

Drug Enforcement Administration, Justice

§ 1313.05

to the Administrator, the Administrator shall issue his order on the issuance or denial of the application for and import, export, or transshipment permit. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon the applicant.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS

Sec.

1313.01 Scope.

1313.02 Definitions.

1313.03 Forms applicable to this part.

1313.05 Requirements for an established business relationship.

1313.08 Requirements for establishing a record as an importer.

IMPORTATION OF LISTED CHEMICALS

1313.12 Notification prior to import.

1313.13 Requirements of import declaration.

1313.14 Disposition of import declaration.

1313.15 Qualification of regular importers.

1313.16 Updated notice for change in circumstances.

1313.17 Return declaration for imports.

EXPORTATION OF LISTED CHEMICALS

1313.21 Notification prior to export.

1313.22 Export declaration.

1313.23 Disposition of export declaration.

1313.24 Waiver of 15-day advance notice for chemical exporters.

1313.25 Foreign import restrictions.

1313.26 Updated notice for change in circumstances.

1313.27 Return declaration for exports.

TRANSSHIPMENTS, IN-TRANSIT SHIPMENTS AND INTERNATIONAL TRANSACTIONS INVOLVING LISTED CHEMICALS

1313.31 Advance notice of importation for transshipment or transfer.

1313.32 Notification of international transactions.

1313.33 Contents of an international transaction declaration.

1313.34 Disposition of the international transaction declaration.

1313.35 Return declaration or amendment to Form 486 for international transactions.

1313.41 Suspension of shipments.

1313.42 Prohibition of shipments from certain foreign sources.

HEARINGS

1313.51 Hearings generally.

1313.52 Purpose of hearing.

1313.53 Waiver of modification of rules.

1313.54 Request for hearing.

1313.55 Burden of proof.

1313.56 Time and place of hearing.

1313.57 Final order.

AUTHORITY: 21 U.S.C. 802, 830, 871(b), 971.

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

§ 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995]

§ 1313.02 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 13969, Mar. 24, 1997]

§ 1313.03 Forms applicable to this part.

Form	Access/ submission
DEA Form 486, Import/Export Declaration for List I and List II Chemicals.	electronic.
DEA Form 486A Import Declaration for ephedrine, pseudoephedrine, and phenylpropanolamine (including drug products containing these chemicals).	electronic.

[81 FR 97036, Dec. 30, 2016]

§ 1313.05 Requirements for an established business relationship.

To document that an importer or exporter has an established business relationship with a customer, the importer or exporter must provide the Administrator with the following information in accordance with the waiver of 15-day advance notice requirements of § 1313.15 or § 1313.24:

(a) The name and street address of the chemical importer or exporter and of each regular customer;

§ 1313.08

(b) The telephone number, contact person, and where available, the facsimile number for the chemical importer or exporter and for each regular customer;

(c) The nature of the regular customer's business (*i.e.*, importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(d) The duration of the business relationship;

(e) The frequency and number of transactions occurring during the preceding 12-month period;

(f) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical importer or exporter and regular customer;

(g) The method of delivery (direct shipment or through a broker or forwarding agent); and

(h) Other information that the chemical importer or exporter considers relevant for determining whether a customer is a regular customer.

[72 FR 17407, Apr. 9, 2007]

§ 1313.08 Requirements for establishing a record as an importer.

To establish a record as an importer, the regulated person must provide the Administrator with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15:

(a) The name, DEA registration number (where applicable), street address, telephone number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) The frequency and number of transactions occurring during the preceding 12 month period.

[72 FR 17407, Apr. 9, 2007]

IMPORTATION OF LISTED CHEMICALS

§ 1313.12 Notification prior to import.

(a) Each regulated person who seeks to import a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter,

must notify the Administration of the intended import by filing an import declaration (on DEA Form 486/486A) not later than 15 calendar days before the date of release by a customs officer at the port of entry. Regulated persons who seek to import a listed chemical below the threshold quantities identified in § 1310.04(f) are not required to file an import declaration in advance of the release by a customs officer.

(b) A complete and accurate declaration (DEA Form 486/486A) must be filed with the Administration through the DEA Diversion Control Division secure network application not later than 15 calendar days prior to the date of release by a customs officer at the port of entry. The declaration must be signed and dated by the importer and must contain the address of the final destination for the shipment, which for List I chemicals must be a registered location of the importer. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The 15 calendar days shall begin on the date that the regulated person submits a completed declaration, without regard to the date that the Administration assigns a transaction identification number. Listed chemicals meeting or exceeding the threshold quantities identified in § 1310.04(f) of this chapter or for which no threshold has been established may not be imported until a transaction identification number has been issued.

(c) The 15-calendar-day advance notification requirement for listed chemical imports may be waived, in whole or in part, for the following:

(1) Any importation that meets both of the following requirements:

(i) The regulated person has satisfied the requirements for reporting to the Administration as a regular importer of the listed chemicals.

(ii) The importer intends to transfer the listed chemicals to a person who is a regular customer for the chemical, as defined in § 1300.02 of this chapter.

(2) A specific listed chemical, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

21 CFR Ch. II (4–1–19 Edition)

(d) For imports meeting the requirements of paragraph (c)(1) of this section, the declaration (DEA Form 486/486A) must be filed with the Administration through the DEA Diversion Control Division secure network application at least three business days before the date of release by a customs officer at the port of entry. The declaration must be signed and dated by the importer and must contain the address of the final destination for the shipment, which must be a registered location of the importer (for List I chemicals). Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The importer may proceed with the import transaction only once the transaction identification number has been issued.

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person must submit quarterly reports to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration, not later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual importation:

- (1) The name of the listed chemical;
- (2) The quantity and date imported;
- (3) The name and full business address of the supplier;
- (4) The foreign port of embarkation; and
- (5) The port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) has been waived for imports of the following listed chemicals:

- (1) Acetone.
- (2) 2-Butanone (or Methyl Ethyl Ketone or MEK).
- (3) Toluene.

[54 FR 31665, Aug. 1, 1989, as amended at 59 FR 51367, Oct. 11, 1994; 60 FR 32464, June 22, 1995; 66 FR 46520, Sept. 6, 2001; 67 FR 49569, July 31, 2002; 72 FR 17407, Apr. 9, 2007; 75 FR 10683, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012; 81 FR 97036, Dec. 30, 2016]

§ 1313.13 Requirements of import declaration.

(a) Any List I or List II chemical listed in § 1310.02 of this chapter may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United States. Chemical importations into the United States for immediate transfer/transshipment outside the United States must comply with the procedures set forth in § 1313.31 and all other applicable laws.

(b) The DEA Form 486/486A 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 chemical importer; the name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the broker or forwarding agent (if any); and

(2) The name and description of each listed chemical as it appears on the label or container, the name of each chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof; and

(3) The date of release by a customs officer at the port of entry, the foreign port and country of export, and the port of entry; and

(4) 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; and

(5) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the person or persons to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

(c) Any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit, on the import declaration (DEA Form 486A), all information known to the importer on the chain of distribution of the chemical from the manufacturer to the

§ 1313.14

importer. Ephedrine, pseudoephedrine, or phenylpropanolamine include each of the salts, optical isomers, and salts of optical isomers of the chemical.

(d) Import declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

[81 FR 97036, Dec. 30, 2016]

§ 1313.14 Disposition of import declaration.

The importer, or their agent, must submit an official record of the import declaration and/or required data concerning the import transaction to a customs officer at the port of entry in compliance with all import control requirements of agencies with import control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. For List I chemicals, the final destination of the import transaction must only be the registered location of the importer (*i.e.*, drop shipments are prohibited). A regulated person must maintain an official record of the declaration (available from the DEA Diversion Control Division secure network application after the Administration issues a transaction identification number) in accordance with part 1310 of this chapter as the record of the import. Official records of import declarations involving listed chemicals must be retained for two years.

[81 FR 97037, Dec. 30, 2016]

§ 1313.15 Qualification of regular importers.

(a) Each regulated person seeking designation as a “regular importer” shall provide, by certified mail return receipt requested, to the Administration such information as is required under § 1313.08 documenting their status as a regular importer.

(b) Each regulated person making application under paragraph (a) of this section shall be considered a “regular importer” 30 calendar days after receipt of the application by the Administration, as indicated on the return receipt, unless the regulated person is otherwise notified in writing by the Administration.

21 CFR Ch. II (4–1–19 Edition)

(c) The Administrator, may, at any time, disqualify a regulated person's status as a regular importer on the grounds that the chemical being imported may be diverted to the clandestine manufacture of a controlled substance.

(d) Unless the Administration notifies the chemical importer to the contrary, the qualification of a regular importer of any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that importer as a regular importer of all three of these chemicals.

(e) All chemical importers shall be required to file a DEA Form 486 as required by Section 1313.12.

[60 FR 32464, June 22, 1995, as amended at 62 FR 13969, Mar. 24, 1997; 72 FR 17407, Apr. 9, 2007; 81 FR 97037, Dec. 30, 2016]

§ 1313.16 Updated notice for change in circumstances.

(a) In the case of a notice under § 1313.12(a) submitted by a regulated person, if the transferee identified in the notice is not a regular customer, the importer may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under § 1313.12(a) or (d) is submitted to the Administration, if circumstances change and the importer will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15 calendar day period beginning on the date on which the update is filed with the Administration, or, if the import is being made by a regular importer or intended for transfer to a regular customer, three business days. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a

transferee or quantity identified in the original notice under § 1313.12(a) or (d). Amended declarations must be submitted to the Administration through the DEA Diversion Control Division secure network application. The amendment must be signed and dated by the importer. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. Such shipment of listed chemicals may not be imported into the United States until the transaction identification number has been issued.

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the importer involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in § 1313.12(a) or (d) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§ 1313.51 through 1313.57, order the suspension of the transfer of the listed chemical by the importer involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the Administration ordering the suspension before the expiration of the 15-day period with respect to the importation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph (d), disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the importer, the importer may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an importer transfers a listed chemical.

[72 FR 17407, Apr. 9, 2007, as amended at 81 FR 97037, Dec. 30, 2016]

§ 1313.17 Return declaration for imports.

(a) *Return information.* Within 30 calendar days after actual receipt of a listed chemical at the importer's registered location or place of business if not required to be registered, the importer must file a report with the Administration 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 listed chemical was released by a customs officer at the port of entry; the date on which the listed chemical arrived at the importer's registered location or place of business; the actual quantity of the listed chemical released; the actual quantity of the listed chemical that arrived at the importer's location; the date of any subsequent transfer; a description of the subsequent transfer, including the actual quantity transferred, chemical, container, and name of transferees; the actual port of entry; and any other information as the Administration may specify. A single report may include the particulars of both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30 calendar day period, the importer must file supplemental reports not later than 30 calendar days from the date of any further distribution, until the distribution or other disposition of all chemicals imported under the import declaration or any amendment or other update is accounted for. Upon receipt and review, the Administration will assign each completed report a transaction identification number. In determining whether the importer has complied with the requirement to file within 30 calendar days, the report shall be deemed filed on the first date on which a complete report is filed.

§ 1313.21

21 CFR Ch. II (4–1–19 Edition)

(b) If an importation for which a DEA Form 486/486A has been filed fails to take place, the importer must report to the Administration that the importation did not occur through the DEA Diversion Control Division secure network application.

(c) *Denied release at the port of entry.* In the event that a shipment of listed chemicals has been denied release by a customs officer at the port of entry for any reason, the importer who attempted to have the shipment released, within 5 business days of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Diversion Control Division secure network application. This report must include the following information: The quantity of the listed chemical denied release; the date on which release was denied; and the basis for the denied release. Upon the importer's report of a denied release, the DEA will assign the report a transaction identification number and the import declaration will be void and of no effect. No shipment of listed chemicals denied release for any reason will be allowed entry into the United States without a subsequent refiling of an import declaration. Following such refiling the importer may request release of the listed chemicals immediately after receipt of a transaction identification number without regard to the 15 day advance filing requirement in § 1313.12(b).

[81 FR 97037, Dec. 30, 2016]

EXPORTATION OF LISTED CHEMICALS

§ 1313.21 Notification prior to export.

(a) Each regulated person who seeks to export a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter, or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, must notify the Administration of the intended export by filing an export declaration (DEA Form 486) not later than 15 calendar days before the date of release by a customs officer at the port of export. Regulated persons who seek to export a listed chemical below the

threshold quantities identified in § 1310.04(f) are not required to file an export declaration in advance of the export.

(b) A complete and accurate declaration (DEA Form 486) must be filed with the Administration through the DEA Diversion Control Division secure network application not later than 15 calendar days prior to the date of release by a customs officer at the port of export. The declaration must be signed and dated by the exporter and must contain the address from which the listed chemicals will be shipped for exportation. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The 15 calendar days shall begin on the date that the regulated person files a completed declaration without regard to the date that the Administration assigns a transaction identification number. Exporters may not request release of a listed chemical until a transaction identification number has been issued.

(c) The 15 calendar day advance notification requirement for listed chemical exports may be waived, in whole or in part, for:

(1) Any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship, as defined in § 1300.02 of this chapter, with a foreign customer.

(2) A specific listed chemical to a specified country, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For exports meeting the requirements of paragraph (c)(1) of this section, the declaration (DEA Form 486) must be filed with the Administration through the DEA Diversion Control Division secure network application at least three business days before the date of release by a customs officer. The declaration must be signed and dated by the exporter and must contain the address from which the listed chemicals will be shipped for exportation. Upon receipt and review, the Administration will assign a transaction identification number to each completed declaration. The exporter

may only proceed with the export transaction once the transaction identification number has been issued.

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person must submit quarterly reports with the Regulatory Section, Diversion Control Division, Drug Enforcement Administration, not later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Such report shall contain the following information regarding each individual exportation:

- (1) The name of the listed chemical;
 - (2) The quantity and date exported;
 - (3) The name and full business address of the foreign customer;
 - (4) The port of embarkation; and
 - (5) The foreign port of entry.
- (f) The 15 day advance notification requirement set forth in paragraph (a) of this section has been waived for exports of the following listed chemicals to the following countries:

Name of Chemical	Country
[Reserved]	

(g) No person shall export or cause to be exported any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Act or the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

(h) Export declarations shall become void and of no effect 180 calendar days after the date the declaration is deemed filed with the Administration.

[54 FR 31665, Aug. 1, 1989, as amended at 59 FR 51367, Oct. 11, 1994; 60 FR 32464, June 22, 1995; 62 FR 13969, Mar. 24, 1997; 66 FR 46520, Sept. 6, 2001; 67 FR 49569, July 31, 2002; 75 FR 10683, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012; 81 FR 97038, Dec. 30, 2016]

§ 1313.22 Export declaration.

(a) Any List I or List II chemical listed in § 1310.02 of this chapter which meets or exceeds the quantitative threshold criteria established in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) The export declaration (DEA Form 486) must include all 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 chemical exporter; the name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) of the export broker, if any;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The anticipated date of release by a customs officer at the port of export, the port of export, and the foreign port and country of entry; and

(4) 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 chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s); and a copy of the foreign permit, license or registration issued by the competent national authority of the consignee and any intermediate consignees.

(c) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable by the foreign competent national authority may be returned to the U.S. chemical exporter of record. The regulated person must provide notification through

§ 1313.23

the DEA Diversion Control Division secure network application (this does not require a DEA Form 486) outlining the circumstances within a reasonable time following the return. Upon receipt and review, the Administration will assign the completed notice a transaction identification number. The notice will not be deemed filed until the Administration issues a transaction identification number. Listed chemicals so returned may not be reexported until the exporter has filed a new DEA Form 486 and the Administration has issued a new transaction identification number. 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.

[81 FR 97038, Dec. 30, 2016]

§ 1313.23 Disposition of export declaration.

The exporter, or their agent, must submit an official record of the export declaration and/or required data concerning the export transaction to a customs officer at the port of export in compliance with all export control requirements of agencies with export control authorities under the Act or statutory authority other than the Controlled Substances Import and Export Act. An official record of the declaration (available from the DEA Diversion Control Division secure network application after the Administration issues a transaction identification number) must be maintained by the chemical exporter as the official record of the export in accordance with part 1310 of this chapter. Export declarations involving a listed chemical must be retained for two years.

[81 FR 97038, Dec. 30, 2016]

§ 1313.24 Waiver of 15-day advance notice for chemical exporters.

(a) Each regulated person shall provide to the Administration the identity and information listed in the definition of established business relationship in §1300.02 of this chapter for an established business relationship with a foreign customer not later than August 31, 1989.

21 CFR Ch. II (4–1–19 Edition)

(b) Not later than October 31, 1989, each regular customer so identified in notifications made under §1313.24(a) shall be a regular customer for purposes of waiving the 15-day advance notice requirement, unless the regulated person is otherwise notified in writing by the Administration.

(c) Each foreign customer identified on an initial DEA Form 486 submitted after the effective date of the implementation of part 1313 shall, after the expiration of the 15-day period, qualify as a regular customer, unless the Administration otherwise notifies the regulated person in writing.

(d) Unless the Administration notifies the chemical exporter to the contrary, the qualification of a regular customer for any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that customer as a regular customer for all three of these chemicals.

(e) The Administrator may notify any chemical exporter that a regular customer has been disqualified or that a new customer for whom a notification has been submitted is not to be accorded the status of a regular customer. In the event of a disqualification of an established regular customer, the chemical exporter will be notified in writing of the reasons for such action.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 55077, Oct. 24, 1991; 62 FR 13969, Mar. 24, 1997; 75 FR 10684, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.25 Foreign import restrictions.

Any export from the United States in violation of the law of the country to which the chemical is exported is subject to the penalties of Title 21 United States Code 960(d).

§ 1313.26 Updated notice for change in circumstances.

(a) In the case of a notice under §1313.21(a) submitted by a regulated person, if the transferee identified in the notice, *i.e.*, the foreign importer, is not a regular customer, the regulated person may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under § 1313.21(a) is submitted to the Administration, if circumstances change and the exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the exporter must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be). The exporter may not transfer the listed chemical until after the expiration of the 15 calendar day period beginning on the date on which the update is filed with the Administration. Except, if the listed chemical is intended for transfer to a regular customer, the exporter may not transfer the listed chemical until after the expiration of three business days. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section. Amended declarations must be submitted to the Administration through the DEA Diversion Control Division secure network application. The amendment must be signed and dated by the exporter. Upon receipt and review, the Administration will assign each completed amendment a transaction identification number. The amendment will not be deemed filed until the Administration issues a transaction identification number.

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the exporter involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in § 1313.21(a) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§ 1313.51 through 1313.57, order the suspension of the transfer of the listed chemical by

the exporter involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the Administration ordering the suspension before the expiration of the 15-day period with respect to the exportation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph (d), disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the exporter, the exporter may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

[72 FR 17408, Apr. 9, 2007, as amended at 81 FR 97039, Dec. 30, 2016]

§ 1313.27 Return declaration for exports.

(a) *Return information.* Within 30 calendar days after a listed chemical is released by a customs officer at the port of export, the exporter must file a report with the Administration 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 listed chemical left the registered location or place of business; the date on which the listed chemical was released by a customs officer at the port of export; the actual quantity of listed chemical that left the registered location or place of business; the actual quantity of the listed chemical released by a customs officer at the port of export; chemical; container; name of transferees; and any other information as the Administration may specify. Upon receipt and review, the Administration

§ 1313.31

will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number. In determining whether the exporter has complied with the requirement to file within 30 calendar days, the report shall be deemed filed on the first date on which a complete report is filed.

(b) If an exportation for which a DEA Form 486 has been filed fails to take place, the exporter must report to the Administration that the exportation did not occur through the DEA Diversion Control Division secure network application.

(c) *Denied release at the port of export.* In the event that a shipment of listed chemicals has been denied release by a customs officer at the port of export for any reason, the exporter who attempted to have the shipment released must, within 5 business days of the denial, report to the Administration that the shipment was denied release and the reason for denial. Such report must be transmitted to the Administration through the DEA Diversion Control Division secure network application. This report must include the following information: The quantity of the listed chemicals denied release; the date on which release was denied; and the basis for the denied release. Upon the exporter's report of a denied release, DEA will assign the report a transaction identification number and the export declaration will be void and of no effect. No shipment of listed chemicals denied release for any reason will be allowed to be released from the United States without a subsequent refiling of a complete and accurate export declaration. Following such refiling, the exporter may request the release of the listed chemicals immediately after receipt of a transaction identification number without regard to the 15 day advance filing required by § 1313.21(b).

[81 FR 97039, Dec. 30, 2016]

21 CFR Ch. II (4–1–19 Edition)

TRANSSHIPMENTS, IN-TRANSIT SHIPMENTS AND INTERNATIONAL TRANSACTIONS INVOLVING LISTED CHEMICALS

§ 1313.31 Advance notice of importation for transshipment or transfer.

(a) A quantity of a chemical listed in § 1310.02 of this chapter that meets or exceeds the threshold reporting requirements found in § 1310.04(f) of this chapter may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that advance notice is given to the Administration.

(b) Advance notification must be provided to the Regulatory Section, Diversion Control Division, Drug Enforcement Administration, not later than 15 calendar days prior to the proposed date the listed chemical will transship or transfer through the United States. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate notification is required for each shipment of listed chemicals to be transferred or transshipped. The written notification (not a DEA Form 486) must contain the following information:

- (1) The date the notice was executed;
- (2) The complete name and description of the listed chemical as it appears on the label or container.
- (3) The name of the listed chemical as designated by § 1310.02 of this chapter.
- (4) The number of containers and the size or weight of the container for each listed item;
- (5) The net weight of each listed chemical given in kilograms or parts thereof;
- (6) The gross weight of the shipment given in kilograms or parts thereof;
- (7) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) and type of business of the foreign exporter;
- (8) The foreign port and country of export;
- (9) The approximate date of exportation;
- (10) The complete identification of the exporting carrier;

(11) The name, address, business, telephone number, and, where available, the facsimile number of the importer, transferor, or transshipper;

(12) The U.S. port of entry;

(13) The approximate date of entry;

(14) The name/business name, address/business address, and contact information (*e.g.*, telephone number(s), email address(es), etc.) and type of business of the consignee at the foreign port or country of entry;

(15) The shipping route from the U.S. port of export to the foreign port or country of entry at final destination;

(16) The approximate date of receipt by the consignee at the foreign port of entry; and

(17) The signature of the importer, transferor or transshipper, or his agent, accompanied by the agent's title.

(c) Unless notified to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved.

(d) No waiver of the 15-day advance notice will be given for imports of listed chemicals in quantities meeting or exceeding threshold quantities for transshipment or transfer outside the United States.

[54 FR 31665, Aug. 1, 1989, as amended at 67 FR 49569, July 31, 2002; 75 FR 10684, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012; 81 FR 97039, Dec. 30, 2016]

§ 1313.32 Notification of international transactions.

(a) A broker or trader must notify the Administration prior to an international transaction involving a listed chemical which meets or exceeds the threshold quantities identified in § 1310.04(f) of this chapter or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, in which the broker or trader participates. Notification must be made not later than 15 calendar days before the transaction is to take place. In order to facilitate an international transaction involving listed chemicals and implement the purpose of the Act, regulated persons may wish to provide advance notification to the Administration as far in advance of the 15 calendar days as possible.

(b) A completed DEA Form 486 must be submitted to the Administration through the DEA Diversion Control Division secure network application, not later than 15 calendar days prior to the international transaction. The DEA Form 486 must be signed and dated by the broker or trader. Upon receipt and review, the Administration will assign a transaction identification number to each completed notification. A notification is not deemed filed, and therefore is not valid, until the Administration assigns the notification a transaction identification number. An international transaction may not take place until after a transaction identification number has been assigned and the expiration of the 15 calendar day period beginning on the date on which the broker or trader submits a complete notification to the Administration.

(c) No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

(d) After a notice under paragraph (a) of this section is submitted to the Administration, if circumstances change and the broker or trader will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the broker or trader must amend the notice through the DEA Diversion Control Division secure network application to identify the most recent prospective transferee or the most recent quantity or both (as applicable) and may not transfer the listed chemical until after the expiration of the 15 calendar day period beginning on the date on which the update is submitted to the Administration. The preceding sentence applies with respect to changing circumstances regarding a

§ 1313.33

transferee or quantity identified in an amendment to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

[81 FR 97039, Dec. 30, 2016]

§ 1313.33 Contents of an international transaction declaration.

(a) An international transaction involving a chemical listed in § 1310.02 of this chapter which meets the threshold criteria established in § 1310.04 of this chapter may be arranged by a broker or trader if the chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any broker or trader who desires to arrange an international transaction, defined in 21 U.S.C. 802(42), involving a listed chemical which meets the threshold criteria set forth in § 1310.04 of this chapter must notify the Administration through the procedures outlined in § 1313.32(b).

(c) The DEA Form 486 must include:

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

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The anticipated date of release at the foreign port of export, the anticipated foreign port and country of ex-

21 CFR Ch. II (4–1–19 Edition)

port, and the foreign port and country of entry; and

(4) 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 chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

[60 FR 32465, June 22, 1995, as amended at 77 FR 4238, Jan. 27, 2012; 81 FR 97040, Dec. 30, 2016]

§ 1313.34 Disposition of the international transaction declaration.

The broker or trader must retain an official record of the declaration (DEA Form 486) (available from the DEA Diversion Control Division secure network application after the Administration issues a transaction identification number) as the official record of the international transaction. In accordance with part 1310 of this chapter, declarations involving listed chemicals must be retained for two years.

[81 FR 97040, Dec. 30, 2016]

§ 1313.35 Return declaration or amendment to Form 486 for international transactions.

(a) Within 30 calendar days after an international transaction is completed, the broker or trader must file a report with the Administration through the DEA Diversion Control Division secure network application about the particulars of the transaction. This report must include the following information: The date(s) on which the listed chemical was released by the foreign customs officer(s) at the port(s); the actual quantity of listed chemical that left the country of export; the actual quantity of the listed chemical released by a customs officer at the port of entry; chemical; container; name of transferees; and the transaction identification and any other information as the Administration may specify. Upon receipt and review, the Administration will assign a completed report a transaction identification number. The report will not be deemed filed until the Administration has issued a transaction identification number.

(b) If an international transaction for which a DEA Form 486 has been filed

fails to take place, the broker or trader must report to the Administration that the international transaction did not occur utilizing the DEA Diversion Control Division secure network application as soon as the broker or trader becomes aware of the circumstances.

[81 FR 97040, Dec. 30, 2016]

§ 1313.41 Suspension of shipments.

(a) The Administrator may suspend any importation or exportation of a chemical listed in § 1310.02 of this chapter based on evidence that the chemical proposed to be imported or exported may be diverted to the clandestine manufacture of a controlled substance. If the Administrator so suspends, he shall provide written notice of such suspension to the regulated person. Such notice shall contain a statement of the legal and factual basis for the order.

(b) Upon service of the order of suspension, the regulated person to whom the order applies under paragraph (a) of this section must, if he desires a hearing, file a written request for a hearing pursuant to §§ 1313.51–1313.57.

§ 1313.42 Prohibition of shipments from certain foreign sources.

(a) If the Administrator determines that a foreign manufacturer or distributor of ephedrine, pseudoephedrine, or phenylpropanolamine has refused to cooperate with a request by the Administrator for information known to the manufacturer or distributor on the distribution of the chemical, including sales, the Administrator may issue an order prohibiting the importation of the chemical in any case where the manufacturer or distributor is part of the chain of distribution.

(b) Not later than 60 days prior to issuing the order to prohibit importation, the Administrator shall publish in the *FEDERAL REGISTER* a notice of intent to issue the order. During the 60-day period, imports from the foreign manufacturer or distributor may not be restricted under this section.

[75 FR 10172, Mar. 5, 2010]

HEARINGS

§ 1313.51 Hearings generally.

In any case where a regulated person requests a hearing regarding the suspension of a shipment of a listed chemical, the procedures for such hearing shall be governed generally by the procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 6053 of the Chemical Diversion and Trafficking Act (Pub. L. 100–690), by 21 CFR 1313.52–1313.57, and by the procedures for administrative hearings under the Controlled Substances Act set forth in §§ 1316.41–1316.67 of this chapter.

§ 1313.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall cause a hearing to be held for the purpose of receiving factual evidence regarding the issues involved in the suspension of shipments within 45 days of the date of the request, unless the requesting party requests an extension of time.

§ 1313.53 Waiver of modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1313.54 Request for hearing.

(a) Any person entitled to a hearing pursuant to § 1313.52 and desiring a hearing shall, within 30 days after receipt of the notice to suspend the shipment, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) If any person entitled to a hearing or to participate in a hearing pursuant to § 1313.41 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

§ 1313.55

(c) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1313.57.

§ 1313.55 Burden of proof.

At any hearing regarding the suspension of shipments, the Agency shall have the burden of proving that the requirements of this part for such suspension are satisfied.

§ 1313.56 Time and place of hearing.

(a) If any regulated person requests a hearing on the suspension of shipments, a hearing will be scheduled no later than 45 days after the request is made, unless the regulated person requests an extension to this date.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1313.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order regarding the suspension of shipment. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon each party in the hearing.

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

Subpart A—General

Sec.

- 1314.01 Scope.
- 1314.02 Applicability.
- 1314.03 Definitions.
- 1314.05 Requirements regarding packaging of nonliquid forms.
- 1314.10 Effect on state laws.
- 1314.15 Loss reporting.

21 CFR Ch. II (4–1–19 Edition)

Subpart B—Sales by Regulated Sellers

- 1314.20 Restrictions on sales quantity.
- 1314.25 Requirements for retail transactions.
- 1314.30 Recordkeeping for retail transactions.
- 1314.35 Training of sales personnel.
- 1314.40 Self-certification.
- 1314.42 Self-certification fee; time and method of fee payment.
- 1314.45 Privacy protections.
- 1314.50 Employment measures.

Subpart C—Mail-Order Sales

- 1314.100 Sales limits for mail-order sales.
- 1314.101 Training of sales personnel.
- 1314.102 Self-certification.
- 1314.103 Self-certification fee; time and method of fee payment.
- 1314.105 Verification of identity for mail-order sales.
- 1314.110 Reports for mail-order sales.
- 1314.115 Distributions not subject to reporting requirements.

Subpart D—Order To Show Cause

- 1314.150 Order to show cause.
- 1314.155 Suspension pending final order.

AUTHORITY: 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

SOURCE: 71 FR 56024, Sept. 26, 2006, unless otherwise noted.

Subpart A—General

§ 1314.01 Scope.

This part specifies the requirements for retail sales of scheduled listed chemical products to individuals for personal use.

§ 1314.02 Applicability.

(a) This part applies to the following regulated persons who sell scheduled listed chemical products for personal use:

(1) Regulated sellers of scheduled listed chemical products sold at retail for personal use through face-to-face sales at stores or mobile retail vendors.

(2) Regulated persons who engage in a transaction with a non-regulated person and who ship the products to the non-regulated person by the U.S. Postal Service or by private or common carriers.

(b) The requirements in subpart A apply to all regulated persons subject