

§ 1315.01

1315.27 Abandonment of quota.

Subpart D—Procurement and Import Quotas

1315.30 Procurement and import quotas.
1315.32 Obtaining a procurement quota.
1315.33 Power of attorney.
1315.34 Obtaining an import quota.
1315.36 Amending an import quota.

Subpart E—Hearings

1315.50 Hearings generally.
1315.52 Purpose of hearing.
1315.54 Waiver or modification of rules.
1315.56 Request for hearing or appearance; waiver.
1315.58 Burden of proof.
1315.60 Time and place of hearing.
1315.62 Final order.

SOURCE: 72 FR 37448, July 10, 2007, unless otherwise noted.

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

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.

21 CFR Ch. II (4–1–10 Edition)

(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.

Subpart B—Assessment of Annual Needs

§ 1315.11 Assessment of annual needs.

(a) The Administrator shall determine the total quantity of ephedrine,