INFORMATION AND INSTRUCTIONS FOR DEA FORM-486A

(IMPORT DECLARATION FOR EPHEDRINE, PSEUDOEPHEDRINE AND PHENYLPROPANOLAMINE)

The DEA Form-486A is to be used to (1) notify the Drug Enforcement Administration (DEA) of all imports of Ephedrine, Pseudoephedrine, Phenylpropanolamine, and scheduled listed chemical products into the United States and (2) as a Return Declaration for the actual date and quantity imported and distributed to Transferees of these imports no later than 30 days after importation, as required by the Controlled Substances Import and Export Act (21 U.S.C. 971).

The following instructions supplement the parts of the Import Declaration that are not self explanatory. Detailed requirements are found in Title 21 C.F.R. Parts 1300, 1310 (chemical codes) and 1313.

1. The DEA Form-486A must be completed in triplicate and utilized as follows:

   (a) Copy 1 is the importer's copy and must be retained on file by the importer for two (2) years as the official record of import.

   (b) Copy 2 is a DEA (Initial Submission) copy, it must be completed and signed (see instruction # 13). It must also be received at DEA at least fifteen (15) days prior to importation. It can be mailed to Drug Enforcement Administration, 8701 Morrissette Drive, Attn: Import/Export Unit (ODGI), Springfield, VA 22152 or transmitted by facsimile to (202) 307-4702. After the DEA has entered the data from this copy into its database the DEA will provide the importer with the DEA TRANSACTION ID NUMBER. This number must be recorded on Page 1 and 2 for any amendments to the transaction submitted by the importer.

   (c) Copy 3 is a DEA (Return Declaration) copy and must be mailed or faxed to DEA <u>within 30 days after the date of importation</u>. The importer must record the DEA TRANSACTION ID NUMBER on Page 1 and 2 of this copy prior to its submission to the DEA. See instructions # 8, #10, and # 12 for additional requirements of this copy.

2. Blocks 1 through 3b are self explanatory.

3. In block 4a, fill in the name of the foreign manufacturer. A foreign manufacturer means the company outside of the United States that manufactured the Ephedrine, Pseudoephedrine, Phenylpropanolamine, or scheduled listed chemical products that are to be imported. This block is required to be filled in.

4. In block 5a, fill in the name of the foreign distributor. A foreign distributor means the company outside of the United States that has obtained the Ephedrine, Pseudoephedrine, Phenylpropanolamine, or scheduled listed chemical products, from the foreign manufacturer who supplied the exporter. This block should be blank if the foreign manufacturer supplied the exporter.

5. In block 6a, fill in the name and description of the chemical to be imported. See Figure 1 for examples of the bulk and scheduled listed chemical product. A 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.

6. In block 6b, fill in the quota allowed for the current year (enter the current year within the brackets), the quota used to date, and the amount of quota remaining for the current year.

7. In block 6c, fill in the number of containers, size, and net weight in kilograms for each chemical to be importer (use the Conversion Factors listed below to express as base). For drug products, show the number of dosage units. See Figure 1 for examples of the bulk and scheduled listed chemical product.

Conversion Factors	Percent	C.F.
Ephedrine HCl	81.92%	0.8192
Ephedrine Sulfate	77.12%	0.7712
Pseudoephedrine HCl	81.92%	0.8192
Pseudoephedrine Sulfate	77.12%	0.7712
Phenylpropanolamine HCL	80.57%	0.8057

Figure 1

6a Name and Description of chemical appearing on label or container and chemical code from 21 CFR 1310.02	6b.	6c. Number of containers, size, net weight (express as base) in kilograms for each chemical listed. For drug products, show number of dosage units.	6d.
For Bulk: Pseudoephedrine HCl Drug Code – 8112 **For a Scheduled Listed Chemical Product:** "Brand name" tablets (Ephedrine HCL) Drug Code – 8113		3 X 150 kg drum = 450 kg net wt. 450 x 0.8192 = 368.64 kg 25 mg/ tablet X 100 tablets/bottle X 48 bottles/case X 100 cases/pallet X 2 pallets = 24 kgs 24 kgs x 0.8192 = 19.66 kgs	

8. Block 6d is to be completed only after the importation has occurred. Fill in the actual date and actual net weight (express as base) of the import received for the entire importation. Sign and date in block 9 to confirm the actual date and net weight in block 6d. Blocks 6d and 9 must be completed on Copy 3 only.

9. Blocks 7a through 8 are self explanatory.

10. Block 9 must be signed to confirm the actual date and net weight in block 6d (see instruction # 7).

11. For an initial submission, blocks 10a through 10e must be completed by the importer with the applicable information for the first Transferee. **Transferee** means the person to whom an importer transfers (including sales) a listed chemical or a scheduled listed chemical product. If there is a second Transferee blocks 11a through 11e must be completed by the importer. If there is a third Transferee blocks 12a to12e must be completed by the importer. If there are more than three (3) Transferees the importer must complete another Page 2 of the DEA Form-486A and submit it with Page 1 and Page 2.

12. Blocks 10f through 10g of Copy 3 must be completed by the importer after the chemical has been distributed to the first Transferee. The same applies to blocks 11f through 11g of Copy 3 if there was a second Transferee and blocks 12f through 12g of Copy 3 if there was a third Transferee. If all the initial import is not distributed within 30 days of the actual import date entered in block 6d by the importer, the importer must file supplemental Return Declarations to DEA 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. Copy 3 can be mailed or facsimiled to DEA or you may create a PDF of Copy 3 and e-mail it to chemical.imex@usdoj.gov.

13. Block 13 must be completed and signed for the initial submission.

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 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 24 minutes, 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.