

§ 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).
 - (vi) Recent unforeseen emergencies such as floods and fires.