

**INSTRUCTIONS FOR COMPLETING THE DEA FORM 488:  
Application for Import Quota for Ephedrine, Pseudoephedrine, and  
Phenylpropanolamine**

The DEA-488 must be filed on or before April 1 of the year preceding the calendar year for which the import quota is being applied. Regulations governing quotas are included in Title 21, Code of Federal Regulations, Part 1315. Copies of these regulations may be ordered from: The Government Printing Office, Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Submit the completed form to:

Drug Enforcement Administration  
Office of Diversion Control (ODE)  
8701 Morrisette Drive  
Springfield, VA 22152

The following instructions are for those items which are not completely self-explanatory:

**Item 11.** Under the “current year” heading, write the year in which the application is being submitted, and write the 1<sup>st</sup> and 2<sup>nd</sup> preceding year to the “current year” under the corresponding headings. Under the “quota requested” heading write the year for which the quota is being requested, the year entered in item 4.

**Item 12(I).** For each of the corresponding years enter the known or estimated inventory in grams of anhydrous acid, base, or alkaloid as of December 31 of that year. The inventory should be separated into the following subcategories: bulk material, in-process material, and contained in finished dosage forms.

**Item 12(II).** Worksheet A should **only** be completed for domestic sales and/or utilization for the year for which the import quota is being requested. For the domestic and export disposition (sales)/utilization, subcategories (a) and (b), respectively, the information should be entered for the 1<sup>st</sup> and 2<sup>nd</sup> preceding years, current year and year quota requested categories.

**Item 13.** Enter any new substances, controlled substances or List I chemicals, which would be manufactured from the List I chemical for which the quota application is being submitted. Also include the yield of the reaction or synthesis of the new substance.

**Item 14.** List each dosage form in which the requested List I chemical will be manufactured, packaged, or labeled. Include the strengths of the manufactured dosage forms. Enter the amount of the List I chemical used or estimated to be used for the manufacture of each dosage form for each year. Provide the authority by which you may legally market the product under the Federal, Food, Drug & Cosmetic Act.

### **Privacy Act Information**

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

**Purpose:** Control importation of ephedrine, pseudoephedrine, phenylpropanolamine, into the United States.

**Routine Uses:** The Import/Export Declaration produces information required for law enforcement 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. Persons 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 reporting burden for this collection of information is estimated to average 1 hour, including the time for reviewing instructions, searching existing data sources, 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. 1117-0047, Washington, D.C.