

Import / Export Declaration for List I and List II Chemicals

SEE REVERSE INSTRUCTIONS FOR PRIVACY ACT

OMB Approval No. 1117-0023

1a. Type of Transaction: IMPORT EXPORT INTERNATIONAL

1b. Type of Submission: ORIGINAL AMENDED WITHDRAWAL

1c. **WARNING!** 15-day advance notice required for initial shipment or for company that has lost regular importer or regular customer status. See 21 C.F.R. Part 1313 for further details.
 I certify I have met the conditions for the waiver of 15-day advance notice requirement.

DEA use only

2a. U.S. IMPORTER/ U.S. EXPORTER / U.S. BROKER
 (Name, address, telephone, and fax no.)

2b. IF IMPORT, LIST FOREIGN CONSIGNOR; IF EXPORT OR INTERNATIONAL TRANSACTION, LIST FOREIGN TRANSFEREE.
 (Name, address, telephone, and fax no.)

DEA Number (for List I only): _____

Purchase/Invoice no. (optional) _____

Foreign permit no. (if applicable) _____

3. Listed Chemicals to be Imported / Exported / Brokered

3a. Name and Description of chemical appearing on label or container. For drug products, show dosage strength and dosage size.	3b. Name of chemicals as designated by Title 21 C.F.R. 1310.02	3c. Number of containers, size, net weight of each chemical (kg)	3d. DATE OF ACTUAL IMPORT/EXPORT AND ACTUAL QUANTITY (To be completed by person named in (1d).)

4a. FOREIGN DOMESTIC

PORT OF EXPORTATION: _____

APPROX. DEPARTURE DATE: _____

4b. FOREIGN DOMESTIC

PORT OF IMPORTATION: _____

APPROX. ARRIVAL DATE: _____

5. MODE OF TRANSPORTATION, NAME OF VESSEL, OR NAME OF CARRIER: _____

SIGNATURE OF AUTHORIZED INDIVIDUAL (Print or Type Name below Signature)

DATE: _____

6. RETURN DECLARATION FOR EXPORTS AND INTERNATIONAL TRANSACTIONS (Name & Quantity of List I and List II Chemicals exported to the Transferee or resulting from International Transaction. MUST be returned within 30 days from actual date of export (3d). If same as 3d, write "same as 3d.")

SIGNATURE:

DATE:

For IMPORTS: List TRANSFEREE(S) UPON INITIAL APPLICATION (Names, address, telephone, and fax no.) Fill in 7 through 9. USE SEPARATE SHEET IF MORE THAN 3 TRANSFEREES.

7a. NAME OF TRANSFEREE OF IMPORT

7b. ADDRESS OF TRANSFEREE OF IMPORT

7c. Name & Quantity of List I and List II chemical to be Imported for this transferee. (Enter names as shown on labels; numbers and sizes of packages; and strength.)

7d. Name & Quantity of List I and List II Chemical Actually Imported and Date Imported for this Transferee

7e. RETURN DECLARATION (Name & Quantity of List I and List II Chemical Distributed to the Transferee. MUST be returned within 30 days of date of actual import (7d) If amount not completely distributed, send a Return Declaration 30 days from the next distribution.). If the whole order was distributed, may say "all import distributed" and the date.

SIGNATURE:

DATE:

8a. NAME OF TRANSFEREE OF IMPORT

8b. ADDRESS OF TRANSFEREE OF IMPORT

8c. Name & Quantity of List I and List II chemical to be Imported for this transferee. (Enter names as shown on labels; numbers and sizes of packages; and strength.)

8d. Name & Quantity of List I and List II Chemical Actually Imported and Date Imported for this Transferee.

8e. RETURN DECLARATION (Name & Quantity of List I and List II Chemical Distributed to the Transferee. MUST be returned within 30 days from actual date of import (8d) If amount not completely distributed, send a Return Declaration 30 days from the next distribution.). If the whole order was distributed, may say "all import distributed" and the date.

SIGNATURE:

DATE:

9a. NAME OF TRANSFEREE OF IMPORT

9b. ADDRESS OF TRANSFEREE OF IMPORT

9c. Name & Quantity of List I and List II chemical to be Imported for this transferee. (Enter names as shown on labels; numbers and sizes of packages; and strength.)

9d. Name & Quantity of List I and List II Chemical Actually Imported and Date Imported for this Transferee.

9e. RETURN DECLARATION (Name & Quantity of List I and List II Chemical Distributed to the Transferee. MUST be returned within 30 days of date of actual import (9d) If amount not completely distributed, send a Return Declaration 30 days from the next distribution.). If the whole order was distributed, may say "all import distributed" and the date.

SIGNATURE:

DATE:

INSTRUCTIONS FOR COMPLETING IMPORT/EXPORT DECLARATION, DEA FORM 486
(Also available on-line at www.deadiversion.usdoj.gov)

This form is to be used in notifying DEA of all imports, exports, and international transactions as required by the Controlled Substances Import and Export Act (21 U.S.C. 971). The following instructions supplement the parts of the DEA Form 486 that are not completely self-explanatory. Detailed requirements are found in Title 21 CFR Parts 1300, 1310 and 1313.

Initial Completion of Form

Fill in 1a – 5, except for 3d. For imports, fill in information for transferees in 7a – 7c, 8a -8c, and 9a - 9c. If the importer is the end user, fill in 7a with “end user”; leave 7b blank; in 7c write “same as 3c”. Sign at the bottom of page 1 and date.

Completing Form Upon Completion of the Transaction

Upon completion of the import, export, or international transaction, fill in 3d, Date of Actual Import/Export and Actual Quantity for the entire transaction. For exporters and international transactions, not later than 30 days after the actual date of export or international transaction, complete 6, sign and date. For importers fill in 7d, 8d, and 9d, Name and Quantity of Chemical Actually Imported and Date for each Transferee, as appropriate. Not later than 30 days after the actual date of import, complete, sign, and date 7e, 8e, 9e, Return Declaration, as appropriate. If the entire quantity of chemicals imported is not distributed within 30 days, not later than 30 days after the next distribution is complete, sign, and date whatever portions of 7e, 8e, or 9e were distributed.

“**List I chemical**” means the following substances: (1) N-acetylanthranilic acid and its salts (2) **Anthranilic acid** and its salts (3) Benzaldehyde (4) Benzyl cyanide (5) Ephedrine and its salts, optical isomers, and salts of optical isomers (6) Ergonovine and its salts (7) Ergotamine and its salts (8) Ethylamine and its salts (9) gamma-Butyrolactone (GBL) (10) Hydriodic acid (11) Hypophosphorous acid and its salts, (12) Isosafrole (13) Methylamine and its salts (14) 3,4-Methylenedioxyphenyl-2-propanone (15) N-Methylephedrine and its salts, optical isomers, and salts of optical isomers (16) N-Methylpseudoephedrine and its salts, optical isomers, and salts of optical isomers (17) Nitroethane (18) Norpseudoephedrine and its salts, optical isomers, and salts of optical isomers (19) Phenylacetic acid and its salts and esters (20) Phenylpropanolamine and its salts, optical isomers, and salts of optical isomers (21) Phosphorus (red) (22) Phosphorus (white or yellow) (23) Piperidine and its salts (24) Piperonal (heliotropine) (25) Propionic anhydride (26) Pseudoephedrine and its salts, optical isomers, and salts of optical isomers (27) Safrole (See 21 CFR Part 1310 for updated list.)

“**List II chemical**” means the following substances: (1) Acetic anhydride (2) Acetone (3) Benzyl chloride (4) Ethyl ether (5) Hydrochloric acid (6) Hydrogen chloride gas (7) Methyl ethyl ketone (2-Butanone) (8) Methyl isobutyl ketone (9) Potassium permanganate (10) Sulfuric acid (11) Toulene (See 21 CFR Part 1310 for updated list.)

“**Transferee**” means a person/entity to whom an importer or exporter transfers (including sales) a listed chemical.

Part 1. The terms “Importer” and “Exporter” include the regulated person who, as the principal party in interest in the import or export transaction, has the power and responsibility for determining and controlling the bringing in or taking out of any chemical listed in 21 CFR 1310.02 that meets or exceeds the threshold quantity found in 21 CFR 1310.04. **If the 15-day advance notification requirement has been waived, the regulated person must check block 1(c).**

The term “Broker” means a legal entity that assists in arranging an international transaction in a listed chemical by (1) negotiating contracts; (2) serving as an agent or intermediary; or (3) fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing. **Waiver of the 15-day advance notification does not apply to international transactions.**

Part 2. The foreign consignor is the supplier of the chemical. The foreign transferee is the foreign person importing the chemical.

Part 3. EXAMPLES

Conversion Factors

	<u>Percent</u>	<u>C.F.</u>		<u>Percent</u>	<u>C.F.</u>
Ephedrine HCl	81.92%	0.8192	Pseudoephedrine HCl	81.92%	0.8192
Ephedrine Sulfate	77.12%	0.7712	Pseudoephedrine Sulfate	77.12%	0.7712
Phenylpropanolamine HCL	80.57%	0.8057			

3a. Name and Description of chemical appearing on label or container. For drug products, show dosage strength and dosage size.	3b. Name of chemicals as designated by Title 21 CFR 1310.02	3c. Number of containers, size, net weight of each chemical (kg)
<p>For Bulk Piperonal</p> <p>For Drug Products (report in base weight)</p> <p>"Brand Name" tablets (ephedrine HCl)</p>	<p>Piperonal</p> <p>Ephedrine</p>	<p>3 X 150 kg drums 450 kg net wt</p> <p>25 mg per tablet 100 tablets per bottle 48 bottles per case 100 cases per pallet 2 pallets = 24 kg 24 kg x 0.8192 = 19.66 kgs</p>

INSTRUCTIONS FOR DISTRIBUTING DEA FORM 486

For **Import Declaration** distribute as follows: Copy 1 must be retained on file by the regulated person as the official record of import. Import declaration forms must be retained for two years. Copy 2 is a DEA copy. This form must be received at P.O. 27284, Washington, D.C. 20038 or sent via electronic facsimile to telephone no. 202-307-4702 at least 15 days prior to importation. Regulated persons who have satisfied the requirements for waiver of the 15-day advance notice described in 21 CFR 1313.15 are required to provide notification on or before the day of importation. Copy 3 is also a DEA copy and must be sent to DEA not later than 30 days after the actual date of importation with the actual date of import, the actual quantity imported, and the Return Declaration filled in, signed, and dated. If the entire import is not distributed, not later than 30 days after the next distribution, complete, sign, and date a supplemental Return Declaration. The importer must file a supplemental Return Declarations not later than 30 days from the date of any further distribution until the disposition of all chemicals imported under the import notification have been distributed. Make a copy and mail or fax to DEA.

For **Export Declaration** distribute as follows: Copy 1 must be retained on file by the regulated person as the official record of export. Export declaration forms must be retained for two years. Copy 2 is a DEA copy. This form must be received at P.O. Box 27284, Washington, D.C. 20038 or via electronic facsimile to telephone no. 202-307-4702 at least 15 days prior to exportation. Regulated persons who have satisfied the requirements for waiver of the 15-day advance notice described in 21 CFR 1313.24 are required to provide notification on or before the day of exportation. Copy 3 is also a DEA copy and must be sent to DEA not later than 30 days after the actual date of exportation with the actual date of export, the actual quantity exported, and the Return Declaration filled in with the name of the foreign importer, signed, and dated. Fax or mail to DEA.

For **International Transaction Declaration** distribute as follows: Copy 1 must be retained on file by the broker or trader as the official record of the international transaction. Declaration forms must be retained for two years. Copy 2 is the DEA copy. Notification must be received at P.O. Box 27284, Washington, D.C. 20038 or via electronic facsimile to telephone no. 202-307-4702 at least 15 days prior to the international transaction. Waiver of the 15-day advance notification does not apply to international transactions. Copy 3 is also a DEA copy and must be sent to DEA 30 days after the actual date of the international transaction with the actual date of international transaction, the actual quantity imported/exported, and the Return Declaration filled in, signed, and dated. Fax or mail to DEA.

Privacy Act Information

Authority: Section 1018 of the Controlled Substances Import and Export Act

Purpose: To obtain information regarding the import/export of certain chemicals to prevent the illicit manufacture of controlled substances.

Routine Uses: The Import/Export Declaration produces information required for law enforcement purposes. Disclosure of information is made to the following categories of users for the purposes stated:

- A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- C. Person registered under the Controlled Substances Act (P.L. 91-513) for the purpose of verifying the registration of customers

Effect: Failure to complete this form will preclude the import/export of the chemicals mentioned.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a current valid OMB control number. Public report burden for this collection of information is estimated to average 12 minutes per response for exports and international transactions, 15 minutes per response for imports, and 5 minutes per response for Return Declarations, including the time for reviewing instructions, searching existing data source, 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 FOI and Records Management Section, Drug Enforcement Administration, Washington, D.C. 20537; and the Office of Management and budget, Paperwork Reduction Project No. 1117-486a, Washington, D.C. 20503.