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§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

used to manufacture controlled substances.

AUTHORITY: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

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1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

1310.21 Sale by Federal departments or agencies of chemicals which could be

(1) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN) 8512

(2) Anthranilic acid, its esters, and its salts 8530

(3) Benzyl cyanide 8735

(4) Ephedrine, its salts, optical isomers, and salts of optical isomers 8113

(5) Ergonovine and its salts 8675

(6) Ergotamine and its salts 8676

(7) N-Acetylanthranilic acid, its esters, and its salts 8522

(8) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8317

(9) Phenylacetic acid, its esters, and its salts 8791

(10) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers 1225

(11) Piperidine and its salts 2704

(12) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers 8112

(13) 3,4-Methylenedioxyphenyl-2-propanone 8502

(14) Methylamine and its salts ... 8520

(15) Ethylamine and its salts 8678

(16) Propionic anhydride 8328

(17) Isosafrole 8704

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(18) Safrole 8323

(19) Piperonal 8750

(20) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine) 8115

(21) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8119

(22) Hydriodic Acid 6695

(23) Benzaldehyde 8256

(24) Nitroethane 6724

(25) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone) 2011

(26) Red phosphorus 6795

(27) White phosphorus (Other names: Yellow Phosphorus) 6796

(28) Hypophosphorous acid and its salts (Including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite and sodium hypophosphite) 6797

(29) N-phenethyl-4-piperidone (NPP) 8332

(30) Iodine 6699

(31) Ergocristine and its salts 8612

(b) List II chemicals:

(1) Acetic anhydride 8519

(2) Acetone 6532

(3) Benzyl chloride 8570

(4) Ethyl ether 6584

(5) Potassium permanganate 6579

(6) 2-Butanone (or Methyl Ethyl Ketone or MEK) 6714

(7) Toluene 6594

(8) Hydrochloric acid (including anhydrous hydrogen chloride) 6545

(9) Sulfuric acid 6552

(10) Methyl Isobutyl Ketone (MIBK) 6715

(11) Sodium Permanganate 6588

shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

(1) The name and address of the petitioner;

(2) The name of the chemical to which the petition pertains;

(3) The name and address of the manufacturer(s) of the chemical (if known);

(4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;

(5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested

persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 71 FR 60826, Oct. 17, 2006; 72 FR 20046, Apr. 23, 2007; 72 FR 35391, July 2, 2007; 72 FR 40238, July 24, 2007; 76 FR 17781, Mar. 31, 2011; 82 FR 32460, July 14, 2017]

§ 1310.03 Persons required to keep records and file reports.

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or “end use” and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in § 1310.05.

(c)(1) Each regulated person who engages in a transaction with a nonregulated person which:

(i) Involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance); and

(ii) Uses or attempts to use the U.S. Postal Service or any private or commercial carrier must, on a monthly basis, report to the Administration each such transaction conducted during the previous month as specified in §§ 1310.05(e) and 1310.06(k) on DEA Form 453 through the DEA Diversion Control Division secure network application.

(2) Each regulated person who engages in an export transaction which:

(i) Involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma hydroxybutyric acid (including drug products containing these chemicals or controlled substance); and

(ii) Uses or attempts to use the U.S. Postal Service or any private or commercial carrier must, on a monthly basis, report each such transaction conducted during the previous month as specified in §§ 1310.05(e) and 1310.06(k) on DEA Form 453 through the DEA Diversion Control Division secure network application.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996; 67 FR 14861, Mar. 28, 2002; 68 FR 57804, Oct. 7, 2003; 70 FR 294, Jan. 4, 2005; 81 FR 97022, Dec. 30, 2016]

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person’s place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) For those listed chemicals for which thresholds have been established, the quantitative threshold or

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the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

- (1) List I chemicals:
 - (i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals.

Code	Chemical	Threshold by base weight
8522	N-Acetylanthranilic acid, its esters, and its salts	40 kilograms.
8530	Anthranilic acid, its esters, and its salts	30 kilograms.
8256	Benzaldehyde	4 kilograms.
8735	Benzyl cyanide	1 kilogram.
8675	Ergonovine and its salts	10 grams.
8676	Ergotamine and its salts	20 grams.
8678	Ethylamine and its salts	1 kilogram.
6695	Hydriodic acid	1.7 kilograms (or 1 liter by volume).
8704	Isosafrole	4 kilograms.
8520	Methylamine and its salts	1 kilogram.
8502	3,4-Methylenedioxyphenyl-2-propanone	4 kilograms.
8115	N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
8119	N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
6724	Nitroethane	2.5 kilograms.
8317	Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
8791	Phenylacetic acid, its esters, and its salts	1 kilogram.
2704	Piperidine and its salts	500 grams.
8750	Piperonal (also called heliotropine)	4 kilograms.
8328	Propionic anhydride	1 gram.
8323	Safrole	4 kilograms.

(ii) For List I chemicals that are contained in scheduled listed chemical products as defined in §1300.02 of this chapter, the thresholds established in paragraph (g) of this section apply only to non-retail distribution, import, and

export. Sales of these products at retail are subject to the requirements of part 1314 of this chapter.

- (2) List II Chemicals:
 - (i) Imports and Exports

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	500 gallons	1,500 kilograms.
(C) Benzyl chloride	N/A	4 kilograms.
(D) Ethyl ether	500 gallons	1,364 kilograms.
(E) Potassium permanganate	N/A	500 kilograms.
(F) 2-Butanone (MEK)	500 gallons	1,455 kilograms.
(G) Toluene	500 gallons	1,591 kilograms.
(H) Sodium permanganate	N/A	500 kilograms

(ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	50 gallons	150 kilograms.
(C) Benzyl chloride	N/A	1 kilogram.
(D) Ethyl ether	50 gallons	135.8 kilograms.
(E) Potassium permanganate	N/A	55 kilograms.
(F) 2-Butanone (MEK)	50 gallons	145 kilograms.
(G) Toluene	50 gallons	159 kilograms.
(H) Anhydrous Hydrogen chloride	N/A	0.0 kilograms.
(I) Sodium permanganate	N/A	55 kilograms

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(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

(iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in §1310.08(b).

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid (1) Anhydrous Hydrogen chloride.	50 gallons	27 kilograms.
(B) Sulfuric acid	50 gallons	

(v) Export and International Transactions to Designated Countries, and Importations for Transshipment or Transfer to Designated Countries

Chemical	Threshold by volume	Threshold by weight
(A) Methyl Isobutyl Ketone (MIBK).	500 gallons	1523 kilograms.
(B) Reserved.		

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in §1300.02 of this chapter. All such transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in this part and notification provisions as set forth in part 1313 of this chapter.

(1) Listed chemicals for which no thresholds have been established:

(i) Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers (APAAN)

(ii) Ephedrine, its salts, optical isomers, and salts of optical isomers;

(iii) Ergocristine and its salts

(iv) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

(v) Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)

(vi) Iodine
(vii) N-phenethyl-4-piperidone (NPP)

(viii) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

(ix) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers

(x) Red phosphorus
(xi) White phosphorus (Other names: Yellow Phosphorus)

(2) [Reserved]

(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. For purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:

(1) For chemical mixtures containing List I chemicals or List II chemicals other than those in paragraph (h)(2) of this section, the threshold is determined by the weight of the listed chemical in the chemical mixture.

(2) For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.

(3) If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

[54 FR 31665, Aug. 1, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1310.04, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 1310.05 Reports.

(a)(1) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part. The regulated person will orally report to the

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Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. The regulated person must file a written report of the transaction(s) with the Special Agent in Charge of the DEA Divisional Office as set forth in §1310.06 within 15 calendar days after the regulated person becomes aware of the circumstances of the event.

(2) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(b)(1) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person will orally report to the Special Agent in Charge of the DEA Divisional Office at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. Unless the loss or disappearance occurs during an import or export transaction, the supplier is responsible for reporting all in-transit losses of any listed chemical by their agent or the common or contract carrier. In an import transaction, once a shipment has been released by the customs officer at the port of entry, the importer is responsible for reporting all in-transit losses of any listed chemical by their

agent or the common or contract carrier. In an export transaction, the exporter is responsible for reporting all in-transit losses of any listed chemical by their agent or the common or contract carrier until the shipment has been released by the customs officer at the port of export. The regulated person must also file a complete and accurate DEA Form 107, in accordance with §1310.06(d), with the Administration through the DEA Diversion Control Division secure network application within 15 calendar days after becoming aware of the circumstances requiring the report. Unusual or excessive losses or disappearances must be reported whether or not the listed chemical is subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss or disappearance of a listed chemical was unusual or excessive, the regulated persons should consider, among others, the following factors:

(i) The actual quantity of a listed chemical;

(ii) The specific listed chemical involved;

(iii) Whether the loss or disappearance of the listed chemical can be associated with access to those listed chemicals by specific individuals, or whether the loss or disappearance can be attributed to unique activities that may take place involving the listed chemical; and

(iv) A pattern of losses or disappearances over a specific time period, whether the losses or disappearances appear to be random, and the result of efforts taken to resolve the losses.

(v) If known, the regulated person should also consider whether the specific listed chemical was a likely candidate for diversion as well as local trends and other indicators of the diversion potential of the listed chemical.

(2) Each regulated person must orally report any domestic regulated transaction in a tableting machine or an encapsulating machine to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located when the order is placed with the seller. The regulated person also must

file a report of the transaction (on DEA Form 452) with the Administration through the DEA Diversion Control Division secure network application within 15 calendar days after the order has been shipped by the seller. A report (DEA Form 452) may list more than one machine for a single transaction. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until a transaction identification number has been issued by the Administration.

(c) *Imports and exports of tableting machines and encapsulating machines.* (1) Each regulated person who imports or exports a tableting machine, or encapsulating machine, must file a report of such importation or exportation on DEA Form 452 with the Administration through the DEA Diversion Control Division secure network application, at least 15 calendar days before the anticipated arrival at the port of entry or port of export. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may report to the Administration as far in advance as possible. A separate report (DEA Form 452) must be filed for each shipment, in accordance with §1310.06(e). Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until a transaction identification number has been issued by the Administration. The importer or exporter may only proceed with the transaction once the transaction identification number has been issued. Any tableting machine or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(2) *Denied release at the port of entry.* In the event that a shipment of

tableting or encapsulating machine(s) has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to import the shipment must, within 5 business days of the denial, report to the Administration that the shipment was denied, the basis for denial, and such other information as is required by §1310.06(g). Such report must be transmitted to the Administration through the DEA Diversion Control Division secure network application. Upon the importer's report of a denied entry, DEA will assign the report a transaction identification number and the original import notification will be void and of no effect. No shipment of tableting machines or encapsulating machines denied entry for any reason will be allowed entry without a subsequent refiling of an amended DEA Form 452 by the regulated person. In such circumstances, the regulated person may proceed with the release of the tableting machines or encapsulating machines upon receipt of a transaction identification number for the refilled and amended DEA Form 452 without regard to the 15-day advance filing requirement in paragraph (c)(1) of this section, so long as the article is otherwise cleared for entry under U.S. customs laws.

(d) Each regulated bulk manufacturer of a listed chemical must submit manufacturing, inventory and use data on an annual basis as set forth in §1310.06(j). This data must be submitted annually to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration, on or before the 15th day of March of the year immediately following the calendar year for which submitted. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A business entity which manufactures a listed chemical may elect to report separately by individual 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 drugs or other products that are exempted under paragraph (1)(iv) or (v) of the definition of regulated transaction in §1300.02 of this

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chapter except as set forth in §1310.06(i)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption are not required to report for that listed chemical. For purposes of these reporting requirements, internal consumption consists of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption includes (but is not 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(j) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report must be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph (d) 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 forms of products which contain a listed chemical.

(e) Each regulated person required to report pursuant to §1310.03(c) must file a report containing the transaction identification number for each such transaction (if the regulated person is required to obtain a transaction identification number under part 1313 of 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

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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:

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(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,

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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),

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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).

(1) 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 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 encap-

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ulating 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
- (12) Suriname
- (13) Uruguay
- (14) Venezuela

(c) Domestic transactions of Methyl Isobutyl Ketone (MIBK).

(d) Import transactions of Methyl Isobutyl Ketone (MIBK) destined for the United States.

(e) Export transactions, international transactions, and import transactions for transshipment or

transfer of Methyl Isobutyl Ketone (MIBK) destined for Canada or any country outside of the Western Hemisphere.

(f) Domestic and international transactions of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one-fluid-ounce (30 milliliters) or less, and no greater than one package per transaction.

(g) Import transactions of anhydrous hydrogen chloride.

(h) Domestic distribution of anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container.

(i) Domestic distribution of anhydrous hydrogen chloride by pipeline.

(j) Domestic and international return shipments of reusable containers from customer to producer containing residual quantities of red phosphorus or white phosphorus in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(k) Domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container.

(l) Domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene, unless regulated because of being formulated with other List I or List II chemical(s) above the concentration limit.

[57 FR 43615, Sept. 22, 1992, as amended at 60 FR 19510, Apr. 19, 1995; 60 FR 32461, June 22, 1995; 62 FR 13968, Mar. 24, 1997; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 68 FR 37414, June 24, 2003; 68 FR 53292, Sept. 10, 2003; 69 FR 74971, Dec. 15, 2004; 72 FR 10928, Mar. 12, 2007; 72 FR 35931, July 2, 2007]

§ 1310.09 Temporary exemption from registration.

(a) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before

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July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(c) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export GBL is temporarily exempted from the registration requirement, provided that the DEA receives a proper application for registration on or before July 24, 2000. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(d) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export the List I chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts), is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 17, 2001. The exemption will remain in effect for each person who has made such application until the Ad-

ministration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(e) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before June 30, 2003. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(f) Except for chemical mixtures containing the listed chemicals in paragraph (e) of this section, each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before February 14, 2005. The exemption will remain in effect for each person who

has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(g) Any person who distributes, imports, or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(h) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated N-phenethyl-4-piperidone (NPP), including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing NPP pursuant to §1310.13 on or before June 22, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports or exports a chemical mixture containing N-phenethyl-4-piperidone (NPP) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA

notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(i) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to manufacture, distribute, import, or export regulated iodine, including regulated iodine chemical mixtures pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that the Administration receives a proper application for registration or application for exemption for a chemical mixture containing iodine on or before August 31, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports, or exports a chemical mixture containing iodine whose application for exemption is subsequently denied by the Administration must obtain a registration with the Administration. A temporary exemption from the registration requirement will also be provided for these persons, provided that the Administration receives a properly completed application for registration on or before 30 days following the date of official Administration notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until the Administration takes final action on their registration application.

(j) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain ephedrine, and/or pseudoephedrine, pursuant to Sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before August

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24, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, 1313, and 1315 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports, or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(k)(1) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated GBL-containing chemical mixtures, pursuant to sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before July 29, 2010. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a GBL-containing chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following

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the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(1)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated ergocristine and its salts, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing ergocristine and its salts pursuant to §1310.13 on or before May 2, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing ergocristine and its salts whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(m)(1) Each person required by Sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain red phosphorus, white phosphorus, hypophosphorous acid (and its salts), pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided

that DEA receives a properly completed application for registration or application for exemption on or before July 5, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture which contains red phosphorus, white phosphorus, hypophosphorous acid (and its salts) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(n)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated alpha-phenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that the DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing alpha-phenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, pursuant to §1310.13 on or before August 14, 2017. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310,

1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing alpha-phenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that the DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until the DEA takes final action on their registration application.

[62 FR 27693, May 21, 1997, as amended at 62 FR 53960, Oct. 17, 1997; 65 FR 21647, Apr. 24, 2000; 66 FR 52675, Oct. 17, 2001; 68 FR 23203, May 1, 2003; 69 FR 74971, Dec. 15, 2004; 72 FR 20046, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40239, July 24, 2007; 72 FR 40744, July 25, 2007; 75 FR 37306, June 29, 2010; 76 FR 17781, Mar. 31, 2011; 76 FR 31829, June 2, 2011; 77 FR 4237, Jan. 27, 2012; 82 FR 32460, July 14, 2017]

§ 1310.10 Removal of the exemption of drugs distributed under the Federal Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

(1) The scope, duration, and significance of the diversion;

(2) Whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) Whether the listed chemical can be readily recovered from the drug or group of drugs.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of

this section, the Administrator shall issue and publish in the FEDERAL REGISTER his proposal to remove the drug or group of drugs from the exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

- (1) The package sizes and manner of packaging of the drug product;
- (2) The manner of distribution and advertising of the drug product;
- (3) Evidence of diversion of the drug product;
- (4) Any actions taken by the manufacturer to prevent diversion of the drug product; and
- (5) Such other factors as are relevant to and consistent with the public health and safety, including the factors described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, the Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in

the FEDERAL REGISTER his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any such comments raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) While a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) For a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the FEDERAL REGISTER, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) Applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

(2) There is a significant change in the data that led to the issuance of the final rule.

[60 FR 32461, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002; 75 FR 38922, July 7, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

[60 FR 32462, June 22, 1995]

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-823, 830, and 957-958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as reinstated exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]	

§ 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this section are exempted by the Administrator from application of sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to this §1310.12 or §1310.13 affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts related to exempt chemical mixtures, including distribution in violation of 21 U.S.C. 842(a)(11).

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
N-Acetylanthranilic acid, its salts and esters.	8522	20% by Weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Alpha-phenylacetoacetonitrile, and its salts, optical isomers, and salts of optical isomers. (APAAN).	8512	Not exempt at any concentration.	Chemical mixtures containing any amount of APAAN are not exempt.
Anthranilic acid, and its salts and esters.	8530	50% by Weight	Concentration is based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	50% by Weight or Volume.	
Benzyl cyanide	8570	20% by Weight or Volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Ergocristine and its salts	8612	Not exempt at any concentration.	Chemical mixtures containing any amount of ergocristine and its salts are not exempt.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.
Ergotamine and its salts	8676	Not exempt at any concentration.	Chemical mixtures containing amount of any ergotamine, including its salts, are not exempt.

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
Ethylamine and its salts	8678	20% by Weight or Volume	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Concentration is based on ethylamine in the mixture and not the combination of ethylamine and carrier solvent, if any.
Gamma-Butyrolactone	2011	70% by weight or volume.	The weight is determined by measuring the mass of hypophosphorous acid and its salts in the mixture, the concentration limit is calculated by summing the concentrations of all forms of hypophosphorous acid and its salts in the mixture. The Administration does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. Therefore, any solution consisting of hypophosphorous acid (and its salts), dispersed in water, alcohol, or another inert carrier, is not considered a chemical mixture and is therefore subject to chemical regulatory controls at all concentrations.
Hydriodic acid	6695	20% by Weight or Volume.	
Hypophosphorous acid and its salts.	6797	30% by weight if a solid, weight or volume if a liquid.	
Iodine	6699	2.2	Calculated as weight/volume (w/v).
Isosafrole	8704	20% by Weight or Volume	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with safrole.
Methylamine and its salts ..	8520	20% by Weight	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone.	8502	20% by Weight.	
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by Weight	Concentration based on any combination of salts N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers.
N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by Weight	Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane	6724	20% by Weight or Volume.	Concentration based on any combination of norpseudoephedrine, phenylpropranolamine and their salts, optical isomers and salts of optical isomers.
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by Weight	
N-phenethyl-4-piperidone (NPP).	8332	Not exempt at any concentration.	Chemical mixtures containing any amount of NPP are not exempt.
Phenylacetic acid, and its salts and esters.	8791	40% by Weight	Concentration is based on any combination of phenylacetic acid and its salts and esters.
Phenylpropranolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by Weight	Concentration based on any combination of phenylpropranolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Piperidine, and its salts	2704	20% by Weight or Volume	Concentration based on any combination of piperidine and its salts. Concentration based on weight if a solid, weight or volume if a liquid.
Piperonal	8750	20% by Weight or Volume.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
Propionic anhydride	8328	20% by Weight or Volume.	
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	Not exempt at any concentration.	
Red Phosphorus	6795	80% by weight.	Concentration in a mixture cannot exceed 20% if taken alone or in any combination with isosafrole.
Safrole	8323	20% by Volume	
White phosphorus	6796	Not exempt at any concentration.	Chemical mixtures containing any amount of white phosphorus are not exempt due to concentration, unless otherwise exempted.
List II Chemicals			
Acetic Anhydride	8519	20% by Weight or Volume.	

TABLE OF CONCENTRATION LIMITS—Continued

	DEA chemical code number	Concentration	Special conditions
Acetone	6532	35% by Weight or Volume	Exports only; Limit applies to acetone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride	8568	20% by Weight or Volume.	Exports only; Limit applies to 2-butanone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
2-butanone	6714	35% by Weight or Volume	
Ethyl ether	6584	35% by Weight or Volume	Exports only; Limit applies to ethyl ether or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid	6545	20% by Weight or Volume	Hydrogen chloride in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on hydrogen chloride in the mixture and not the combined weight of the carrier solvent, if any.
Methyl isobutyl ketone	6715	35% by Weight or Volume	Exports only pursuant to § 1310.08; Limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate ..	6579	15% by Weight.	Sulfuric acid in an inert carrier solvent, such as aqueous or alcoholic solutions, is not considered a mixture. Weight is based on sulfuric acid in the mixture and not the combined weight of the carrier solvent, if any.
Sodium Permanganate	6588	15% by Weight.	
Sulfuric acid	6552	20% by Weight or Volume	
Toluene	594	35% by Weight or Volume	Exports only; Limit applies to toluene or any combination of acetone, ethyl ether, 2-butanone, methyl isobutyl ketone, and toluene if present in the mixture by summing the concentrations for each chemical.

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) Chemical mixtures that are distributed directly to an incinerator for destruction or directly to an authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700-22; persons distributing the mixture to the incinerator or recycler must maintain and make available to agents of the Administration, upon request, such documentation for a period of no less than two years.

(2) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all of the components of the paint or coating for use

in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents.

(3) Iodine products classified as iodophors that exist as an iodine complex to include poloxamer-iodine complex, polyvinyl pyrrolidone-iodine complex (*i.e.*, povidone-iodine), undecoylium chloride iodine,

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nonylphenoxy poly (ethyleneoxy) ethanol-iodine complex, iodine complex with phosphate ester of alkylaryloxy polyethylene glycol, and iodine complex with ammonium ether sulfate/polyoxyethylene sorbitan monolaurate.

(4) Iodine products that consist of organically bound iodine (a non-ionic complex) (e.g., iopamidol, iohexol, and amiodarone.)

(e) The Administrator may, at any time, terminate or modify the exemption for any chemical mixture which has been granted an exemption pursuant to the concentration limits as specified in paragraph (c) of this section or pursuant to the category exemption as specified in paragraph (d) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exemption for a product or group of products for which evidence of diversion has been found, as well as the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may modify any part of the criteria for exemption as specified in paragraphs (c) and (d) of this section upon evidence of diversion or attempted diversion. In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the FEDERAL REGISTER. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Ad-

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ministrator shall publish in the FEDERAL REGISTER a final order.

[68 FR 23204, May 1, 2003, as amended at 69 FR 74971, Dec. 15, 2004; 71 FR 60826, Oct. 17, 2006; 72 FR 20047, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40745, July 25, 2007; 75 FR 37306, June 29, 2010; 76 FR 17781, Mar. 31, 2011; 76 FR 31830, June 2, 2011; 82 FR 32460, July 14, 2017]

§ 1310.13 Exemption of chemical mixtures; application.

(a) The Administrator may, by publication of a Final Rule in the FEDERAL REGISTER, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture and:

(i) If the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared; and

(ii) If a group of mixtures (e.g. formulations having identical function and containing the same listed chemical(s)), the information required in paragraph (c)(3)(i) of this section and a brief narrative of their use.

(4) (i) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or

(ii) If a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.

(5) (i) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and

(ii) If a group of mixtures, how the group's properties differ from the properties of the listed chemical.

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria set forth in paragraph (a) of this section.

(7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under this section.

(8) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator will notify the applicant in writing of the acceptance or rejection of the application for filing. If the application is not accepted for filing, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is subsequently granted, the applicant shall again be notified in

writing and the Administrator shall issue, and publish in the FEDERAL REGISTER, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

(f) The Administrator may, at any time, terminate or modify an exemption for any product pursuant to paragraph (e) of this section. In terminating or modifying an exemption, the Administrator shall issue, and publish in the FEDERAL REGISTER, notification of the removal of an exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(g) A manufacturer of an exempted chemical mixture shall notify DEA in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new application will be required only if reformulation results in a new product having a

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different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer seeking exemption must apply for such an exemp-

tion. A formulation granted exemption by publication in the FEDERAL REGISTER will not be exempted for all manufacturers.

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt chemical mixtures for the purposes set forth in this section and are exempted by the Administrator from application of Sections 302, 303, 310, 1007, 1008, and 1018 of the Act (21 U.S.C. 822, 823, 830, 957, 958, and 971):

TABLE 1 TO PARAGRAPH (i)—EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name ¹	Form	Date
Cerilliant Corporation ...	1R,2S(-)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	1S,2R(+)-Ephedrine-D ₃ hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	1S,2R(+)-Ephedrine-D ₃ hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	1S,2R(+)-Ephedrine hydrochloride 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	Pseudoephedrine-D ₃ hydrochloride 0.1 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	R,R(-)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20) methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	S,S(+)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
E.I. DuPont deNemours & Co.	RC-5156	Liquid	4/22/2005
E.I. DuPont deNemours & Co.	VH-6037	Liquid	4/22/2005
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 5 mg/ml.	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, Pyridine-Free Single Solution, 2 mg/ml.	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 2 mg/ml Single Solution NON-HAZ	Liquid	11/26/2018
GFS Chemicals	WaterMark® Karl-Fisher Reagent, 5 mg/ml, Stabilized, Pyridine-Based	Liquid	11/26/2018
Hawthorne Products, Inc.	Sole Pack Hoof Dressing	Paste	8/14/2007
Hawthorne Products, Inc.	Sole Pack Hoof Packing	Paste	8/14/2007
Lord Corporation	Chemlok TS701-52	Liquid	05/03/2018
Lord Corporation	Chemlok TS701-53	Liquid	05/03/2018

TABLE 1 TO PARAGRAPH (I)—EXEMPT CHEMICAL MIXTURES—Continued

Manufacturer	Product name ¹	Form	Date
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of ephedrine in blood, serum, or urine.	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of pseudoephedrine in blood, serum, or urine.	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of phenylpropanolamine in blood, serum, or urine.	Liquid	9/26/2007
Reichhold, Inc	Beckosol® 12021-00 AA-200, IA-441, P531-T	Liquid	5/05/2005
Reichhold, Inc	Urotuf® L06-30S, F78-50T	Liquid	5/05/2005
Reichhold, Inc	Beckosol AA-220	Liquid	6/14/2005
Sigma-Aldrich	Hydranal®-Composite 1	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 2	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5K	Liquid	5/29/2013
Sigma-Aldrich	Hydranal®-Composite 5	Liquid	5/29/2013
Standard Homeopathic Co.	Baby Cough Syrup	Liquid	9/28/2012
Standard Homeopathic Co.	Defend Cough & Cold Night	Liquid	9/28/2012
Standard Homeopathic Co.	Defend Cough & Cold	Liquid	9/28/2012
Standard Homeopathic Co.	Diarrex	Liquid	9/28/2012
Waterbury Companies, Inc.	Waterbury 332500	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 332762	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 332400	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 346201	Liquid	4/11/2005

¹ Designate product line if a group.

[68 FR 23204, May 1, 2003, as amended at 75 FR 10681, Mar. 9, 2010; 75 FR 53869, Sept. 2, 2010; 76 FR 31830, June 2, 2011; 81 FR 97025, Dec. 30, 2016; 85 FR 4586, Jan. 27, 2020]

§ 1310.14 Removal of exemption from definition of regulated transaction.

The Administrator finds that the following drugs or groups of drugs are being diverted to obtain a listed chemical for use in the illicit production of a controlled substance and removes the drugs or groups of drugs from exemption under paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter pursuant to the criteria listed in § 1310.10 of this part:

(a) Nonprescription drugs containing ephedrine, its salts, optical isomers, and salts of optical isomers.

(b) Nonprescription drugs containing phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(c) Nonprescription drugs containing pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

[75 FR 38922, July 7, 2010, as amended at 77 FR 4237, Jan. 27, 2012]

§ 1310.16 Exemptions for certain scheduled listed chemical products.

(a) Upon the application of a manufacturer of a scheduled listed chemical product, the Administrator may by regulation provide that the product is exempt from part 1314 of this chapter if the Administrator determines that the product cannot be used in the illicit manufacture of a controlled substance.

(b) An application for an exemption under this section must contain all of the following information:

(1) The name and address of the applicant.

(2) The exact trade name of the scheduled listed chemical product for which exemption is sought.

(3) The complete quantitative and qualitative composition of the drug product.

(4) A brief statement of the facts that the applicant believes justify the granting of an exemption under this section.

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Federal, Food, Drug, and Cosmetic Act.

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(6) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested under paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section.

(e) If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect.

(f) The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

[71 FR 56024, Sept. 26, 2006]

§ 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

(a) A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance, unless the Administrator certifies in writing to the head of the department or agency that there is no reasonable cause to believe that the sale of the specific chemical to a specific person would result in the illegal manufacture of a controlled substance. For purposes of this requirement, reasonable cause to believe means that the Administration has knowledge of facts which would cause a reasonable person to reasonably conclude that a chemical would be diverted to the illegal manufacture of a controlled substance.

(b) A Federal department or agency must request certification by submitting a written request to the Administrator, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A request for certification may be transmitted directly to the Office of Diversion Control, Drug Enforcement Administration, through electronic facsimile media. A request for certification must be submitted no later than fifteen calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from Federal departments' or agencies' stocks, Federal departments or agencies may wish to submit requests as far in advance of the fifteen calendar days as possible. The written notification of the proposed sale must include:

- (1) The name and amount of the chemical to be sold;
- (2) The name and address of the prospective bidder;
- (3) The name and address of the prospective end-user, in cases where a sale is being brokered;
- (4) Point(s) of contact for the prospective bidder and, where appropriate, prospective end-user; and
- (5) The end use of the chemical.

(c) Within fifteen calendar days of receipt of a request for certification, the Administrator will certify in writing to the head of the Federal department or agency that there is, or is not, reasonable cause to believe that the sale of the specific chemical to the specific bidder and end-user would result in the illegal manufacture of a controlled substance. In making this determination, the following factors must be considered:

(1) Past experience of the prospective bidder or end-user in the maintenance of effective controls against diversion of listed chemicals into other than legitimate medical, scientific, and industrial channels;

(2) Compliance of the prospective bidder or end-user with applicable Federal, state and local law;

(3) Prior conviction record of the prospective bidder or end-user relating to listed chemicals or controlled substances under Federal or state laws; and

(4) Such other factors as may be relevant to and consistent with the public health and safety.

(d) If the Administrator certifies to the head of a Federal department or agency that there is no reasonable cause to believe that the sale of a specific chemical to a prospective bidder and end-user will result in the illegal manufacture of a controlled substance, that certification will be effective for one year from the date of issuance with respect to further sales of the same chemical to the same prospective bidder and end-user, unless the Administrator notifies the head of the Federal department or agency in writing that the certification is withdrawn. If the certification is withdrawn, DEA will also provide written notice to the bidder and end-user, which will contain a statement of the legal and factual basis for this determination.

(e) If the Administrator determines there is reasonable cause to believe the sale of the specific chemical to a specific bidder and end-user would result in the illegal manufacture of a controlled substance, DEA will provide written notice to the head of a Federal department or agency refusing to certify the proposed sale under the authority of 21 U.S.C. 890. DEA also will

provide, within fifteen calendar days of receiving a request for certification from a Federal department or agency, the same written notice to the prospective bidder and end-user, and this notice also will contain a statement of the legal and factual basis for the refusal of certification. The prospective bidder and end-user may, within thirty calendar days of receipt of notification of the refusal, submit written comments or written objections to the Administrator's refusal. At the same time, the prospective bidder and end-user also may provide supporting documentation to contest the Administrator's refusal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which the refusal is based, the Administrator will reconsider the refusal of the proposed sale in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original refusal of certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original refusal. Such affirmation of the original refusal will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

(f) If the Administrator determines there is reasonable cause to believe that an existing certification should be withdrawn, DEA will provide written notice to the head of a Federal department or agency of such withdrawal under the authority of 21 U.S.C. 890. DEA also will provide, within fifteen calendar days of withdrawal of an existing certification, the same written notice to the bidder and end-user, and this notice also will contain a statement of the legal and factual basis for the withdrawal. The bidder and end-user may, within thirty calendar days of receipt of notification of the withdrawal of the existing certification, submit written comments or written objections to the Administrator's withdrawal. At the same time, the bidder and end-user also may provide supporting documentation to contest the Administrator's withdrawal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which

the withdrawal of the existing certification is based, the Administrator will reconsider the withdrawal of the existing certification in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original withdrawal of the existing certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original withdrawal of the existing certification. Such affirmation of the original withdrawal of the existing certification will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

[68 FR 62737, Nov. 6, 2003, as amended at 75 FR 10681, Mar. 9, 2010]

PART 1311—REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS

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AUTHORITY: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

SOURCE: 70 FR 16915, Apr. 1, 2005, unless otherwise noted.

Subpart A—General

§ 1311.01 Scope.

This part sets forth the rules governing the creation, transmission, and storage of electronic orders and prescriptions.

[75 FR 16310, Mar. 31, 2010]

§ 1311.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[75 FR 16310, Mar. 31, 2010]