(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 § 1314.15 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.

§ 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.

§ 1314.105 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 Import/Export Unit, 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 Import/Export Unit, 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 amemded at 75 FR 10684, Mar. 9, 2010]

§ 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 § 1300.02(b)(29) 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.

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