

PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

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.
- (2) Other distribution of the chemical consistent with the legitimate medical and scientific needs of the United States.