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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).

§ 1303.23 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), the extent of any diversion of the controlled substance, 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 or II, the Administrator shall allocate to each applicant who is not currently manufacturing such class 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 § 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) the national rate 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), any risk of diversion of the controlled substance, and recent unforeseen emergencies such as floods and fires.
- (c) The Administrator shall, on or before July 1 of each year, adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to § 1303.24.

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