§ 1315.21 Individual manufacturing quotas.

The Administrator shall, on or before July 1 of each year, fix for and issue to each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine who applies for a manufacturing quota an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that chemical. Any manufacturing quota fixed and issued by the Administrator is subject to his authority to reduce or limit it at a later date pursuant to §1315.26 and to his authority to revoke or suspend it at any time pursuant to §§1301.36, 1309.43, 1309.44, or 1309.45 of this chapter.

§ 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. 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: