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location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§1310.01(f)(1)(iv) or 1310.01(f)(1)(v) except as set forth in §1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in §1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug dosage form products which contain a listed chemical.

(e) Each regulated person required to report pursuant to §1310.03(c) of this part shall either:

(1) Submit a written report, containing the information set forth in §1310.06(i) of this part, on or before the 15th day of each month following the month in which the distributions took place. The report shall be submitted under company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant, to the Chemical Control

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Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; 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 Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, ATTN: Electronic Reporting.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2461, Jan. 22, 1992; 61 FR 14024, Mar. 29, 1996; 61 FR 17958, Apr. 23, 1996; 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002; 67 FR 49569, July 31, 2002]

§ 1310.06 Content of records and reports.

(a) Each record required by §1310.03 shall include the following:

(1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model and serial number).

(4) The method of transfer (company truck, picked up by customer, etc.).

(5) The type of identification used by the purchaser and any unique number on that identification.

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be

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considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

(c) Each report required by Section 1310.05(a) shall include the information as specified by Section 1310.06(a) and, where obtainable, the registration number of the other party, if such party is registered. A report submitted pursuant to §1310.05(a)(1) or (a)(4) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under §1310.05(a)(4), the circumstances of such loss must be provided (in-transit, theft from premises, etc.)

(d) A suggested format for the reports is provided below:

Supplier:

Registration Number _____
 Name _____
 Business Address _____
 City _____
 State _____
 Zip _____
 Business Phone _____

Purchaser:

Registration Number _____
 Name _____
 Business Address _____
 City _____
 State _____
 Zip _____
 Business Phone _____
 Identification _____

Shipping Address (if different than purchaser Address):

Street _____
 City _____
 State _____
 Zip _____
 Date of Shipment _____
 Name of Listed Chemical(s) _____
 Quantity and Form of Packaging _____

Description of Machine:

Make _____
 Model _____
 Serial # _____
 Method of Transfer _____

If Loss or Disappearance:

Date of Loss _____
 Type of Loss _____
 Description of Circumstances _____

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, D.C. 20503.

(e) Each report of an importation of a tableting machine or an encapsulating machine required by §1310.05(c) shall include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, telex number, and, where available, the facsimile number of the import broker or forwarding agent, if any;

(2) The description of each machine (including make, model, and serial number) and the number of machines being received;

(3) The proposed import date, and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsimile number of the consignor in the foreign country of exportation.

(f) Each report of an exportation of a tableting machine or an encapsulating machine required by §1310.05(c) shall include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, telex number, and, where available, the facsimile number of the export broker, if any;

(2) The description of each machine (including make, model, and serial number) and the number of machines being shipped;

(3) The proposed export date, the U.S. Customs Port of exportation, and the foreign Port of Entry; and

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(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

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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