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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).

#### § 1303.21 Individual manufacturing quotas.

- (a) The Administrator shall, on or before December 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in Schedule I 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. The Administrator may establish an individual manufacturing quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if they determine it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance. 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; 83 FR 32790, July 16, 2018; 88 FR 60141, Aug. 31, 2023]