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

Subpart D — Procurement and Import Quotas

§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 Section 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 **Section 1321.01** of this chapter for the current mailing address.

(f) The Administrator shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

(1) All quantities of the chemical necessary to manufacture products that the applicant is authorized to manufacture pursuant to **Section 1315.23**; and

(2) Such other quantities of the chemical as the applicant has applied to procure and use and are consistent with his past use, his estimated needs, and the total quantity of the chemical that will be produced.

(g) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the UN Reporting & Quota Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in **Section 1321.01** of this chapter for the current mailing address. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that he finds, after considering the factors enumerated in paragraph (f) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(h) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of ephedrine, pseudoephedrine, or phenylpropanolamine during the current calendar year, must, at or before the time of placing an order with another manufacturer or importer requiring the distribution of a quantity of the chemical, certify in writing to the other registrant that the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine ordered does not exceed the person's unused and available procurement quota of the chemical for the current calendar year. The written certification must be executed by a person authorized to sign the registration application pursuant to **Section 1301.13** or **Section 1309.32**(g) of this chapter or by a person granted power of attorney under **Section 1315.33** to sign the certifications. A copy of such certification must be retained by the person procuring the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine

for two years from the date of the certification. Registrants must not fill an order from persons required to apply for a procurement quota under paragraph (b) of this section unless the order is accompanied by a certification as required under this section.

(i) The certification required by paragraph (h) of this section must contain all of the following:

(1) The date of the certification.

(2) The name and address of the registrant to whom the certification is directed.

(3) A reference to the purchase order number to which the certification applies.

(4) The name of the person giving the order to which the certification applies.

(5) The name of the chemical to which the certification applies.

(6) A statement that the quantity (expressed in grams) of the chemical to which the certification applies does not exceed the unused and available procurement quota of the chemical, issued to the person giving the order, for the current calendar year.

(7) The signature of the individual authorized to sign a certification as provided in paragraph (h) of this section.

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