Drug Enforcement Administration, Justice

§ 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 §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, e-mail 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.
8. For each form of the chemical (bulk or dosage unit), the applicant must state the quantity desired for import during the next calendar year.
9. 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 §1321.01 of this chapter for the current mailing address.
10. The Administrator may at his discretion request additional information from an applicant.
11. 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 §1315.23; and
§ 1315.36 Amending an import quota.

(a) An import quota authorizes the registered importer to import up to the set quantity of ephedrine, pseudoephedrine, or phenylpropanolamine and distribute the chemical or drug products on the DEA Form 488. An importer must apply to change the quantity to be imported.

(b) Any person to whom an import quota has been issued may at any time request an increase in the quota quantity by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The Administrator may increase the import quota of the person if and to the extent that he determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. The Administrator shall specify a period of time for which the approval is in effect or shall provide that the approval is in effect until the Administrator notifies the applicant in writing that the approval is terminated.

(c) With respect to the application under paragraph (b) of this section, the Administrator shall approve or deny the application within 60 days of receiving the application. If the Administrator does not approve or deny the application within 60 days of receiving it, the application is deemed to be approved and the approval remains in effect until the Administrator notifies the applicant in writing that the approval is terminated.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10684, Mar. 9, 2010]

§ 1315.52 Purpose of hearing.

(a) The Administrator may, in his sole discretion, 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 assessment of national needs.

(b) If requested by a person applying for or holding a procurement, import, or 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 the quota to the person, but the Administrator need not hold a hearing on suspension of a quota under §1301.36 or §1309.43 of this chapter separate from a hearing on the suspension of registration under that section.

(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.

[72 FR 37448, July 10, 2007, as amended at 75 FR 10684, Mar. 9, 2010]