

understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-3, 830, and 957-8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(f)(1)(iv)(A), the following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]	

PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is amended by revising paragraphs (c), (d) introductory text, (d)(1), (h) and (i); redesignating paragraph (m) as paragraph (o) and adding new paragraphs (m) and (n) to read as follows:

§ 1313.02 Definitions.

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(c) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term *regulated transaction* means:

(1) A distribution, receipt, sale, importation, exportation, or international transaction of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not

relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1310 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(A) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient (for purposes of this paragraph, the term "therapeutically insignificant quantities" shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs; Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in Section 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(B) The Administrator has determined pursuant to the criteria in Section 1310.10 that:

(1) The drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(2) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator;

(v) Any transaction in a chemical mixture listed in Section 1310.13.

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(h) The term *regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(i) The term *established record as an importer* means that the regulated