listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 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.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Sec.
1310.01 Definitions.
1310.02 Substances covered.
1310.03 Persons required to keep records and file reports.
1310.04 Maintenance of records.
1310.05 Reports.
1310.06 Content of records and reports.
1310.07 Proof of identity.
1310.08 Excluded transactions.
1310.09 Temporary exemption from registration.
1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.
§ 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 regarding such manufacture specified in Section 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 Section 1310.05.

§ 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 oc-
curred, except that records may be
kept at a single, central location of the
regulated person if the regulated per-
son has notified the Administration of
the intention to do so. Written notifi-
cation must be submitted by registered
or certified mail, return receipt re-
quested, 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 re-
trievable and available for inspection
and copying by authorized employees
of the Administration under the provi-

(e) The regulated person with more
than one place of business where
records are required to be kept shall
device a system to detect any party
purchasing from several individual lo-
ations 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 estab-
lished, the quantitative threshold or
the cumulative amount for multiple
transactions within a calendar month,
to be utilized in determining whether a
receipt, sale, importation or exporta-
tion is a regulated transaction is as
follows:

(1) List I Chemicals:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Anthranilic acid and its salts</td>
<td>30 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(ii) Benzyl cyanide</td>
<td>1 kilogram</td>
<td>10 grams</td>
</tr>
<tr>
<td>(iii) Ergonovine and its salts</td>
<td>20 grams</td>
<td>40 kilograms</td>
</tr>
<tr>
<td>(iv) Ergotamine and its salts</td>
<td>20 grams</td>
<td>40 kilograms</td>
</tr>
<tr>
<td>(v) N-Acetylanthranilic acid and its salts</td>
<td>20 grams</td>
<td>40 kilograms</td>
</tr>
<tr>
<td>(vi) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>2.5 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(vii) Phenylacetic acid and its salts</td>
<td>2.5 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(viii) Phenypropanolamine, its salts, optical isomers, and salts of optical isomers</td>
<td>2.5 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(ix) Piperidine and its salts</td>
<td>500 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(x) Pseudoprophedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>500 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xi) 3, 4-Methylenedioxyphenyl-2-propanone</td>
<td>4 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xii) Ethylamine and its salts</td>
<td>1 gram</td>
<td>1 gram</td>
</tr>
<tr>
<td>(xiii) Propionic anhydride</td>
<td>4 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xiv) Isosafrole</td>
<td>4 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xv) Saffrole</td>
<td>4 kilograms</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xvi) N-Methylphedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>1 kilogram</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xvii) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers</td>
<td>1 kilogram</td>
<td>1 kilogram</td>
</tr>
<tr>
<td>(xviii) Hydriotic acid (57%)</td>
<td>1.7 kilograms (or 1 liter by volume)</td>
<td>4 Kilograms</td>
</tr>
<tr>
<td>(xix) Benzaldehyde</td>
<td>2.5 Kilograms</td>
<td>4 Kilograms</td>
</tr>
<tr>
<td>(xx) Nitroethane</td>
<td>2.5 Kilograms</td>
<td>4 Kilograms</td>
</tr>
</tbody>
</table>

(2) List II Chemicals:

(i) Imports and Exports

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Acetic anhydride</td>
<td>250 gallons</td>
<td>1,023 kilograms</td>
</tr>
<tr>
<td>(B) Acetone</td>
<td>500 gallons</td>
<td>1,500 kilograms</td>
</tr>
<tr>
<td>(C) Benzyl chloride</td>
<td>N/A</td>
<td>4 kilograms</td>
</tr>
<tr>
<td>(D) Ethyl ether</td>
<td>500 gallons</td>
<td>1,364 kilograms</td>
</tr>
<tr>
<td>(E) Potassium permanganate</td>
<td>N/A</td>
<td>500 kilograms</td>
</tr>
<tr>
<td>(F) 2-Butanone (MEK)</td>
<td>500 gallons</td>
<td>1,455 kilograms</td>
</tr>
<tr>
<td>(G) Toluene</td>
<td>500 gallons</td>
<td>1,591 kilograms</td>
</tr>
</tbody>
</table>

(ii) Domestic Sales

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Chemical by volume

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Acetic anhydride</td>
<td>250 gallons</td>
<td>1,023 kilograms</td>
</tr>
<tr>
<td>(B) Acetone</td>
<td>50 gallons</td>
<td>150 kilograms</td>
</tr>
<tr>
<td>(C) Benzyl chloride</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>(D) Ethyl ether</td>
<td>50 gallons</td>
<td>135.8 kilograms</td>
</tr>
<tr>
<td>(E) Potassium permanganate</td>
<td>N/A</td>
<td>55 kilograms</td>
</tr>
<tr>
<td>(F) 2-Butanone (MEK)</td>
<td>50 gallons</td>
<td>145 kilograms</td>
</tr>
<tr>
<td>(G) Toluene</td>
<td>50 gallons</td>
<td>159 kilograms</td>
</tr>
</tbody>
</table>

(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 set forth in § 1310.08(b)

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

Chemical by volume

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Threshold by volume</th>
<th>Threshold by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Methyl Isobutyl Ketone (MIBK)</td>
<td>500 gallons .....</td>
<td>1523 kilograms.</td>
</tr>
<tr>
<td>(B) Reserved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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 § 1310.01(f). All such transactions, regardless of size, are subject to record-keeping and reporting requirements as set forth in this part 1310 and notification provisions as set forth in part 1313 of this chapter.

(1) List of Chemicals For Which No Thresholds Have Been Established:

   (i) Ephedrine, its salts, optical isomers, and salts of optical isomers

   (ii) [Reserved]

   (2) [Reserved]

§ 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person makes the report is located, as follows:

   (1) 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.

   (2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

   (3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

   (4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located 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. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in § 1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. 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.

(c) Each regulated person who imports or exports a tableting machine, or encapsulation machine, shall file a report (not a 486) of such importation or exportation with the Administration at the following address on or before the date of importation or exportation:
Drug Enforcement Administration, Justice

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Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

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 wish to report to the Administration as far in advance as possible. A copy of the report may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media. 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.

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in §1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington, D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. 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 drug or other products which are exempted under §§1310.01(f)(1)(i) or 1310.01(f)(1)(v) except as set forth in §1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal use shall not be required to report that listed chemical. For purposes of this section, normal business records shall 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

§ 1310.06

records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

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

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

**Supplier:**
- Registration Number
- Name
- Business Address
- City
- State
- Zip
- Business Phone

**Purchaser:**
- Registration Number
- Name
- Business Address
- City
- State
- Zip
- Business Phone
- Identification

**Shipping Address (if different than purchaser Address):**
- Street
- City
- State
- Zip

**Date of Shipment**

**Name of Listed Chemical(s)**

**Quantity and Form of Packaging**

**Description of Machine:**
- Make
- Model
- Serial #
- Method of Transfer

**If Loss or Disappearance:**
- Date of Loss
- Type of Loss

**Description of Circumstances**

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

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

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

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

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

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

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

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

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

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

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

(g) Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record. A brief written report outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038, following the return within a reasonable time.

This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

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

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

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

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

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

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year.

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

§ 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 transactions, 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 at the time the order is placed. 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
§ 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.

(b) Exports, transshipments, and international transactions of hydrochloric 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.

§ 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

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]
registration requirement, provided that the person submits a proper application for registration on or before 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 §1300.02(b)(28)(1)(D) 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.

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

(a) The Administrator may remove from exemption under §1310.01(b)(28)(i)(D) 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 under paragraph (a) of this section 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...
§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(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:

<table>
<thead>
<tr>
<th>Exempt Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier</td>
</tr>
<tr>
<td>[Reserved]</td>
</tr>
</tbody>
</table>

§ 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in §1310.03(b)(28)(i)(D)(i), may request that the Administrator exempt the product as one which contains ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.
§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-3, 830, and 957-8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

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

(d) In addition to the drug products listed in the compendium set forth in §1310.01(b)(28)(i)(D)(1), the following drug products, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt drug products for the purposes set forth in this section:

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Product name</th>
<th>Form</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Reserved]</td>
<td>.........</td>
<td>..........</td>
<td>.........</td>
</tr>
</tbody>
</table>