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Title 21 – Food and Drugs

Chapter II – Drug Enforcement Administration, Department of Justice

Part 1315 – Importation and Production Quotas for Ephedrine, Pseudoephedrine, and Phenylpropanolamine

Subpart C – Individual Manufacturing Quotas

Authority: 21 U.S.C. 802, 821, 826, 871(b), 952.

Source: 72 FR 37448, July 10, 2007, unless otherwise noted.

Editorial Note: Nomenclature changes to part appear at 82 FR 97041, Dec. 30, 2016.

§ 1315.24 Inventory allowance for individual manufacturing quotas.

- (a) For the purpose of determining individual manufacturing quotas pursuant to § 1315.23, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:
 - (1) For current manufacturers, 40 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or
 - (2) For new manufacturers, 40 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.
- (b) During each calendar year, each registered manufacturer receiving a manufacturing quota shall be allowed to maintain an inventory of a chemical not exceeding 55 percent of their estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 55 percent of their estimated net disposal, their quota for that chemical is automatically suspended and shall remain suspended until their inventory is less than 50 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 55 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.
- (c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to them under an individual manufacturing quota, and their inventory of that chemical is less than 30 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 40 percent of the estimated net disposal for that year.

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