

§ 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 to § 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 manu-

factured 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

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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

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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,