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

Part 1303 Quotas

PART 1303—QUOTAS

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

GENERAL INFORMATION

§ 1303.01 Scope of part 1303.

Procedures governing the establishment of production and manufacturing quotas on basic classes of controlled substances listed in schedules I and II pursuant to section 306 of the Act (21 U.S.C. 826) are governed generally by that section and specifically by the sections of this part.

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.02 Definitions.

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.

[62 FR 13958, Mar. 24, 1997]

§ 1303.03 Types of quotas.

The three types of quotas are:

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

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

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

[88 FR 60139, Aug. 31, 2023]

§ 1303.04 Subcategories of manufacturing and procurement quotas.

The five subcategories of manufacturing and procurement quotas are:

(a) ***Quota for commercial sale.*** This is a quota for the amount of bulk active pharmaceutical ingredients (API) initially acquired by a registrant for the manufacture of approved schedule I or II controlled substance drug products by the Food and Drug Administration (FDA), and bulk API acquired by outsourcing facilities, manufacturers, etc. This quota category is used to capture bulk API moving from a bulk manufacturer to other registered manufacturers for their commercial manufacturing efforts. This type of quota may only be used to support commercial manufacturing efforts and may not be used to support other manufacturing efforts.

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

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

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

(3) Return of material after the specified manufacturing activity has been completed or return of rejected material to the upstream manufacturer for destruction or additional processing.

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

(d) ***Quota for replacement.*** This is a type of individual manufacturing quota or procurement quota that is granted to a registrant after the registrant disposes of material that was initially intended for commercial sale, but for some reason was unable to be marketed. This quota is separate and shall not count against a registrant's other issued quota. Replacement quota will be granted on a case-by-case basis. The merits of the request will be determined by the specifics of the registrant's justification and situation. DEA will review the submitted DEA Form 41 or DEA Form 222 documenting the destruction of the controlled substance and evaluate the justification for the destruction to determine if replacement quota is warranted and whether or not the destroyed material is required to meet the legitimate demand of the market. Replacement quota is intended to replace material from the current quota year and not a means to replace disposed samples, analytical samples, product development material, or inventory acquired under previous quota years.

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

[88 FR 60139, Aug. 31, 2023]

§ 1303.05 Estimation of Diversion.

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

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

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

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

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

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

[88 FR 60139, Aug. 31, 2023]

AGGREGATE PRODUCTION QUOTAS

§ 1303.11 Aggregate production quotas.

(a) The Administrator shall determine the total quantity of each basic class of controlled substance listed in Schedule I or II necessary to be manufactured 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. The Administrator may establish an aggregate production quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

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

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

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

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

(4) Projected demand for such class as indicated by procurement quotas requested pursuant to § 1303.12;

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states; and

(7) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which 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) The Administrator shall, on or before September 1 of each year, publish in the FEDERAL REGISTER, general notice of an aggregate production quota for any basic class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. 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. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 30 days after the date of publication of the notice. 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 his final order determining the aggregate production quota for the basic class of controlled substances. 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 copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

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

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973; 77 FR 4235, Jan. 27, 2012; 83 FR 32789, July 16, 2018; 88 FR 60140, Aug. 31, 2023]

§ 1303.12 [Reserved]

§ 1303.13 Adjustments of aggregate production quotas.

(a) The Administrator may at any time increase or reduce the aggregate production quota for a basic class of controlled substance listed in Schedule I or II which he has previously fixed pursuant to § 1303.11.

(b) In determining to adjust the aggregate production quota, the Administrator shall consider the following factors:

(1) Changes in the demand for that class, changes in the national rate of net disposal of the class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class;

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

(3) Whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to § 1303.24(b);

(4) Whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to § 1303.24(b) or abandoned pursuant to § 1303.27;

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which 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) The Administrator in the event he determines to increase or reduce the aggregate production quota for a basic class of controlled substance, shall publish in the FEDERAL REGISTER general notice of an adjustment in the aggregate production quota for that class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. 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. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact raised by a state objecting to the proposed adjusted quota as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice. 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 his final order determining the aggregate production for the basic class of controlled substance. 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 copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

[37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973; 83 FR 32790, July 16, 2018]

PROCUREMENT QUOTAS

§ 1303.15 Procurement quotas.

(a) 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 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.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in schedule I or II (except raw opium being imported by the registrant pursuant to an import permit) for purposes of manufacturing, shall apply on DEA Form 250 for procurement quota and shall state separately for each subcategory, as defined in 21 CFR 1303.04, each quantity of such basic class. A separate application must be made for each basic class desired to be procured or used. The applicant shall state whether he intends to manufacture the basic class himself or purchase it from another manufacturer. The applicant shall state separately 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. 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. 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. 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. 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. 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. Copies of DEA Form 250 may be obtained from, and shall be filed with, the UN Reporting and Quota Section, Diversion Control Division. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(c) 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 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 his past use, his estimated needs, and the total quantity of such class that will be produced.

(d) 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 with the UN Reporting and Quota Section, Diversion Control Division. 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 such person if and to the extent that he finds, after considering the factors enumerated in paragraph (c) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(e) 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 he manufactures 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.

(f) 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 paragraph (b) of this section 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.

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973. Redesignated and amended at 88 FR 60140, Aug. 31, 2023]

§ 1303.16 Inventory allowance for procurement quotas.

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

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

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

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

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

(b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 50 percent of his estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 50 percent of their estimated net disposal, their quota for that class is

automatically suspended and shall remain suspended until his inventory is less than 45 percent of their estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 50 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

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

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

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

[88 FR 60141, Aug. 31, 2023]

§ 1303.17 Abandonment of procurement quota.

Any manufacturer assigned a procurement quota for any basic class of controlled substance listed in schedule I or II pursuant to § 1303.12 may at any time abandon their right to manufacture all or any part of such quota by filing a notice of such abandonment with the UN Reporting and Quota Section, Diversion Control Division, Drug Enforcement Administration in the online Quota Management System. The Administrator may, in their discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

[88 FR 60141, Aug. 31, 2023]

Individual Manufacturing Quotas

§ 1303.21 Individual manufacturing quotas.

(a) The Administrator shall, on or before December 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in Schedule I or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. The Administrator may establish an individual manufacturing quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule

I or II controlled substance, if they determine it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. Any manufacturing quota fixed and issued by the Administrator shall be subject to his authority to reduce or limit it at a later date pursuant to § 1303.26 and to his authority to revoke or suspend it at any time pursuant to § 1301.36 of this chapter.

(b) No individual manufacturing quota shall be required for registrants listed in § 1303.12(e).

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997; 83 FR32790, July 16, 2018; 88 FR 60141, Aug. 31, 2023]

§ 1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota and shall state separately for each subcategory, as defined in § 1303.04, each quantity of such class. Copies of DEA Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the UN Reporting and Quota Section, Diversion Control Division. 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 basic class desired to be manufactured. The applicant shall state:

(a) The name and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the basic class.

(b) For the basic class 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 § 1303.24; and

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

(c) For the basic class in the next calendar year,

(1) The desired individual manufacturing quota; and

(2) 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.

(d) 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.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 51 FR 5319, Feb. 13, 1986; 62 FR 13958, Mar. 24, 1997; 75 FR 10677, Mar. 9, 2010; 81 FR 97020, Dec. 30, 2016; 83 FR 32790, July 16, 2018; 88 FR 60141, Aug. 31, 2023]

§ 1303.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I or II, the Administrator shall allocate to each applicant who is currently manufacturing such class 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 § 1303.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, 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), the extent of any diversion of the controlled substance, and recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I or II, the Administrator shall allocate to each applicant who is not currently manufacturing such class 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 § 1303.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) the national rate 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), any risk of diversion of the controlled substance, and recent unforeseen emergencies such as floods and fires.

(c) The Administrator shall, on or before July 1 of each year, 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 § 1303.24.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973; 83 FR 32790, July 16, 2018; 88 FR 60141, Aug. 31, 2023]

§ 1303.24 Inventory allowance for individual manufacturing quotas.

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

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

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

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

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to them under an individual manufacturing quota, and their inventory of that class is less than 30 percent of their estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 40 percent of the estimated net disposal for that year.

[88 FR 60142, Aug. 31, 2023]

§ 1303.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a basic class of controlled substance listed in Schedule I or II may file with the Administrator an application on Administration Form 189 for an increase in such quota in order for him to meet his estimated net disposal, inventory and other requirements during the remainder of such calendar year.

(b) The Administrator, in passing upon a registrant's application for an increase in his individual manufacturing quota, shall take into consideration any occurrences since the filing of such registrant's initial quota application that may require an increased manufacturing rate by such registrant during the balance of the calendar year. In passing upon such application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the basic class of controlled substance to be manufactured under § 1303.11 exceeds the aggregate of all the individual manufacturing quotas for the basic class of controlled substance, and the equitable distribution of such excess among other registrants.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a basic class of controlled substance listed in Schedule I or II which he has previously fixed in order to prevent the aggregate of the individual manufacturing quotas and import permits outstanding or to be granted from exceeding the aggregate production quota which has been established for that class pursuant of § 1303.11, as adjusted pursuant to § 1303.13. If a quota assigned to a new manufacturer pursuant to § 1303.23(b), or if a quota assigned to any manufacturer is increased pursuant to § 1303.24(c), or if an import permit issued to an importer pursuant to part 1312 of this chapter, causes the total quantity of a basic class to be manufactured and imported during the year to exceed the aggregate production quota which has been established for that class pursuant to § 1303.11, as adjusted pursuant to § 1303.13, the Administrator may proportionately reduce the individual manufacturing quotas and import permits

of all other registrants to keep the aggregate production quota within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 1303.24(b) or § 1301.36 of this chapter, or is abandoned pursuant to § 1303.27.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

§ 1303.27 Abandonment of quota for Individual Manufacturing Quota.

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

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 51 FR 5319, Feb. 13, 1986; 62 FR 13958, Mar. 24, 1997; 88 FR 60142, Aug. 31, 2023]

HEARINGS

§ 1303.31 Hearings generally.

(a) In any case where the Administrator shall hold a hearing regarding the determination of an aggregate production quota pursuant to § 1303.11(c), or regarding the adjustment of an aggregate production quota pursuant to § 1303.13(c), the procedures for such hearing shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 1303.32-1303.37, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41-1316.67 of this chapter.

(b) In any case where the Administrator shall hold a hearing regarding the issuance, adjustment, suspension, or denial of a procurement quota pursuant to § 1303.12, or the issuance, adjustment, suspension, or denial of an individual manufacturing quota pursuant to §§ 1303.21-1303.27, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedures Act (5 U.S.C. 551-559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§ 1303.32-1303.37, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41-1316.67 of this chapter.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.32 Purpose of hearing.

(a) The Administrator may, in his sole discretion, and shall, if determined by the Administrator to be necessary under § 1303.11(c) or 1303.13(c) based on objection by a state, 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 aggregate production quota.

(b) If requested by a person applying for or holding a procurement quota or an 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 such quota to such person, but the Administrator need not hold a hearing on the suspension of a quota pursuant to § 1301.36 of this chapter separate from a hearing on the suspension of registration pursuant to those sections.

(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.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997; 83 FR 32790, July 16, 2018]

§ 1303.33 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.

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.34 Request for hearing or appearance; waiver.

(a) Any applicant or registrant who desires a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota shall, within 30 days after the date of receipt of the issuance, adjustment, suspension, or denial of such quota, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter. Any interested person who desires a hearing on the determination of an aggregate production quota shall, within the time prescribed in § 1303.11(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 a hearing.

(b) Any interested person who desires to participate in a hearing on the determination or adjustment of an aggregate production quota, which hearing is ordered by the Administrator pursuant to § 1303.11(c) or § 1303.13(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 such hearing in the form prescribed in § 1316.48 of this chapter.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, may, within the period permitted for filing a request for a hearing of notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such 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 therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) 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 or to participate in the hearing, unless he shows good cause for such failure.

(e) 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 pursuant to § 1303.37 without a hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.35 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an aggregate production quota, 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 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.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

§ 1303.36 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota pursuant to § 1303.34, the Administrator shall hold such hearing. 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.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section or in the notice of hearing published in the FEDERAL REGISTER pursuant to § 1303.11(c) or § 1303.13 (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 thereof by the presiding officer at the hearing.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1303.37 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 aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as 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.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]