

§ 1310.07

(4) The name, address, telephone, telex, and, where available, the facsimile number of the consignee in the country where the shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

(g) Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record. A brief written report outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 27284, Washington, DC 20038, following the return within a reasonable time. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

(h) Each annual report required by Section 1310.05(d) shall provide the following information for each listed chemical manufactured:

(1) The name, address and chemical registration number (if any) of the manufacturer and person to contact for information.

(2) The aggregate quantity of each listed chemical that the company manufactured during the preceding calendar year.

(3) The year-end inventory of each listed chemical as of the close of business on the 31st day of December of each year. (For each listed chemical, if the prior period's ending inventory has not previously been reported to DEA, this report should also detail the beginning inventory for the period.) For purposes of this requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material.

(4) The aggregate quantity of each listed chemical used for internal consumption during the preceding calendar year, unless the chemical is produced solely for internal consumption.

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from Section 1310.01(f)(1)(iv) or

21 CFR Ch. II (4-1-03 Edition)

1310.01(f)(1)(v) during the preceding calendar year.

(6) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as anhydrous base or acid in kilogram units of measure.

(i) Each monthly report required by § 1310.05(e) of this part shall 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) Name of the chemical and total amount shipped (i.e. Pseudoephedrine, 250 grams).

(5) Date of shipment.

(6) Product name (if drug product).

(7) Dosage form (if drug product) (i.e., pill, tablet, liquid).

(8) Dosage strength (if drug product) (i.e., 30mg, 60mg, per dose etc.).

(9) Number of dosage units (if drug product) (100 doses per package).

(10) Package type (if drug product) (bottle, blister pack, etc.).

(11) Number of packages (if drug product) (10 bottles).

(12) Lot number (if drug product).

(j) Information provided in reports required by § 1310.05(e) of this part which is exempt from disclosure under section 552(a) of Title 5, by reason of section 552(b)(6) of Title 5, will be provided the same protections from disclosure as are provided in section 310(c) of the Act (21 U.S.C. 830(c)) for confidential business information.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2462, Jan. 22, 1992; 59 FR 51364, Oct. 11, 1994; 60 FR 32461, June 22, 1995; 61 FR 14024, Mar. 29, 1996; 61 FR 32926, June 26, 1996; 67 FR 14862, Mar. 28, 2002; 67 FR 49569, July 31, 2002]

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export

transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau, or, if the business entity is a registrant, by verification of the registration. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm's listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity of the business entity.

(c) When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative.

(d) For sales to individuals or cash purchasers, the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver's license and one other form of identification. Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person shall diligently obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove

the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

(e) For a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

(f) With respect to electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders and with § 1310.07(e).

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32461, June 22, 1995]

§ 1310.08 Excluded transactions.

Pursuant to 21 U.S.C. 802(39)(A)(iii), regulation of the following transactions has been determined to be unnecessary for the enforcement of the Chemical Diversion and Trafficking Act and, therefore, they have been excluded from the definitions of regulated transactions:

(a) Domestic and import transactions of hydrochloric and sulfuric acids but not including anhydrous hydrogen chloride.

(b) Exports, transshipments, and international transactions of hydrochloric (including anhydrous hydrogen chloride) and sulfuric acids, except for exports, transshipments and international transactions to the following countries:

- (1) Argentina
- (2) Bolivia
- (3) Brazil
- (4) Chile
- (5) Colombia
- (6) Ecuador
- (7) French Guiana
- (8) Guyana
- (9) Panama
- (10) Paraguay
- (11) Peru