
This content is from the eCFR and is authoritative but unofficial.

Title 21 – Food and Drugs

Chapter II – Drug Enforcement Administration, Department of Justice

Part 1303 – Quotas

Aggregate Production Quotas

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

§ 1303.11 Aggregate production quotas.

- (a) The Administrator shall determine the total quantity of each basic class of controlled substance listed in Schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. The Administrator may establish an aggregate production quota in terms of pharmaceutical dosage-forms prepared from or containing the schedule I or II controlled substance, if he determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.
- (b) In making his determinations, the Administrator shall consider the following factors:
 - (1) Total net disposal of the class by all manufacturers during the current and 2 preceding years;
 - (2) Trends in the national rate of net disposal of the class;
 - (3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
 - (4) Projected demand for such class as indicated by procurement quotas requested pursuant to § 1303.12;
 - (5) The extent of any diversion of the controlled substance in the class;
 - (6) Relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states; and
 - (7) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, 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.
- (c) The Administrator shall, on or before September 1 of each year, publish in the FEDERAL REGISTER, general notice of an aggregate production quota for any basic class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him, except that the Administrator shall hold a hearing if he determines it is necessary to resolve an issue of material fact

raised by a state objecting to the proposed quantity for the class as excessive for legitimate United States' needs. In the event the Administrator decides to hold a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 30 days after the date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the FEDERAL REGISTER his final order determining the aggregate production quota for the basic class of controlled substances. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class and transmitted to each state attorney general.

- (d) For any year for which the approved aggregate production quota for a covered controlled substance, as defined in § 1303.05(d), is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Administrator, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

[36 FR 7786, Apr. 24, 1971, as amended at 37 FR 15919, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973; 77 FR 4235, Jan. 27, 2012; 83 FR 32789, July 16, 2018; 88 FR 60140, Aug. 31, 2023]