

§ 1314.01

Subpart B—Sales by Regulated Sellers

- 1314.20 Restrictions on sales quantity.
- 1314.25 Requirements for retail transactions.
- 1314.30 Recordkeeping for retail transactions.
- 1314.35 Training of sales personnel.
- 1314.40 Self-certification.
- 1314.42 Self-certification fee; time and method of fee payment.
- 1314.45 Privacy protections.
- 1314.50 Employment measures.

Subpart C—Mail-Order Sales

- 1314.100 Sales limits for mail-order sales.
- 1314.105 Verification of identity for mail-order sales.
- 1314.110 Reports for mail-order sales.
- 1314.115 Distributions not subject to reporting requirements.

Subpart D—Order To Show Cause

- 1314.150 Order to show cause.
- 1314.155 Suspension pending final order.

AUTHORITY: 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

SOURCE: 71 FR 56024, Sept. 26, 2006, unless otherwise noted.

Subpart A—General

§ 1314.01 Scope.

This part specifies the requirements for retail sales of scheduled listed chemical products to individuals for personal use.

§ 1314.02 Applicability.

(a) This part applies to the following regulated persons who sell scheduled listed chemical products for personal use:

(1) Regulated sellers of scheduled listed chemical products sold at retail for personal use through face-to-face sales at stores or mobile retail vendors.

(2) Regulated persons who engage in a transaction with a non-regulated person and who ship the products to the non-regulated person by the U.S. Postal Service or by private or common carriers.

(b) The requirements in subpart A apply to all regulated persons subject to this part. The requirements in subpart B apply to regulated sellers as defined in § 1300.02 of this chapter. The requirements in subpart C apply to regulated persons who ship the products to

21 CFR Ch. II (4–1–10 Edition)

the customer by the U.S. Postal Service or by private or common carriers.

§ 1314.03 Definitions.

As used in this part, the term “mail-order sale” means a retail sale of scheduled listed chemical products for personal use where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer. Mail-order sale includes purchase orders submitted by phone, mail, fax, Internet, or any method other than face-to-face transaction.

§ 1314.05 Requirements regarding packaging of nonliquid forms.

A regulated seller or mail order distributor may not sell a scheduled listed chemical product in nonliquid form (including gel caps) unless the product is packaged either in blister packs, with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

§ 1314.10 Effect on State laws.

Nothing in this part preempts State law on the same subject matter unless there is a positive conflict between this part and a State law so that the two cannot consistently stand together.

§ 1314.15 Loss reporting.

(a) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, any unusual or excessive loss or disappearance of a scheduled listed chemical product under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(b) Each report submitted under paragraph (a) of this section must, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved.

(c) Written reports of losses must be filed within 15 days after the regulated

Drug Enforcement Administration, Justice

§ 1314.30

person becomes aware of the circumstances of the event.

(d) A report submitted under this section must include a description of the circumstances of the loss (in-transit, theft from premises, *etc.*).

(e) A suggested format for the report is provided below:

Regulated Person

Registration number (if applicable) _____

Name _____

Business address _____

City _____

State _____

Zip _____

Business phone _____

Date of loss _____

Type of loss _____

Description of circumstances _____

Subpart B—Sales by Regulated Sellers

§ 1314.20 Restrictions on sales quantity.

(a) Without regard to the number of transactions, a regulated seller (including a mobile retail vendor) may not in a single calendar day sell any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products.

(b) A mobile retail vendor may not in any 30-day period sell an individual purchaser more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, or 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1314.25 Requirements for retail transactions.

(a) Each regulated seller must ensure that sales of a scheduled listed chemical product at retail are made in accordance with this section and §1314.20.

(b) The regulated seller must place the product so that customers do not have direct access to the product before the sale is made (in this paragraph referred to as “behind-the-counter” placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility where customers do have direct

access. Mobile retail vendors must place the product in a locked cabinet.

(c) The regulated seller must deliver the product directly into the custody of the purchaser.

§ 1314.30 Recordkeeping for retail transactions.

(a)(1) Except for purchase by an individual of a single sales package containing not more than 60 milligrams of pseudoephedrine, the regulated seller must maintain, in accordance with criteria issued by the Administrator, a written or electronic list of each scheduled listed chemical product sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales (referred to as the “logbook”). The logbook may be maintained on paper or in electronic form.

(2) Effective November 27, 2006, if a logbook is maintained on paper, it must be created and maintained in a bound record book.

(b) The regulated seller must not sell a scheduled listed chemical product at retail unless the purchaser does the following:

(1) Presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B).

(2) Signs the logbook and enters in the logbook his or her name, address, and the date and time of the sale.

(c) For records created electronically, the regulated seller may use an electronic signature system to capture the signature and may have the computer automatically enter the date and time of the sale. The regulated seller may ask the purchaser for their name and address and enter information if it is not feasible for the purchaser to enter the information electronically.

(d) The regulated seller must determine that the name entered in the logbook corresponds to the name provided on identification presented and that the date and time entered are correct.

(e) The regulated seller must enter in the logbook the name of the product and the quantity sold. Examples of methods of recording the quantity sold