phenylbutanoate) and its optical isomers

(xi) *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts

(xii) N-phenethyl-4-piperidone (NPP)

(xiii) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, and its salts

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

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

(xvi) Red phosphorus

(xvii) 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*.

EDITORIAL NOTE: At 87 FR 67552, Nov. 9, 2022, §1310.4 was amended, however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§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 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 refiled 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 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 1313of this chapter) and information set forth in §1310.06(k), on or before the 15th day of each month following the month in which the distributions took place.

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

(1) Distributions of sample packages of drug products when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(2) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as defined in §1300.02 of this chapter, except that this paragraph does not apply to sales of scheduled listed chemical products at retail.

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

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

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

(g) The Administrator may revoke any or all of the exemptions listed in paragraph (f) of this section for an individual regulated person if the Administrator finds that drug products distributed by the regulated person are being used in violation of the regulations in this chapter or the Controlled Substances Act. The Administrator will notify the regulated person of the revocation, as provided in §1313.41(a) of this chapter. The revocation will be effective upon receipt of the notice by the person. The regulated person has the right to an expedited hearing regarding the revocation, as provided in §1313.56(a) of this chapter.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2461, Jan. 22, 1992; 61 FR 14024, Mar. 29, 1996; 61 FR 17958, Apr. 23, 1996; 62 FR 13968, Mar. 24, 1997; 67 FR 14862, Mar. 28, 2002; 67 FR 49569, July 31, 2002; 68 FR 57804, Oct. 7, 2003; 71 FR 56024, Sept. 26, 2006; 75 FR 10680, Mar. 9, 2010; 77 FR 4236, Jan. 27, 2012; 81 FR 97022, Dec. 30, 2016]

§1310.06 Content of records and reports.

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

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

(2) The date of the regulated transaction.

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

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

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

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