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

Subpart D — Procurement and Import Quotas

§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 Section 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, email 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 Drug & Chemical Evaluation Section. See the Table of DEA Mailing Addresses in **Section 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 July 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 Section 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]