or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. Any manufacturing quota fixed and issued by the Administrator shall be subject to his authority to reduce or limit it at a later date pursuant to §1303.26 and to his authority to revoke or suspend it at any time pursuant to §§1301.36 of this chapter.

(b) No individual manufacturing quota shall be required for registrants listed in §1303.12(e).

[36 FR 7786, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13958, Mar. 24, 1997]

§1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in Schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota for such quantity of such class. Copies of DEA Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the UN Reporting and Quota Section, Diversion Control Division. 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 basic class desired to be manufactured. The applicant shall state:

(a) The name and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the basic class.

(b) For the basic class 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 §1303.24; and

(5) The actual or estimated inventory as of December 31;

(c) For the basic class in the next calendar year,

(1) The desired individual manufacturing quota; and

(2) Any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the econolic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

[36 FR 7786, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 51 FR 5319, Feb. 13, 1986; 62 FR 13958, Mar. 24, 1997; 75 FR 10677, Mar. 9, 2010; 81 FR 97020, Dec. 30, 2016]

§1303.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I or II, the Administrator shall allocate to each applicant who is currently manufacturing such class 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 §1303.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I