### § 1313.54 Request for hearing.

(a) Any person entitled to a hearing pursuant to § 1313.52 and desiring a hearing shall, within 30 days after receipt of the notice to suspend the shipment, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) If any person entitled to a hearing or to participate in a hearing pursuant to § 1313.41 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(c) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1313.57.

### § 1313.55 Burden of proof.

At any hearing regarding the suspension of shipments, the Agency shall have the burden of proving that the requirements of this part for such suspension are satisfied.

### § 1313.56 Time and place of hearing.

(a) If any regulated person requests a hearing on the suspension of shipments, a hearing will be scheduled no later than 45 days after the request is made, unless the regulated person requests an extension to this date.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

### § 1313.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order regarding the suspension of shipment. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon each party in the hearing.

# PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

## Subpart A—General



## Subpart B—Sales by Regulated Sellers



## Subpart C—Mail-Order Sales



## Subpart D—Order To Show Cause



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 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 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) 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'').

(b) The regulated seller must not sell a scheduled listed chemical product at retail unless the sale is made in accordance with the following:

(1) The purchaser 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) The purchaser signs the logbook as follows:

(i) For written logbooks, enters in the logbook his name, address, and the date and time of the sale.

(ii) For electronic logbooks, provides a signature using one of the following means:

(A) Signing a device presented by the seller that captures signatures in an electronic format. The device must display the warning notice in paragraph (d) of this section. Any device used must preserve each signature in a manner that clearly links that signature to the other electronically captured logbook information relating to the prospective purchaser providing that signature.

(B) Signing a bound paper book.

(*1*) The bound paper book must include, for such purchaser, either—

(*i*) A printed sticker affixed to the bound paper book at the time of sale that either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or

(*ii*) A unique identifier that can be linked to that information and that is written into the book by the seller at the time of sale.

(*2*) The purchaser must sign adjacent to the printed sticker or written unique identifier related to that sale. The bound paper book must display the warning notice in paragraph (d) of this section.

(C) Signing a printed document that includes, for the purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. The document must be printed by the seller at the time of the sale. The document must contain a clearly identified signature line for a purchaser to sign. The printed document must display the warning notice in paragraph (d) of this section. Each signed document must be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(3) 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 include the weight of the product per

package and number of packages of each chemical, the cumulative weight of the product for each chemical, or quantity of product by Universal Product Code. These examples do not exclude other methods of displaying the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology. Such electronic records must be provided pursuant to paragraph (g) of this section in a human readable form such that the requirements of paragraph (a) of this section are satisfied.

(c) The logbook maintained by the seller must include the prospective purchaser's name, address, and the date and time of the sale, as follows:

(1) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct.

(2) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(3) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(d) The regulated seller must include in the written or electronic logbook or display by the logbook, the following notice:

WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.

(e) The regulated seller must maintain each entry in the written or electronic logbook for not fewer than two years after the date on which the entry is made.

(f) A record under this section must be kept at the regulated seller's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(g) The records required to be kept under this section must be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of section 510 of the Act (21 U.S.C. 880).

(h) A record developed and maintained to comply with a State law may be used to meet the requirements of this section if the record includes the information specified in this section.

[76 FR 74698, Dec. 1, 2011]

### § 1314.35 Training of sales personnel.

Each regulated seller must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for delivering the products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the regulated seller has submitted to the Administration a self-certification that all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated seller to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated seller maintains a copy of each self-certification and all records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

### § 1314.40 Self-certification.

(a) A regulated seller must submit to the Administration the self-certification referred to in § 1314.35(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in

§ 1314.35(a), the certification includes a statement that the regulated seller understands each of the requirements that apply under this part and agrees to comply with the requirements.

(b) When a regulated seller files the initial self-certification, the Administration will assign the regulated seller to one of twelve groups. The expiration date of the self-certification for all regulated sellers in any group will be the last day of the month designated for that group. In assigning a regulated seller to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of the self-certification. After the initial certification period, the regulated seller must update the self-certifications annually.

(c) The regulated seller must provide a separate certification for each place of business at which the regulated seller sells scheduled listed chemical products at retail.

### § 1314.42 Self-certification fee; time and method of fee payment.

(a) A regulated seller must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of $21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated seller shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

[73 FR 79323, Dec. 29, 2008]

### § 1314.45 Privacy protections.

To protect the privacy of individuals who purchase scheduled listed chemical products, the disclosure of information in logbooks under § 1314.30 is restricted as follows:

(a) The information shall be disclosed as appropriate to the Administration and to State and local law enforcement agencies.

(b) The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.

(c) A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

[71 FR 56024, Sept. 26, 2006, as amended at 77 FR 4238, Jan. 27, 2012]

### § 1314.50 Employment measures.

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

## Subpart C—Mail-Order Sales

### § 1314.100 Sales limits for mail-order sales.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in a single calendar day sell to 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) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in any 30-day period sell to 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.

### § 1314.101 Training of sales personnel.

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for preparing and packaging scheduled listed chemical products for delivery to purchasers through the Postal Service or any private or commercial carrier or who deal either directly or indirectly with purchasers by obtaining payments for the products, the regulated person has submitted to the Administration a self-certification that all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated person to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated person maintains a copy of each self-certification and all records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

[76 FR 20523, Apr. 13, 2011]

### § 1314.102 Self-certification.

(a) A regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must submit to the Administration the self-certification referred to in § 1314.101(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in § 1314.101(a), the certification includes a statement that the regulated person understands each of the requirements that apply in this part and agrees to comply with the requirements.

(b) When a regulated person files the initial self-certification, the Administration will assign the regulated person to one of twelve groups. The expiration date of the self-certification for all regulated persons in any group will be the last day of the month designated for that group. In assigning a regulated person to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of self-certification. After the initial certification period, the regulated person must update the self-certification annually.

(c) The regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must provide a separate certification for each place of business at which the regulated person sells scheduled listed chemical products at retail.

[76 FR 20523, Apr. 13, 2011]

### § 1314.103 Self-certification fee; time and method of fee payment.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Administration must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of $21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated person shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

[76 FR 20523, Apr. 13, 2011]

### § 1314.105 Verification of identity for mail-order sales.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must, prior to shipping the product, receive from the purchaser

a copy of 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). Prior to shipping the product, the regulated person must determine that the name and address on the identification correspond to the name and address provided by the purchaser as part of the sales transaction. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

(b) If the product is being shipped to a third party, the regulated person must comply with the requirements of paragraph (a) to verify that both the purchaser and the person to whom the product is being shipped live at the addresses provided. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

### § 1314.110 Reports for mail-order sales.

(a) Each regulated person required to report under § 1310.03(c) of this chapter must either:

(1) Submit a written report, containing the information set forth in paragraph (b) of this section, on or before the 15th day of each month following the month in which the distributions took place. The report must be submitted under company letterhead, signed by the person authorized to sign on behalf of the regulated seller, to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address); or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(b) Each monthly report must provide the following information for each distribution:

(1) Supplier name and registration number;

(2) Purchaser's name and address;

(3) Name/address shipped to (if different from purchaser's name/address);

(4) Method used to verify the identity of the purchaser and, where applicable, person to whom product is shipped;

(5) Name of the chemical contained in the scheduled listed chemical product and total quantity shipped (e.g. pseudoephedrine, 3 grams);

(6) Date of shipment;

(7) Product name;

(8) Dosage form (e.g., tablet, liquid);

(9) Dosage strength (e.g., 30mg, 60mg, per dose etc.);

(10) Number of dosage units (e.g., 100 doses per package);

(11) Package type (blister pack, etc.);

(12) Number of packages;

(13) Lot number.

[71 FR 56024, Sept. 26, 2006, as amended at 75 FR 10684, Mar. 9, 2010; 81 FR 97040, Dec. 30, 2016]

### § 1314.115 Distributions not subject to reporting requirements.

(a) The following distributions to nonregulated persons are not subject to the reporting requirements in § 1314.110:

(1) Distributions of sample packages when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(2) Distributions by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in the definition of retail distributor in § 1300.02 of this chapter, except that this paragraph (a)(2) does not apply to sales of scheduled listed chemical products at retail.

(3) Distributions to a resident of a long term care facility or distributions

to a long term care facility for dispensing to or for use by a resident of that facility.

(4) Distributions in accordance with a valid prescription.

(b) The Administrator may revoke any or all of the exemptions listed in paragraph (a) of this section for an individual regulated person if the Administrator finds that drug products distributed by the regulated person are being used in violation of the regulations in this chapter or the Controlled Substances Act.

[[71 FR 56024, Sept. 26, 2006, as amended at 77 FR 4238, Jan. 27, 2012]

## Subpart D—Order to Show Cause

### § 1314.150 Order To show cause.

(a) If, upon information gathered by the Administration regarding any regulated seller or a distributor required to submit reports under §1310.03(c) of this chapter, the Administrator determines that a regulated seller or distributor required to submit reports under §1310.03(c) of this chapter has sold a scheduled listed chemical product in violation of Section 402 of the Act (21 U.S.C. 842(a)(12) or (13)), the Administrator will serve upon the regulated seller or distributor an order to show cause why the regulated seller or distributor should not be prohibited from selling scheduled listed chemical products.

(b) The order to show cause shall call upon the regulated seller or distributor to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the prohibition and a summary of the matters of fact and law asserted.

(c) Upon receipt of an order to show cause, the regulated seller or distributor must, if he desires a hearing, file a request for a hearing as specified in subpart D of part 1316 of this chapter. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, as provided in part 1316 of this chapter.

(d) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

### § 1314.155 Suspension pending final order.

(a) The Administrator may suspend the right to sell scheduled listed chemical products simultaneously with, or at any time subsequent to, the service upon the seller or distributor required to file reports under §1310.03(c) of this chapter of an order to show cause why the regulated seller or distributor should not be prohibited from selling scheduled listed chemical products, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause under §1314.150 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the regulated seller or distributor shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the scheduled listed chemical products in his or her possession; or

(2) Place all of the scheduled listed chemical products under seal as described in Section 304 of the Act (21 U.S.C. 824(f)).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the prohibition, including any judicial review, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any regulated seller or distributor whose right to sell scheduled listed chemical products is suspended under this section may request a hearing on the suspension at a time earlier than specified in the order to show cause under §1314.150, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.