

APPLICATION FOR REGISTRATION
Under Controlled Substances Act of 1970

UNITED STATES
DEPARTMENT OF JUSTICE
Drug Enforcement
Administration

INSTRUCTIONS FOR COMPLETING FORM DEA-225

This form is for new applicants only and not for renewal of registration.
This application is for a one year registration period. See form for fee amount.

ADDRESS BLOCK - Information must be TYPED or PRINTED in the blocks provided. The manner in which information is placed on the application is the way your Certificate of Registration will read. Please use the street address of proposed business. **WHEN USING A P.O. BOX YOU MUST ALSO PROVIDE A STREET ADDRESS.**

Taxpayer Identifying Number - The Debt Collection Improvement Act of 1996 (PL 104-134) requires that you furnish your Federal Taxpayer Identifying Number to DEA. This number is required for debt collection procedures should your fee become uncollectable.

Item 1 - **BUSINESS ACTIVITY** - Indicate only one.

Manufacturer / Importer: Registration as a Manufacturer or Importer conveys distribution privileges only for those substance(s) manufactured or imported.

Researchers: Applicants desiring to conduct research with Schedule I substances must submit an original and three (3) copies of a Research Protocol with this application. In the case of a clinical investigation, the applicant must submit an original and three (3) copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) to the FDA and an original and three (3) copies of a certificate of Application for an IND attached to this application. Applicants desiring to conduct research in all schedules must maintain two (2) separate DEA registration numbers: one number to include all Schedule I substances and the second number for all Schedule II through V substances. Dog Handlers can be registered for all Schedules on a single application. See reverse of this page for outline of Research Protocol.

Item 2 - **DRUG SCHEDULES** - Indicate schedule(s) of controlled substance(s) pertaining to your business activity and those that you intend to handle. See drug code sheet for schedules and numbers.

Item 3 - **ORDER FORM BOOKS** - Indicate only if you intend to purchase or transfer Schedule I and II substances. Order form books will be issued to you upon issuance of your DEA registration number.

Item 4 - **OTHER REGISTRATION NUMBERS** - Indicate any other current DEA Registration Numbers for the address shown on this application.

Item 5 - **MANUFACTURERS SCHEDULES AND CATEGORIES** - Indicate schedule(s) of controlled substance(s) you intend to handle. See drug code sheet. Manufacturers must also circle the drug codes listed in Item 8 for which they Bulk Manufacture in Schedule I and II.

Item 6 - **STATE LICENSURE** - Federal Registration by DEA is based upon the applicant being in compliance with applicable state and local laws. Applicants should contact the local state licensing authority prior to completing this application. If your state requires a separate controlled substance license, provide the number. If you have applied for state license and it has not been issued, indicate "Pending". If state licensing authority is not required, indicate "NA". All applicants must answer all parts of item 6. If any are answered "YES", except 6(a), include a statement using the space provided in item 7 of the application.

Item 7 - **EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 6(b), (c), (d), or (e).**

Item 8 - **DRUG CODE NUMBERS** - Codes must coincide with schedules requested for your specific business activity. Researchers requesting Schedule II are only required to report drug codes for Schedule II substances which they manufacture or import as a coincident activity of their registration, or do research with Diprenorphine, Etorphine HCL, or Carfentanil. Read requirements for listing drug codes on the application. See drug code sheet for schedules and numbers.

Item 9 - **PAYMENT METHOD** - Indicate desired method of payment. Make check or money order payable to Drug Enforcement Administration. Checks or money orders drawn on foreign banks will not be accepted. If a credit card is used, provide the number, type of card (VISA or MasterCard), signature, and expiration date. **Application fees are not refundable.**

Item 10 - **FEE EXEMPTION** - Exemption from payment of application fee is limited to federal, state, or local government operated analytical labs or researchers. The address on the application must be that of the affiliated federal, state, or local government; the signature and title of a supervisor (**other than applicant**) must appear on the application.

Item 11 - **APPLICANT SIGNATURE** - Must be completed with an original signature in ink.

NOTE: Once your DEA registration is issued, a renewal application is automatically mailed to you 45 days prior to your expiration date. Any change of address must be reported to the DEA. Renewal applications are **not** forwarded.

Use attached Return Envelope for mailing application and remittance.

Title 21, United States Code, Section 827(g) requires all registrants to report any changes of professional or business address to the DEA. Notification of address changes must be made in writing to the DEA office which has jurisdiction for your registered location. See reverse side of drug code sheet for a list of DEA offices and addresses.

WARNING: Section 843(a)(4)(A) of Title 21, United States Code, states that any person who knowingly or intentionally furnishes false or fraudulent information in this application is subject to imprisonment for not more than four years, a fine of not more than \$30,000.00, or both.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, 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 Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0012, Washington, D.C. 20503.

▼ PRINT YOUR NUMBERS AND LETTERS AS INDICATED BELOW ▼

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 0 1 2 3 4 5 6 7 8 9

Manufacturers Definitions

- A. **Bulk Synthesizer - Extractor:** The term bulk manufacture means the production, preparation, propagation, compounding or processing of a drug or other substances, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by combination of extraction and chemical synthesis, when the final product is to be used for further manufacture (into dosage forms) or a substance to be used for industrial purposes or for repackaging into non-dosage form units for patient or other uses.
- B. **Dosage Form Manufacture:** Means the production, preparation, compounding or processing of a bulk substance into a form which is to be used without additional production, preparation, compounding or processing by an ultimate user; except that such term does not include packaging, repackaging, labeling, or relabeling of a drug or other substance, in conformity with applicable state or local law, by a practitioner as an incident to his administration or dispensing of a drug or substance in the course of his professional practice.
- C. **Repackager-Relabeler:** Means the packaging or repackaging of a drug or other substance or the labeling or relabeling of its container; except that such term does not include the packaging, repackaging, labeling, or relabeling of a drug or other substance, in conformity with applicable state or local law, by a practitioner as an incident to his administration or dispensing of a drug or substance in the course of his professional practice.
- D. **Non-Human Consumption:** Means the production, preparation, propagation, compounding or processing of a drug or other substance whether directly or indirectly or by extraction of substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, where the final product is not to be used for prevention, treatment or mitigation of diseases, but it is to be used for scientific investigation, laboratory analysis, or other non-patient usage.
 - 1. **Industrial Manufacture:** Means the use of controlled substances in the manufacture of non-drug, non-controlled finished product.
 - 2. The tagging of a drug or other substance with radioactive material.
- E. **Disposers:** Means a manufacturer who receives controlled substances for the sole purpose of processing such substances to render them unusable.

Refer to Section 1301.18 of Code of Federal Regulations for an outline of protocols.

- 1. **Investigators:** The protocol must reflect the name, address, institutional affiliation (if appropriate) and qualifications, to include both a curriculum vitae and bibliography, of each investigator in the research project.
- 2. **Purpose:** The protocol must contain a brief description of the purpose of the project.
- 3. **Substances:** The protocol must reflect the name and amount of each Schedule I substance to be utilized in the project.
- 4. **Project:** The protocol must contain a description of the research project, to include the location at which the research will be conducted, the duration of the project, and how the controlled substances will be used.
- 5. **Live Subjects:** If live research subjects will be used, the protocol must reflect the number and species of research subjects, the dosage of controlled substances to be administered, and the route and method of administration to be used.
- 6. **Security:** The protocol must contain a description of the security measures to be applied, including where and how the controlled substances will be stored, and who will have access to them.
- 7. **Records:** The protocol must contain a description of the proposed recordkeeping system documenting receipt and disposition of the controlled substances and the name of who will maintain the records.

Note:

Items # 2, 3, 4, 6, and 7 are for dog handlers. Dog handlers can be registered for all Schedules on a single application.
Items # 1-7 is for Schedule I Researchers only.

