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Title 21 – Food and Drugs

Chapter II – Drug Enforcement Administration, Department of Justice

Part 1303 – Quotas

Procurement Quotas

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

§ 1303.16 Inventory allowance for procurement quotas.

- (a) For the purpose of determining procurement quotas pursuant to § 1303.15, each registered manufacturer shall be allowed as part of such quota an amount sufficient to maintain an inventory:
- (1) Except as provided in paragraph (a)(3) of this section, for current manufacturers, 35 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or
 - (2) Except as provided in paragraph (a)(4) of this section, for new manufacturers, 35 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.
 - (3) For current liquid injectable dosage-form manufacturers, 50 percent of their average estimated net disposal for the current calendar year and the last preceding calendar year; or
 - (4) For new liquid injectable dosage-form manufacturers, 50 percent of their reasonably estimated net disposal for the next calendar year as determined by the Administrator.
- (b) Except as provided in paragraph (c) of this section, during each calendar year, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 50 percent of his estimated net disposal of that class for that year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 50 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until his inventory is less than 45 percent of their 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 50 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.
- (c) For liquid injectable dosage-forms, each registered manufacturer receiving a procurement quota shall be allowed to maintain an inventory of a basic class not exceeding 65 percent of their estimated net disposal of that class for that year during each calendar year, as determined at the time their quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 percent of their estimated net disposal, their quota for that class is automatically suspended and shall remain suspended until their inventory is less than 60 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 65 percent of their estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

- (d) Except as provided in paragraph (e) of this section, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to him under an individual procurement quota, and their inventory of that class is less than 25 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 35 percent of the estimated net disposal for that year.
- (e) For liquid injectable dosage-forms, if, during a calendar year, a registrant has procured the entire quantity of a basic class allocated to them under an individual procurement quota, and their inventory of that class is less than 40 percent of their estimated net disposal of that class for that year, the Administrator may, upon application pursuant to § 1303.15(d), increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

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