(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 §1315.24, and
(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including:
   (i) The trend of (and recent changes in) the applicant’s and the national rates of net disposal,
   (ii) The applicant’s production cycle and current inventory position,
   (iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes,
   (iv) Yield and stability problems,
   (v) Potential disruptions to production (including possible labor strikes), and
   (vi) Recent unforeseen emergencies such as floods and fires.
(b) In fixing individual manufacturing quotas for a chemical, the Administrator shall allocate to each applicant who is not currently manufacturing the chemical 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 §1315.24; and
   (2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including any of the following:
      (i) The trend of (and recent changes in) the national rate of net disposal.
      (ii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.
      (iv) Yield and stability problems.
      (v) Potential disruptions to production (including possible labor strikes).
      (vi) Recent unforeseen emergencies such as floods and fires.
(c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to him under an individual manufacturing quota, and his inventory of that chemical is less than 40 percent of his estimated net disposal for that year, the Administrator may, upon application pursuant to §1315.25, increase the quota of such registrant sufficiently to allow restoration of the
§ 1315.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a chemical may file with the Administrator an application on DEA Form 189 for an increase in the registrant’s quota to meet the registrant’s estimated net disposal, inventory, and other requirements during the remainder of that calendar year.

(b) The Administrator, in passing upon a registrant’s application for an increase in the individual manufacturing quota, shall take into consideration any occurrences since the filing of the registrant’s initial quota application that may require an increased manufacturing rate by the registrant during the balance of the calendar year. In passing upon the application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the chemical to be manufactured under §1315.11 exceeds the aggregate of all the individual manufacturing quotas for the chemical, and the equitable distribution of such excess among other registrants.

§ 1315.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a chemical that he has previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be granted from exceeding the assessment of annual needs that has been established for that chemical pursuant to §1315.11, as adjusted pursuant to §1315.13. If a quota assigned to a new manufacturer pursuant to §1315.23(b), or if a quota assigned to any manufacturer is increased pursuant to §1315.24(c), or if an import quota issued to an importer pursuant to §1315.34, causes the total quantity of a chemical to be manufactured and imported during the year to exceed the assessment of annual needs that has been established for that chemical pursuant to §1315.11, as adjusted pursuant to §1315.13, the Administrator may proportionately reduce the individual manufacturing quotas and import quotas of all other registrants to keep the assessment of annual needs within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to §1315.24(b) or §§1301.36, 1309.43, 1309.44, or 1309.45 of this chapter or is abandoned pursuant to §1315.27.

§ 1315.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to §1315.23 may at any time abandon his right to manufacture all or any part of the quota by filing with the Drug & Chemical Evaluation Section a written notice of the abandonment, stating the name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Subpart D—Procurement and Import Quotas

§ 1315.30 Procurement and import quotas.

(a) To determine the estimated needs for, and to insure an adequate and uninterrupted supply of, ephedrine, pseudoephedrine, and phenylpropanolamine the Administrator shall issue procurement and import quotas.

(b) A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for the following purposes:

(1) Manufacturing the bulk chemical into dosage forms.

(2) Manufacturing the bulk chemical into other substances.

(3) Repackaging or relabeling the chemical or dosage forms.

(c) An import quota authorizes a registered importer to import quantities of the chemical for the following purposes:

(1) Distribution of the chemical to a registered manufacturer that has a procurement quota for the chemical.