

**§ 1310.15**

**21 CFR Ch. II (4-1-01 Edition)**

**§ 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.  
1312.30 Schedule III, IV, and V non-narcotic controlled substances requiring an import and export permit.

**TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES**

- 1312.31 Schedule I: Application for prior written approval.  
1312.32 Schedules II, III, IV: Advance notice.

**HEARINGS**

- 1312.41 Hearings generally.  
1312.42 Purpose of hearing.  
1312.43 Waiver or modification of rules.  
1312.44 Request for hearing or appearance; waiver.  
1312.45 Burden of proof.  
1312.46 Time and place of hearing.  
1312.47 Final order.

AUTHORITY: 21 U.S.C. 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

**§ 1312.01 Scope of part 1312.**

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

**§ 1312.02 Definitions.**

Any term contained in this part shall have the definition set forth in section