

non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested pursuant to paragraph (c) of this section is lacking or not readily 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.

[60 FR 32462, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 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(b)(28)(i)(D)(I), 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]	

[60 FR 32463, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

PARTS 1311 [RESERVED]

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

- Sec.
- 1312.01 Scope of part 1312.
- 1312.02 Definitions.

IMPORTATION OF CONTROLLED SUBSTANCES

- 1312.11 Requirement of authorization to import.
- 1312.12 Application for import permit.
- 1312.13 Issuance of import permit.
- 1312.14 Distribution of copies of import permit.
- 1312.15 Shipments in greater or less amount than authorized.
- 1312.16 Cancellation of permit; expiration date.
- 1312.17 Special report from importers.
- 1312.18 Contents of import declaration.
- 1312.19 Distribution of import declaration.

EXPORTATION OF CONTROLLED SUBSTANCES

- 1312.21 Requirement of authorization to export.
- 1312.22 Application for export permit.
- 1312.23 Issuance of export permit.
- 1312.24 Distribution of copies of export permit.
- 1312.25 Expiration date.
- 1312.26 Records required of exporter.
- 1312.27 Contents of special controlled substances invoice.
- 1312.28 Distribution of special controlled substances invoice.
- 1312.29 Domestic release prohibited.