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## Title 21 – Food and Drugs

### Chapter II – Drug Enforcement Administration, Department of Justice

#### Part 1303 – Quotas

##### Individual Manufacturing Quotas

Authority: 21 U.S.C. 821, 826, 871(b).

#### § 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 and shall state separately for each subcategory, as defined in § 1303.04, each 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 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.
- (d) The Administrator may require additional information from an applicant which, in the Administrator's judgment, may be helpful in detecting or preventing diversion, including customer identities and amounts of the controlled substance sold to each customer.

*[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; 83 FR 32790, July 16, 2018; 88 FR 60141, Aug. 31, 2023]*