possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) In the event that the Administrator determines to increase or reduce the assessment of annual needs for a chemical, the Administrator shall publish in the Federal Register general notice of an adjustment in the assessment of annual needs for that chemical as determined under this section. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

(d) 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.

(e) The Administrator may, but is not required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish a notice of the hearing in the Federal Register. The notice shall summarize the issues to be heard and set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice.

(f) 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 the final order determining the assessment of annual needs for the chemical. 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 notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

Subpart C—Individual Manufacturing Quotas

§ 1315.21 Individual manufacturing quotas.

The Administrator shall, on or before July 1 of each year, fix for and issue to each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine who applies for a manufacturing quota an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that chemical. Any manufacturing quota fixed and issued by the Administrator is subject to his authority to reduce or limit it at a later date pursuant to §1315.26 and to his authority to revoke or suspend it at any time pursuant to §§1301.36, 1309.43, 1309.44, or 1309.45 of this chapter.

§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical. Copies of DEA Form 189 may be obtained from the Office of Diversion Control Web site, and must be filed (on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A separate application must be made for each chemical desired to be manufactured. The applicant must state the following:

(a) The name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical.

(b) For the chemical in each of the current and preceding 2 calendar years:

1. The authorized individual manufacturing quota, if any;
2. The actual or estimated quantity manufactured;
3. The actual or estimated net disposal;
4. The actual or estimated inventory allowance pursuant to §1315.24; and
5. The actual or estimated inventory as of December 31.

(c) For the chemical in the next calendar year:

1. The desired individual manufacturing quota; and
2. Any additional factors that the applicant finds relevant to the fixing of the individual manufacturing quota, including any of the following:
§ 1315.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to §1315.23, each registered manufacturer shall be allowed as a part of the quota an amount sufficient to maintain an inventory equal to either of the following:

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a chemical not exceeding 65 percent of his 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