine, pseudoephedrine, and phenylpropanolamine.

§ 1315.02 Definitions.

(a) Except as specified in paragraphs (b) and (c) of this section, any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

(b) The term *net disposal* means, for a stated period, the sum of paragraphs (b)(1) through (b)(3) of this section minus the sum of paragraphs (b)(4) and (b)(5) of this section:

(1) The quantity of ephedrine, pseudoephedrine, or phenylpropanolamine distributed by the registrant to another person.

(2) The quantity of that chemical used by the registrant in the production of (or converted by the registrant into) another chemical or product.

(3) The quantity of that chemical otherwise disposed of by the registrant.

(4) The quantity of that chemical returned to the registrant by any purchaser.

(5) The quantity of that chemical distributed by the registrant to a registered manufacturer of that chemical for purposes other than use in the production of, or conversion into, another chemical or in the manufacture of dosage forms of that chemical.

(c) Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

§ 1315.03 Personal use exemption.

A person need not register as an importer, file an import declaration, and obtain an import quota if both of the following conditions are met:

(a) The person purchases scheduled listed chemical products at retail and imports them for personal use, by means of shipping through any private or commercial carrier or the Postal Service.

(b) In any 30-day period, the person imports no more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, and 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1315.05 Applicability.

This part applies to all of the following:

(a) Persons registered to manufacture (including repackaging or relabeling) or to import ephedrine, pseudoephedrine, or phenylpropanolamine as bulk chemicals.

(b) Persons registered to manufacture (including repackaging or relabeling) or to import prescription and over-the-counter drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine that may be lawfully marketed and distributed in the United States under the Federal Food, Drug, and Cosmetic Act.

§ 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.

[88 FR 60142, Aug. 31, 2023]

§ 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.

[88 FR 60142, Aug. 31, 2023]

Subpart B—Assessment of Annual Needs

§ 1315.11 Assessment of annual needs.

(a) The Administrator shall determine the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine, including drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, necessary to be manufactured and imported during the following calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

(b) In making his determinations, the Administrator shall consider the following factors:

(1) Total net disposal of the chemical by all manufacturers and importers during the current and 2 preceding years;

(2) Trends in the national rate of net disposal of each chemical;

(3) Total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation;

(4) Projected demand for each chemical as indicated by procurement and import quotas requested pursuant to § 1315.32; and

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and the establishment and maintenance of reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemicals or the substances which are manufactured from them, 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.

(c) The Administrator shall, on or before September 1 of each year, publish in the FEDERAL REGISTER, general notice of an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine determined by him under this section. A notice of the publication shall be mailed simultaneously to each person registered to manufacture or import the chemical.

(d) The Administrator shall permit any interested person to file written comments on or objections to the proposed assessment of annual needs and shall designate in the notice the time during which the filings may be made.

(e) The Administrator may, but is not required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish a notice of the hearing in the FEDERAL REGISTER. The notice shall summarize the issues to be heard and set the time for the hearing, which shall not be less than 30 days after the date of publication of the notice.

(f) After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the FEDERAL REGISTER the final order determining the assessment of annual needs for the chemicals. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

[72 FR 37448, July 10, 2007, as amended at 88 FR 60143, Aug. 31, 2023]

§ 1315.13 Adjustments of the assessment of annual needs.

(a) The Administrator may at any time increase or reduce the assessment of annual needs for ephedrine, pseudoephedrine, or phenylpropanolamine that has been previously fixed pursuant to § 1315.11.

(b) In determining to adjust the assessment of annual needs, the Administrator shall consider the following factors:

(1) Changes in the demand for that chemical, changes in the national rate of net disposal of the chemical, and changes in the rate of net disposal of the chemical by registrants holding individual manufacturing or import quotas for that chemical;

(2) Whether any increased demand for that chemical, the national and/or changes in individual rates of net disposal of that chemical are temporary, short term, or long term;

(3) Whether any increased demand for that chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the assessment of annual needs, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to § 1315.24(b);

(4) Whether any decreased demand for that chemical will result in excessive inventory accumulation by all persons registered to handle that chemical (including manufacturers, distributors, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to § 1315.24(b) or abandoned pursuant to § 1315.27;

(5) Other factors affecting medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemical or the substances that are manufactured from it, 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.

(c) In the event that the Administrator determines to increase or reduce the assessment of annual needs for a chemical, the Administrator shall publish in the FEDERAL REGISTER general notice of an adjustment in the assessment of annual needs for that chemical as determined under this section. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

(d) The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(e) The Administrator may, but is not required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish a notice of the hearing in the FEDERAL REGISTER. The notice shall summarize the issues to be heard and set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice.

(f) After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the FEDERAL REGISTER the final order determining the assessment of annual needs for the chemical. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

Subpart C—Individual Manufacturing Quotas

§ 1315.21 Individual manufacturing quotas.

The Administrator shall, on or before December 1 of each year, fix for and issue to each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine who applies for a manufacturing quota an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that chemical. Any manufacturing quota fixed and issued by the Administrator is subject to his authority to reduce or limit it at a later date pursuant to § 1315.26 and to his authority to revoke or suspend it at any time pursuant to §§ 1301.36, 1309.43, 1309.44, or 1309.45 of this chapter.

[72 FR 37448, July 10, 2007, as amended at 88 FR 60143, Aug. 31, 2023]

§ 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. Copies of DEA Form 189 may be obtained from the Office of Diversion Control Web site, and must be filed (on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with the UN Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate application must be made for each chemical desired to be manufactured. The applicant must state the following:

(a) The name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical.

(b) For the chemical in 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 the chemical in the next calendar year,

(1) The desired individual manufacturing quota; and

(2) 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.

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§ 1315.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator shall allocate to each applicant who is currently manufacturing the chemical a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted—

(1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to § 1315.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including:

(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), and

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

(b) In fixing individual manufacturing quotas for a chemical, the Administrator shall allocate to each applicant who is not currently manufacturing the chemical a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the next calendar year, as determined by the Administrator, adjusted—

(1) By the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to § 1315.24; and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including any of the following:

(i) The trend of (and recent changes in) the national rate 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.

(c) On or before July 1 of each year the Administrator shall adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to § 1315.24.

[72 FR 37448, July 10, 2007, as amended at 88 FR 60143, Aug. 31, 2023]

§ 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.

[88 FR 60143, Aug. 31, 2023]

§ 1315.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a chemical may file with the Administrator an application on DEA Form 189 for an increase in the registrant's quota to meet the registrant's estimated net disposal, inventory, and other requirements during the remainder of that calendar year.

(b) The Administrator, in passing upon a registrant's application for an increase in the individual manufacturing quota, shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the calendar year. In passing upon the application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the chemical to be manufactured under § 1315.11 exceeds the aggregate of all the individual manufacturing quotas for the chemical, and the equitable distribution of such excess among other registrants.

§ 1315.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a chemical that he has previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be granted from exceeding the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13. If a quota assigned to a new manufacturer pursuant to § 1315.23(b), or if a quota assigned to any manufacturer is increased pursuant to § 1315.24(c), or if an import quota issued to an importer pursuant to § 1315.34, causes the total quantity of a chemical to be manufactured and imported during the year to exceed the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13, the Administrator may proportionately reduce the individual manufacturing quotas and import quotas of all other registrants to keep the assessment of annual needs within the

limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 1315.24(b) or §§ 1301.36, 1309.43, 1309.44, or 1309.45 of this chapter or is abandoned pursuant to § 1315.27.

§ 1315.27 Abandonment of 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. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

[72 FR 37448, July 10, 2007, as amended at 88 FR 60143, Aug. 31, 2023]

Subpart D—Procurement and Import Quotas

§ 1315.30 Procurement and import quotas.

(a) To determine the estimated needs for, and to insure an adequate and uninterrupted supply of, ephedrine, pseudoephedrine, and phenylpropanolamine the Administrator shall issue procurement and import quotas.

(b) A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for the following purposes:

(1) Manufacturing the bulk chemical into dosage forms.

(2) Manufacturing the bulk chemical into other substances.

(3) Repackaging or relabeling the chemical or dosage forms.

(c) An import quota authorizes a registered importer to import quantities of the chemical for the following purposes:

(1) Distribution of the chemical to a registered manufacturer that has a procurement quota for the chemical.

(2) Other distribution of the chemical consistent with the legitimate medical and scientific needs of the United States.

§ 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.

[88 FR 60143, Aug. 31, 2023]

§ 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. A separate application must be made for each chemical desired to be procured or used.

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

(c) 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.

(d) 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.

(e) DEA Form 250 must be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from the Office of Diversion Control Web site, and must be filed with the UN Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(f) 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 him 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 his past use, his estimated needs, and the total quantity of the chemical that will be produced.

(g) 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that he finds, after considering the factors enumerated in paragraph (f) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(h) 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 paragraph (b) of this section unless the order is accompanied by a certification as required under this section.

(i) The certification required by paragraph (h) 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 (h) of this section.

[72 FR 37448, July 10, 2007, as amended at 73 FR 73555, Dec. 3, 2008; 75 FR 10684, Mar. 9, 2010; 88 FR 60144, Aug. 31, 2023]

§ 1315.33 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his registered location, to sign certifications required under § 1315.32(h) on the registrant's behalf by executing a power of attorney for each such individual. The registrant shall retain the power of attorney in the files, with certifications required by § 1315.32(h), for the same period as any certification bearing the signature of the attorney. The power of attorney must be available for inspection together with other certification records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine

> _____ (Name of registrant)
>
> _____ (Address of registrant)
>
> _____ (DEA registration number)
>
> I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to sign certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine in accordance with Part 1315 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

_____

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____

2. _____

Signed and dated on the __ day of _, (year), at _____.

NOTICE OF REVOCATION

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____

(Signature of person revoking power)

Witnesses:

1. _____

2. _____

Signed and dated on the __ day of _, (year), at _____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

[73 FR 73555, Dec. 3, 2008]

§ 1315.34 Obtaining an import quota.

(a) Any person who is registered to import ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24(c) of this chapter, and who desires to import during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine or drug products containing these chemicals, must apply on DEA Form 488 for an import quota for the chemical. A separate application must be made for each chemical desired to be imported.

(b) The applicant must provide the following information in the application:

(1) The applicant's name and DEA registration number.

(2) The name and address of a contact person and contact information (telephone number, fax number, e-mail address).

(3) Name of the chemical and DEA Chemical Code number.

(4) Type of product (bulk or finished dosage forms).

(5) For finished dosage forms, the official name, common or usual name, chemical name, or brand name, NDC number, and the authority to market the drug product under the Federal Food, Drug and Cosmetic Act of each form to be imported.

(6) The amount requested expressed in terms of base.

(7) For the current and preceding two calendar years, expressed in terms of base:

(i) Distribution/Sales—name, address, and registration number (if applicable) of each customer and the amount sold.

(ii) Inventory as of December 31 (each form—bulk, in-process, finished dosage form).

(iii) Acquisition—imports.

(c) For each form of the chemical (bulk or dosage unit), the applicant must state the quantity desired for import during the next calendar year.

(d) DEA Form 488 must be filed on or before April 1 of the year preceding the calendar year for which the import quota is being applied. Copies of DEA Form 488 may be obtained from the Office of Diversion Control Web site, and must be filed with the UN Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration . See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) The Administrator may at his discretion request additional information from an applicant.

(f) On or before December 1 of the year preceding the calendar year during which the quota shall be effective, the Administrator shall issue to each qualified applicant an import quota authorizing him to import:

(1) All quantities of the chemical necessary to manufacture products that registered manufacturers are authorized to manufacture pursuant to § 1315.23; and

(2) Such other quantities of the chemical that the applicant has applied to import and that are consistent with his past imports, the estimated medical, scientific, and industrial needs of the United States, the establishment and maintenance of reserve stocks, and the total quantity of the chemical that will be produced.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10684, Mar. 9, 2010; 88 FR 60144, Aug. 31, 2023]

§ 1315.36 Amending an import quota.

(a) An import quota authorizes the registered importer to import up to the set quantity of ephedrine, pseudoephedrine, or phenylpropanolamine and distribute the chemical or drug products on the DEA Form 488. An importer must apply to change the quantity to be imported.

(b) Any person to whom an import quota has been issued may at any time request an increase in the quota quantity 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator may increase the import quota of the person if and to the extent that he determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. The Administrator shall specify a period of time for which the approval is in effect or shall provide that the approval is in effect until the Administrator notifies the applicant in writing that the approval is terminated.

(c) With respect to the application under paragraph (b) of this section, the Administrator shall approve or deny the application within 60 days of receiving the application. If the Administrator does not approve or deny the application within 60 days of receiving it, the application is deemed to be approved and the approval remains in effect until the Administrator notifies the applicant in writing that the approval is terminated.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10685, Mar. 9, 2010]

§ 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.

[88 FR 60144, Aug. 31, 2023]

Subpart E—Hearings

§ 1315.50 Hearings generally.

The procedures for the hearing related to assessment of annual needs or to the issuance, adjustment, suspension, or denial of a manufacturing, procurement, or import quota are governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 1002 of the Act (21 U.S.C. 952), by §§ 1315.52 through 1315.62 of this part, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41 through 1316.67 of this chapter.

§ 1315.52 Purpose of hearing.

(a) The Administrator may, in his sole discretion, hold a hearing for the purpose of receiving factual evidence regarding any one or more issues (to be specified by him) involved in the determination or adjustment of any assessment of national needs.

(b) If requested by a person applying for or holding a procurement, import, or individual manufacturing quota, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of the quota to the person, but the Administrator need not hold a hearing on suspension of a quota under § 1301.36 or § 1309.43 of this chapter separate from a hearing on the suspension of registration under that section.

(c) Extensive argument should not be offered into evidence, but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1315.54 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1315.56 Request for hearing or appearance; waiver.

(a) Any applicant or registrant entitled to a hearing under § 1315.52 and who desires a hearing on the issuance, adjustment, suspension or denial of a procurement, import, or individual manufacturing quota must, within 30 days after the date of receipt of the issuance, adjustment, suspension or denial of the application, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any interested person who desires a hearing on the determination of an assessment of annual needs must, within the time prescribed in § 1315.11(c), file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter, including in the request a statement of the grounds for the hearing.

(c) Any interested person who desires to participate in a hearing on the determination or adjustment of an assessment of annual needs, which hearing is ordered by the Administrator under § 1315.11(c) or § 1315.13(c), may do so by filing with the Administrator, within 30 days of the date of publication of notice of the hearing in the FEDERAL REGISTER, a written notice of his intention to participate in the hearing in the form prescribed in § 1316.48 of this chapter.

(d) Any person entitled to a hearing under § 1315.52 or entitled to participate in a hearing under paragraph (c) of this section may, within the period permitted for filing a request for a hearing or notice of appearance, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. The statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted.

(e) If any person entitled to a hearing under § 1315.52 or entitled to participate in a hearing under paragraph (c) of this section fails to file a request for a hearing or notice of appearance or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(f) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order under § 1315.62 without a hearing.

§ 1315.58 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an assessment of annual needs each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement, import, or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

§ 1315.60 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement, import, or individual manufacturing quota under § 1315.54, the Administrator shall hold a hearing.

(b) Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(c) The hearing shall commence at the place and time designated in the notice given under paragraph (b) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to § 1315.11(c) or § 1315.13(c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement by the presiding officer at the hearing.

§ 1315.62 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the assessment of annual needs or on the issuance, adjustment, suspension, or denial of the procurement, import, or individual manufacturing quota, as the case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.