

Import Declaration for Ephedrine, Pseudoephedrine

and Phenylpropanolamine

SEE REVERSE INSTRUCTIONS FOR PRIVACY ACT

OMB Approval No. 1117-0023

1a. Type of Submission: ORIGINAL AMENDED WITHDRAWAL

DEA use only

1b. 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.

2. NAME OF IMPORTER

3. ADDRESS OF IMPORTER

Purchase/Invoice no. (optional) _____

4. IMPORTER'S TELEPHONE NO.

5. E-MAIL OF IMPORTER

6. DEA REGISTRATION NO.

6. NAME OF FOREIGN EXPORTER

7. ADDRESS OF FOREIGN EXPORTER

8. NAME OF FOREIGN MANUFACTURER

9. ADDRESS OF FOREIGN MANUFACTURER

10. NAME OF FOREIGN DISTRIBUTOR (If applicable)

11. ADDRESS OF FOREIGN DISTRIBUTOR (If applicable)

12. NAME OF FOREIGN DISTRIBUTOR (If applicable)

13. ADDRESS OF FOREIGN DISTRIBUTOR (If applicable)

14. EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE TO BE IMPORTED

14a. Name and Description of chemical appearing on label or container and chemical code from 21 CFR 1310.02

14b. Import Quota

14c. Number of containers, size, net weight (express as base) of each chemical (kg). For drug products, show dosage strength and dosage size

14d. DATE OF ACTUAL TOTAL IMPORT and ACTUAL QUANTITY and NAME OF CHEMICAL (To be completed by importer.)

Quota for current year
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Quota used to date
for current year

Amount of quota left

15a. FOREIGN DOMESTIC PORT OF EXPORTATION:

APPROX. DEPARTURE DATE:

15b. FOREIGN DOMESTIC PORT OF IMPORTATION:

APPROX. ARRIVAL DATE:

16. MODE OF TRANSPORTATION, NAME OF VESSEL, OR NAME OF CARRIER:

17. **RETURN DECLARATION FOR IMPORTER WHO IS END USER.** MUST be returned within 30 days from actual date of import (14d). See instructions.

SIGNATURE:

DATE:

18a. NAME OF TRANSFEREE OF IMPORT	18b. ADDRESS OF TRANSFEREE OF IMPORT
18c. Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine to be Imported for this Transferee. <i>(Enter names as shown on labels; numbers and sizes of packages; and strength.)</i>	18d. Name & Quantity of Listed Chemical <u>Actually Imported and Date Imported for this Transferee</u>

18e. **RETURN DECLARATION** (Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine Distributed to the Transferee. MUST be returned within 30 days from actual date of import (14d) 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:

19a. NAME OF TRANSFEREE OF IMPORT	19b. ADDRESS OF TRANSFEREE OF IMPORT
19c. Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine to be Imported for this Transferee. <i>(Enter names as shown on labels; numbers and sizes of packages; and strength.)</i>	19d. Name & Quantity of Listed Chemical <u>Actually Imported and Date Imported for this Transferee</u>

19e. **RETURN DECLARATION** (Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine Distributed to the Transferee. MUST be returned within 30 days from actual date of import (14d) 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:

20a. NAME OF TRANSFEREE OF IMPORT	20b. ADDRESS OF TRANSFEREE OF IMPORT
20c. Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine to be Imported for this Transferee. <i>(Enter names as shown on labels; numbers and sizes of packages; and strength.)</i>	20d. Name & Quantity of Listed Chemical <u>Actually Imported and Date Imported for this Transferee</u>

20e. **RETURN DECLARATION** (Name & Quantity of Ephedrine, Pseudoephedrine, and Phenylpropanolamine Distributed to the Transferee. MUST be returned within 30 days from actual date of import (14d) 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:

SIGNATURE OF IMPORTER (Print or Type Name below Signature)	DATE:
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**INFORMATION AND INSTRUCTIONS FOR DEA-486a
(IMPORT DECLARATION FOR EPHEDRINE, PSEUDOEPHEDRINE
AND PHENYLPROPANOLAMINE)**

This form is to be used to import the Listed Chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, and as a Return Declaration for these imports distributed no later than 30 days after importation, as required by the Combat Methamphetamine Epidemic Act of 2006 (PL 109-177).

The following instructions are to help you fill out the Import Declaration. Detailed requirements are found in Title 21 C.F.R. Parts 1310 (chemical codes) and 1313.

Foreign manufacturer means the manufacturer in a country outside the U.S. of ephedrine, pseudoephedrine, phenylpropanolamine, or schedule listed chemical products to be imported.

Foreign distributor means a distributor in a country outside the U.S. who has obtained the ephedrine, pseudoephedrine, or phenylpropanolamine from the foreign manufacturer or another foreign distributor and supplies the importer.

Scheduled listed chemical product – means a product that (i) contains ephedrine, pseudoephedrine, or phenylpropanolamine (including each of the salts, optical isomers, and salts of optical isomer); and (ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Transferee means a person to whom an importer or exporter transfers (including sales) a listed chemical or a schedule listed chemical product.

1. This form must be completed in triplicate. Copy 1 must be retained on file by the importer of the official record of import. Import declarations forms must be retained for two years.
2. Copy 2 is a DEA copy. This form must be received at P.O. 27284, Washington, D.C. 20038 or 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 C.F.R. 1313.15 are required to provide notification on or before the day of importation. See instruction #9 for Copy 3.
3. In 14b, the quota allowed for the current year, the quota used to date, and the quota left must be filled in.
4. For 14a and 14c, identification of drugs to be imported and list I chemical content should be entered on the form in the following manner for the whole importation:

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			

14c Name and Description of Chemicals Appearing on Label of Container and Chemical Code	14e. Number of Containers, Size, and Net Weight of Each Chemical (expressed as base) (KG). For Drug Products, Show Dosage Strength and Dosage Size.
For Bulk Pseudoephedrine HCl CSA - 8112	3 X 150 kg drum 450 kg net wt. 450 x 0.8192 = 368.64 kg
For scheduled listed chemical products "Brand name" tablets (Ephedrine HCl) CSA - 8113	25 mg per tablet 100 tablets per bottle 48 bottles per case 100 cases per pallet 2 pallets = 24 kgs 24 kg x 0.8192 = 19.66 kgs

5. In block 14d, the actual quantity and date of the import received for the entire importation must be listed on copies 2 and 3.
6. Block 17 is a Return Declaration for an importer who will use the chemicals imported. In the box write, "All the import in 14(d) has been distributed." Sign and date.
7. In blocks 18(c), 19(c), and 20(c), for each Transferee, the name of the chemical(s) shown on labels; number and sizes of packages; strength and chemical code for the ephedrine, pseudoephedrine, and phenylpropanolamine to be imported must be filled in.
8. In 18(d), 19(d), and 20(d), for each Transferee, the name of the chemical(s) shown on labels, number and size of packages; and strength of the chemical(s) actually imported and the date imported must be filled in.
9. Copy 3 is a DEA copy and must be mailed or faxed to DEA within 30 days after the date of importation with the actual date of import, the actual quantity imported, and the Return Declaration filled in, signed, and dated. If all the initial import is not distributed, 30 days after the next distribution, complete, sign, and date a supplemental Return Declaration. The importer must file supplemental Return Declarations no 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.

Privacy Act Information

Authority: Section 1002 of the Controlled Substances Import and Export Act

Purpose: Control importation of ephedrine, pseudoephedrine, phenylpropanolamine, and scheduled listed chemical products into the United States.

Routine Uses: The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are 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 for import return declaration and 24 minutes for import, 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. 1117-0023, Washington, D.C.