

§ 1315.02

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

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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.

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 May 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.

§ 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