DEA Form 225 - New Application for Registration

INSTRUCTIONS

This form is for new applicants. Any person who does not currently possess a DEA registration to conduct business with controlled substances in the following categories may access the application form. The categories of applicant who can apply using this form are manufacturers, distributors, researchers, canine handlers, analytical laboratories, importers, and exporters.

Complete DEA Form 225 Online (If possible, you are encouraged to use the online forms system to apply for your registration.)

Note: **Researchers with Schedule I drugs only** must submit DEA 225 PDF application and the protocol found in **21 CFR 1301.18**. You cannot apply online for your initial application.

Download DEA Form 225 (PDF) to apply via U.S. Postal Service.

Before you enter the form, you may wish to print the instruction pages (recommended) which will assist in completing the form. After completing the form, print, sign and mail to DEA.

INSTRUCTIONS

SECTION 1. APPLICANT IDENTIFICATION

Information must be typed or printed in the blocks provided to help reduce data entry errors. A physical address is required in address line 1; a post office box or continuation of address may be entered in address line 2. Fee exempt applicant must list the address of the fee exempt institution. Applicant must enter a valid social security number (SSN), or a tax identification number (TIN) if applying as a business entity.

Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.

SECTION 2. BUSINESS ACTIVITY

Indicate only one. Each type of business activity requires a separate application. You are required to register as a "manufacturer" if you manufacture a controlled substance or list 1 chemical and then distribute it.

SECTION 3A. SCHEDULES

Applicant should check all schedules to be handled. However, applicant must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule 1 and 2 controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration.

3B. MANUFACTURER ONLY

Mark the chemical/controlled substance schedule(s) handled in each manufacturing stage listed.

3C. SCHEDULE CODES

Report all chemical/drug codes as required for your business activity. Controlled substances manufacturers and importers must obtain a separate chemical registration if they handle chemicals other than an FDA-approved drug product containing 1225, 8112, or 8113.

SECTION 4. STATE LICENSE(S)

Federal registration by DEA is based upon the applicant's compliance with applicable state and local laws. Applicant should contact the local state licensing authority prior to completing this application. If your state requires a license, provide that number on this application.

SECTION 5. LIABILITY

Applicant must answer all four questions for the application to be accepted for processing. If you answer "Yes" to a question, provide an explanation in the space provided. If you answer "Yes" to several questions, then you must provide a separate explanation describing the date, location, nature, and result of each incident. If additional space is required, you may attach a separate page.

SECTION 6. EXEMPTION

Exemption from payment of application fee is limited to federal, state or local government official or institution. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. The address of the fee exempt institution must appear in Section 1.

SECTION 7. METHOD OF PAYMENT

Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. **FEES ARE NON-REFUNDABLE.**

SECTION 8. APPLICANT'S SIGNATURE

Applicant **MUST** sign in this section or application will be returned. Card holder signature in section 7 does not fulfill this requirement.

ATTACHMENTS:

Researcher or canine handler must attach 3 copies of protocol, including curriculum vitae, to conduct research with schedule 1 controlled substances. For clinical investigations, researcher must first submit to FDA a "Notice of Claimed Investigational Exemption for New Drug (IND)". See DEA web site or CFR 1301.18 for details.

- Name, address, DEA registration number (if any)
- Institutional or company affiliation
- Qualifications, including curriculum vitae (**CV)** with a list of publications

Research Project:

- Title of project
- Statement of the purpose
- Name of controlled substances (CS) involved, amount (**with justification**) of each needed and **source**.
- Research protocol (**detailed description of procedures**), including number and species of research subjects, dosage to be administered, route and method of administration, and **duration of project**.
- Location where research will be conducted.
- **Statement of security provisions** for storing and dispensing the CS(s) in order to prevent diversion.
- If investigator plans to manufacture or import the CS(s), statement of quantity to be manufactured or imported and sources of chemicals to be used or substance to be imported.

Authority (if applicable):

- Institutional approval
- Approval of a Human Research Committee for human studies.
- Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number).
- Indication of an approved funded grant (number), if any.

The applicant should mail the items to this address:

U.S. Department of Justice
Drug Enforcement Administration
Attn: Registration Section DRR
P.O. Box 2639
Springfield, VA 22152-2639

See **Title 21 Code of Federal Regulation Section 1301.18** for additional Instructions

DIVERSION FIELD OFFICE CONTACT INFORMATION

For Routine Registration assistance about new applications, renewal applications, order forms, or changes to an application or DEA registration: contact a Registration Program Specialist during normal business hours.

Location	Registration Assistance
PORTLAND DISTRICT OFFICE 100 SW MAIN STREET SUITE 500 PORTLAND, OR 97204	Phone 1: (888) 219 4261 Fax 1: (503) 721 6602

NOTICE TO REGISTRANTS MAKING PAYMENT BY CHECK

Authorization to Convert Your Check:

If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

I*nsufficient Funds*:

The electronic funds transfer from your account will usually occur within 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two more times.

Transaction Information:

The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions". You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights:

You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

ADDITIONAL INFORMATION

No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is 1117-0012. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.

The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.

PRIVACY ACT NOTICE: Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are

§§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and person registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

SCHEDULE AND DRUG CODES

Listed below are examples of schedules 1-5 and List 1 codes. Check all drug and chemical codes you handle as required.

If you bulk manufacture a substance, check the bulk column after the applicable drug code.

For more information, see our website at ***www.deadiversion.usdoj.gov***, 21 CFR 1308, or call 1-800-882-9539.

Canine Handler	must mark schedule 1
Exporter	must mark all schedule 1-5
Importer	must mark all schedule 1-5 & List 1 codes
Manufacturer	must mark all schedule 1, 2 & List 1 codes
Distributor	must mark all schedule 1, drug code 2012
Reverse Distributor	must mark all schedule 1, drug code 2012
Researcher w/Sched 1	must mark schedule 1
Researcher w/Sched 2-5	must mark schedule 2 to be manufactured or imported as part of research

	SCHEDULE 1 NARCOTIC & NON-NARCOTIC	**CODE**	**BULK?**
	3,4-Methylenedioxyamphetamine (MDA)	7400	
	3,4-Methylenedioxymethamphetamine (MDMA)	7405	
	4-Methyl - 2,5 - Dimethoxyamphetamine (DOM, STP)	7395	
	4-Methylaminorex (cis isomer) (U4Euh, McN-422)	1590	
	Alphacetylmethadol (except LAAM)	9603	
	Bufotenine (Mappine)	7433	
	Marihuana	7360	
	Diethyltryptamine (DET) (	7434	
	Difenoxin 1MG/25UG AtSO4 /DU (Motofen)	9167	
	Dimethyltryptamine (DMT)	7435	
	Etorphine (except HCL)	9056	
	Gamma Hydroxybutyric Acid (GHB)	2010	
	Heroin (Diamorphine)	9200	
	Ibogaine	7260	
	Lysergic acid diethylamide (LSD)	7315	
	Mescaline	7381	
	Marihuana	7360	
	Methaqualone (Quaalude)	2565	
	Normorphine	9313	
	Peyote	7415	
	Psilocybin	7437	
	Tetrahydrocannabinols (THC)	7370	
SCHEDULE 2 NARCOTIC & NON-NARCOTIC		**CODE**	**BULK?**

	Amobarbital (Amytal, Tuinal)	2125	
	Amphetamine (Dexedrine, Adderall)	1100	
	Cocaine (Methyl benzoylecgonine)	9041	
	Codeine (Morphine methyl ester)	9050	
	Dextropropoxyphene (bulk)	9273	
	Diphenoxylate	9170	
	Fentanyl (Duragesic)	9801	
	Hydrocodone (Dihydrocodeinone)	9193	
	Hydromorphone (Diaudid)	9150	
	Levo-Alphacetylmethadol (LAAM)	9648	
	Levorphanol (Levo-Dromoran)	9220	
	Meperidine (Demerol, Mepergan)	9230	
	Methadone (Dolophine, Methadose)	9250	
	Methamphetamine (Desoxyn)	1105	
	Methylphenidate (Concerta, Ritalin)	1724	
	Morphine (MS Contin, Roxanol)	9300	
	Opium, powdered	9639	
	Oxycodone (Oxycontin, Percocet)	9143	
	Oxymorphone (Numorphan)	9652	
	Pentobarbital (bulk) (Nembutal)	2270	
	Phencyclidine (PCP)	7471	
	Secobarbital (Seconal, Tuinal)	2315	
SCHEDULE 3 NARCOTIC & NON-NARCOTIC		**CODE**	**BULK?**
	Anabolic Steroids	4000	
	Barbituric acid derivative	2100	
	Benzphetamine (Didrex, Inapetyl)	1228	
	Buprenorphine (Buprenex, Temgesic)	9064	
	Butabarbital	2100	
	Butalbital	2100	
	Codeine combo product (Empirin)	9804	
	Dihydrocodeine combo product (Compal)	9807	
	Dronabinol in sesame oil soft cap (Marinol)	7369	
	Gamma-Hydroxybutyric Acid preparations (Zyrem)	2012	
	Hydrocodone combo products (Lorcet, Vicodin)	9806	
	Ketamine (Ketaset, Ketalar)	7285	
	Morphine combo product	9810	
	Nalorphine (Nalline)	9400	
	Opium combo product (Paregoric)	9809	
	Pentobarbital suppository dosage (FP3)	2270	
	Phendimetrazine (Plegine, Bontril)	1615	
	Thiopental	2100	
SCHEDULE 4 NARCOTIC & NON-NARCOTIC		**CODE**	**BULK?**
	Alprazolam (Xanax	2882	
	Barbital (Veronal, Plexonal)	2145	
	Chloral Hydrate (Noctec)	2465	
	Chlordiazepoxide (Librium)	2744	
	Clonazepam (Klonopin)	2737	
	Clorazepate (Tranxene)	2768	

	Diazepam (Valium)	2765	
	Flurazepam (Dalmane)	2767	
	Lorazepam (Ativan)	2885	
	Meprobamate (Milltown, Equanil)	2820	
	Midazolam (Versed)	2884	
	Oxazepam (Serax, Serenid-D)	2835	
	Phenobarbital (Fastin, Zantryl)	2285	
	Phentermine	1640	
	Temazepam (Restoril)	2925	
	Zolpidem (Ambien, Stilnox)	2783	
SCHEDULE 5 NARCOTIC & NON-NARCOTIC		**CODE**	**BULK?**
	Codeine preparations (Robitussin A-C, Pediacof)	9050	
	Pyrovalerone (Centroton, Thymergix)	1485	
LIST 1 REGULATED CHEMICALS ** ** ONLY manufacturers & importers may select List 1		**CODE**	**BULK?**
	Ephedrine	8113	
	Phenylpropanolamine	1225	
	Pseudoephedrine	8112	

WRITE IN ADDITIONAL CODES

You may write in additional drug codes in this section. Attach a separate sheet if needed.

CONTACT INFORMATION

INTERNET: www.deadiversion.usdoj.gov

TELEPHONE: HQ Call Center (800) 882-9539

WRITTEN INQUIRIES: DEA, Attn: Registration Section/DRR, P.O. Box 2639, Springfield, VA 22152-2639.

All offices are listed on web site (800, 877, and 888 are toll-free)

REGISTRATION

§1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:

(i) Name, address, and DEA registration number; if any.

(ii) Institutional affiliation.

(iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled substances or substances involved and the amount of each needed.

(iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(v) Location where the research will be conducted.

(vi) Statement of the security provisions for storing the controlled substances (in accordance with **Sec. 1301.75**) and for dispensing the controlled substances in order to prevent diversion.

> **SECURITY REQUIREMENTS**
>
> **§1301.75 Physical security controls for practitioners.**
>
> (a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
>
> (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
>
> (c) Sealed mail-back packages and inner liners collected in accordance with **part 1317** of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by **§1317.80**(d).
>
> (d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
>
> (e) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

(vii) If the investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

(3) Authority:

(i) Institutional approval.

(ii) Approval of a Human Research Committee for human studies.

(iii) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(iv) Indication of an approved funded grant (number), if any.

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as proscribed in paragraph (a)(2)(vi) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and Sec. 130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on _____ (Date), pursuant to 21 U.S.C. 355(i) and 21 CFR 130.3, I, _____ (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:

_____
(Name of Investigational Drug).

_____
(Date)

_____
(Signature of Applicant).

(c)In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, by registered mail, return receipt requested. See the Table of DEA Mailing Addresses in **Sec. 1321.01** of this chapter for the current mailing address. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph (c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.

[62 FR 13949, Mar. 24, 1997, as amended at 75 FR 10676, Mar. 9, 2010]