the assessment of annual needs within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to §1315.24(b) or §§1301.36, 1309.43, 1309.44, or 1309.45 of this chapter or is abandoned pursuant to §1315.27.

§1315.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to §1315.23 may at any time abandon his right to manufacture all or any part of the quota by filing with the Drug & Chemical Evaluation Section a written notice of the abandonment, stating the name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Subpart D—Procurement and Import Quotas

§1315.30 Procurement and import quotas.

(a) To determine the estimated needs for, and to insure an adequate and uninterrupted supply of, ephedrine, pseudoephedrine, and phenylpropanolamine the Administrator shall issue procurement and import quotas.

(b) A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for the following purposes:

(1) Manufacturing the bulk chemical into dosage forms.

(2) Manufacturing the bulk chemical into other substances.

(3) Repackaging or relabeling the chemical or dosage forms.

(c) An import quota authorizes a registered importer to import quantities of the chemical for the following purposes:

(1) Distribution of the chemical to a registered manufacturer that has a procurement quota for the chemical.

(2) Other distribution of the chemical consistent with the legitimate medical and scientific needs of the United States.

§1315.32 Obtaining a procurement quota.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to §1309.24 of this chapter, and who desires to use during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing (including repackaging or relabeling), must apply on DEA Form 250 for a procurement quota for the chemical. A separate application must be made for each chemical desired to be procured or used.

(b) The applicant must state separately all of the following:

(1) Each purpose for which the chemical is desired.

(2) The quantity desired for each purpose during the next calendar year.

(3) The quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years.

(c) If the purpose is to manufacture the chemical into dosage form, the applicant must state the official name, common or usual name, chemical name, or brand name of that form. If the dosage form produced is a controlled substance listed in any schedule, the applicant must also state the schedule number and National Drug Code Number, of the substance.

(d) If the purpose is to manufacture another chemical, the applicant must state the official name, common or usual name, chemical name, or brand name of the substance and the DEA Chemical Code Number, as set forth in part 1310 of this chapter.

(e) DEA Form 250 must be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from the Office of Diversion Control Web site, and 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.