

§ 1314.115

(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]

§ 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.

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(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 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.