required to obtain a transaction identification number under part 1313of this chapter) and information set forth in §1310.06(k), on or before the 15th day of each month following the month in which the distributions took place.

(f) Except as provided in paragraph (g) of this section, the following distributions to nonregulated persons, and the following export transactions, are not subject to the reporting requirements in §1310.03(c):

(1) Distributions of sample packages of drug products 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 of drug products 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 defined in §1300.02 of this chapter, except that this paragraph does not apply to sales of scheduled listed chemical products at retail.

(3) Distributions of drug products to a resident of a long term care facility or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(4) Distributions of drug products in accordance with a valid prescription.

(5) Exports which have been reported to the Administrator under §§1313.31 and 1313.32 of this chapter or which are subject to a waiver granted under §1313.21 of this chapter.

(g) The Administrator may revoke any or all of the exemptions listed in paragraph (f) 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. The Administrator will notify the regulated person of the revocation, as provided in §1313.41(a) of this chapter. The revocation will be effective upon receipt of the notice by the person. The regulated person has the right to an expedited hearing regarding the revocation, as provided in §1313.56(a) of this chapter.

[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; 68 FR 57804, Oct. 7, 2003; 71 FR 56024, Sept. 26, 2006; 75 FR 10680, Mar. 9, 2010; 77 FR 4236, Jan. 27, 2012; 81 FR 97022, Dec. 30, 2016]

### §1310.06 Content of records and reports.

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

(1) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address (es), etc.), and, if required, DEA registration number of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The quantity, chemical name, and, if applicable, National Drug Code (NDC) number. If NDC number is not applicable, the form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model, serial number, if any, and whether the machine is manual or electric).

(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 will 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 will 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 U.S. Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, will be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

(c)(1) Each report required by §1310.05(a) must include the information as specified by paragraph (a) of this section, the basis for making the report, and, where obtainable, the registration number of the other party, if such party is registered. A report of an uncommon method of payment or delivery submitted in accordance with §1310.05(a)(1) must also include a reason why the method of payment or delivery was uncommon.

(2) A suggested format for the reports in §1310.05(a)(1) is provided below:

Shipping Address (if different than purchaser Address):

Street _____
City _____
State _____
Zip _____
Date of Shipment _____

Description of Listed Chemical:
Chemical Name _____
Quantity _____
National Drug Code (NDC) Number(s), or Form(s) of Packaging _____

Other:
The basis (*i.e.*, reason) for making the report: _____
Any additional pertinent information: _____

(d) Each report of an unusual or excessive loss or disappearance of a listed chemical required by §1310.05(b)(1) (on DEA Form 107), must include the following information:

(1) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address (es), etc.), and, if applicable, DEA registration number of each party to the regulated transaction.

(2) The date (or estimated date) on which unusual or excessive loss or disappearance occurred, and the actual date on which the unusual or excessive loss or disappearance was discovered by the regulated person.

(3) The quantity, chemical name, and National Drug Code (NDC) number, if applicable or if not the form of packaging of the listed chemical.

(4) The type of business conducted by the regulated person, (*e.g.*, grocery store, pharmacy/drug store, discount department store, warehouse club or superstore, convenience store, specialty food store, gas station, mobile retail vendor, mail-order, etc.) if the regulated person is not a DEA registrant.

(e)(1) Each report of an importation of a tableting machine or an encapsulating machine required by §1310.05(c)(1) (on DEA Form 452) must include the following information:

(i) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the import broker or forwarding agent, if any;

(ii) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received;

(iii) The anticipated date of arrival at the port of entry, and the anticipated port of entry;

(iv) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the consignor in the foreign country of exportation;

(v) The intended medical, commercial, scientific, or other legitimate use of the machine; and

(vi) Any proposed changes in identifying information of the imported machines (*e.g.*, name, brand, serial number, if any, etc.) that will take place after importation.

(2) Each report of an exportation of a tableting machine or an encapsulating machine required by §1310.05(c)(1) (on DEA Form 452) must include the following information:

(i) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the export broker (if applicable);

(ii) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received;

(iii) The anticipated date of arrival at the port of export, the foreign port and country of entry; and

(iv) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the consignee in the country where the shipment is destined; the name(s)/business name(s) and address(es)/business address(es), and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the intermediate consignee(s) (if any).

(f) Each report of a domestic regulated transaction in a tableting machine or encapsulating machine required by §1310.05(b)(2) (on DEA Form 452) must include the following information:

(1) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the regulated person; the name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the purchaser;

(2) A description of each machine (including make, model, serial number, if any, and whether the machine is manual or electric) and the number of machines being received; and

(3) Any changes made by the regulated person in identifying information of the machines (*e.g.*, name, brand, serial number, etc.).

(g) Each report of a denied release by a customs officer at the port of entry of a tableting machine or an encapsulating machine required by §1310.05(c)(2) must include the following information: the quantity of machines denied release; a concise description of the machines denied release; the date on which release was denied; the port where the denial of release was issued from; and the basis for the denial.

(h) *Return information.* (1) Within 30 calendar days after actual receipt of a tableting or encapsulating machine, or within 10 calendar days after receipt of a written request by the Administration to the importer, whichever is sooner, the importer must file a report with the Administration (on DEA Form 452) specifying the particulars of the transaction utilizing the DEA Diversion Control Division secure network application. This report must include the following information: The date on which a customs officer at the port of entry released the machine(s); the date on which the machine(s) arrived at the final destination; the port of entry where the machine(s) were actually released by a customs officer; the actual quantity of machines released by a customs officer; the actual quantity of machines that arrived at the final destination; a description of each tableting or encapsulating machine imported (including make, model, and serial number, if any); any changes in identifying information of the imported machines (*e.g.*, name, brand, serial number, if any, etc.) that will take place after importation; and any other information as the Administration may from time to time specify. Upon receipt and review, the Administration will assign a transaction identification number to a completed report. The report will not be deemed filed until the Administration has issued a transaction identification number. A single return declaration may include the particulars of both the importation and distribution. For DEA reporting purposes, import responsibilities are concluded upon the receipt of the machines by the importer. Once machines are received by the importer, domestic transaction reporting requirements commence. Distributions of tableting and encapsulating machines from the importer to their customers must be reported as domestic regulated transactions in accordance with §1310.05(b)(2).

(2) Within 30 calendar days after the tableting or encapsulating machine is released by a customs officer at the port of export, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration (on DEA Form 452) through the DEA Diversion Control Division secure network application specifying the particulars of the transaction. This report must include the following information: The date on which the machine(s) was (were) released by a customs officer at the port of export; the actual quantity of machines released; a description of each tableting or encapsulating machine released (including make, model, serial number, if any,

and whether the machine is manual or electric); and any other information as the Administration may from time to time specify.

(i) 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 filed with the Administration through the DEA Diversion Control Division secure network application, following the return at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. 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.

(j) Each annual report required by §1310.05(d) must provide the following information for each listed chemical manufactured:

(1) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) and chemical registration number (if any) of the manufacturer.

(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 paragraph (1)(iv) or (v) of the definition of regulated transaction in §1300.02 of this chapter 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.

(k) Each monthly report required by §§1310.03(c) and 1310.05(e) (on DEA Form 453) must provide the following information for each transaction:

(1) Supplier name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) and registration number.

(2) Purchaser's name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.).

(3) Name/business name, address/business address shipped to (if different from purchaser's name/address).

(4) Chemical name, National Drug Code (NDC) number, if applicable, and total amount shipped.

(5) Date of shipment.

(6) Product name (if drug product).

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

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

(9) Number of dosage units (if drug product) (*e.g.*, 100 doses per package).

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

(11) Number of packages (if drug product) (*e.g.*, 10 bottles).

(12) Lot number (if drug product).

(l) Information provided in reports required by §1310.05(e) 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.

[81 FR 97023, Dec. 30, 2016]

### § 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