§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical. Copies of DEA Form 189 may be obtained from the Office of Diversion Control Web site, and must be filed (on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied) 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. A separate application must be made for each chemical desired to be manufactured. The applicant must state the following:

(a) The name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical.
(b) For the chemical in each of the current and preceding 2 calendar years, (1) The authorized individual manufacturing quota, if any; (2) The actual or estimated quantity manufactured; (3) The actual or estimated net disposal; (4) The actual or estimated inventory allowance pursuant to §1315.24; and (5) The actual or estimated inventory as of December 31.
(c) For the chemical in the next calendar year, (1) The desired individual manufacturing quota; and (2) Any additional factors that the applicant finds relevant to the fixing of the individual manufacturing quota, including any of the following: (i) The trend of (and recent changes in) the applicant’s and the national rates of net disposal, (ii) The applicant’s production cycle and current inventory position, (iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes, (iv) Yield and stability problems, (v) Potential disruptions to production (including possible labor strikes), and (vi) Recent unforeseen emergencies such as floods and fires.

§ 1315.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator shall allocate to each applicant who is currently manufacturing the chemical a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted— (1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to §1315.24, and (2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including: (i) The trend of (and recent changes in) the applicant’s and the national rates of net disposal, (ii) The applicant’s production cycle and current inventory position, (iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes, (iv) Yield and stability problems, (v) Potential disruptions to production (including possible labor strikes), and (vi) Recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a chemical, the Administrator shall allocate to each applicant who is not currently manufacturing the chemical a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the next calendar year, as determined by the Administrator, adjusted— (1) By the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to §1315.24; and (2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including any of the following:
§ 1315.24  Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to §1315.23, each registered manufacturer shall be allowed as a part of the quota an amount sufficient to maintain an inventory equal to either of the following:

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a chemical not exceeding 65 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 65 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended under this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to him under an individual manufacturing quota, and his inventory of that chemical is less than 40 percent of his estimated net disposal of that chemical for that year, the Administrator may, upon application pursuant to §1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

§ 1315.25  Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a chemical may file with the Administrator an application on DEA Form 189 for an increase in the registrant’s quota to meet the registrant’s estimated net disposal, inventory, and other requirements during the remainder of that calendar year.

(b) The Administrator, in passing upon a registrant’s application for an increase in the individual manufacturing quota, shall take into consideration any occurrences since the filing of the registrant’s initial quota application that may require an increased manufacturing rate by the registrant during the balance of the calendar year. In passing upon the application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the chemical to be manufactured under §1315.11 exceeds the aggregate of all the individual manufacturing quotas for the chemical, and the equitable distribution of such excess among other registrants.

§ 1315.26  Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a chemical that he has previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be