Research and the DEA Registration

Researcher Conference
Anaheim, California
Wednesday, February 6, 2019

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LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on February 6, 2019, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.
Objectives

- Explain why the DEA issues registrations, the type of registrations that the DEA issues, and how such registrations fit into the closed system of distribution.

- Explain how a researcher obtains a DEA registration, what is required, and what to expect as part of this process.

- Explain the limits of a DEA registration, and the coincident activities that a researcher can perform.
Objectives

- Outline when a researcher would need more than one DEA registration.

- Review some common problems researchers have encountered regarding their DEA registration and how they were resolved.
Misinformation

• Regulatory controls prevent research into new treatment agents

• Researchers are unable to access controlled substances

• Control status is a barrier to funding

• Length of approval process impedes resource allocation
Since 2013 we have reduced the approval of new applications from 161 days to 105 days.

Average days to approve a new application once we have a complete protocol is 95 days.
Applications for Research CI

Avg Number of Days

Number Approved
Conducting Research with CS

• Research remains critical to informing Scientific, Medical, and Policy Decisions.

• The Controlled Substances Act (CSA) establishes a process and procedure to legally research controlled substances.

• Process is straight-forward and brings together multiple authorities (e.g. FDA, DEA, State Authorities)
Controlled Substances Act

October 27, 1970
Controlled Substances Act

Created a System of Controls for the Legitimate
Manufacture
Distribution
Import
Export
Dispensing
Administering
Controlled Substances Act

It provided(s) a system to protect against the diversion of controlled substances into other than legitimate channels.
The mission of the Diversion Control Division is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances (and listed chemicals) from legitimate channels of distribution...
Mission

... while ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.
21 U.S.C. § 822 (a) (2)

Provided for:

A System of Registration
Closed System of Distribution

- Cyclic Investigations
- Record Keeping Requirements
- Security Requirements
- ARCOS
- Established Schedules
- Registration
- Established Quotas

U.S. Drug Enforcement Administration
Diversion Control Division
The Registrant Community

- Total number of DEA registrants: 1,799,696
- Total number of Practitioners: 1,301,380
- Total number of Researchers in Schedule I: 750
- Total number of Researchers in Schedule II-V: 8,079

U.S. Drug Enforcement Administration
Diversion Control Division
First, let’s begin by clarifying a few points.

The truth is that although a DEA registration is a Federal registration it does **NOT** allow you to conduct research with controlled substances anywhere you wish to in the United States. Each registration is based, in part, on state approval.
Registration Requirements

- A DEA registration is **NOT** required for non-controlled substances.

- If you change your last name you are **NOT** required to obtain a new DEA registration number.

- A DEA registration number is **NOT** privileged information, but is available to the public.

U.S. Drug Enforcement Administration
Diversion Control Division
Initiating the Application

• On January 17, 2018, the DEA implemented an on-line automated application process for new and existing Schedule I researchers

• Improves efficiency and security
  – Guides the applicant through the process.
  – allowing researchers to apply and update registration information.
  – Allows the upload of supporting documents.
REGISTRATION APPLICATIONS AND TOOLS

New Registration Applications | Apply Online | PDF Version | Form 225, Form 363, Form 510 (Form 224 unavailable in PDF)
Renewal Request for Applications
Duplicate Receipt of Registration
Duplicate Certificate Request
Online Pharmacy Modifications
Registration Change Requests
Registration Validation
Registration for Disposal of Controlled Substances
Search for an Authorized Collector Location
DEA Form 222 – Official Order Forms
CSOS (Controlled Substance Ordering System)
Section 3. State License(s)

It is mandatory to provide State medical and/or controlled substance licenses/registrations. Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn WITHOUT refund.
Select Your Business Category

Form 224
Practitioner (MD, DO, DDS, DMD, DVM, DPM)
Mid Level Practitioner (NP, PA, OD, etc.)
Pharmacy
Hospital/Clinic
Teaching Institution

Form 225
Manufacturer
Importer
Exporter
Distributor
Rev. Distributor
Researcher
Canine Handler
Analytical Lab

Form 510
Chemical Manufacturer
Chemical Importer
Chemical Exporter
Chemical Distributor

Form 363
Narcotic Treatment Clinics

Select One Business Activity

Applying for a registration with the wrong Business Category/Activity will cause either delay in processing your application or the withdrawal of your application. If you are not certain of your Business Category/Activity, please contact DEA Customer Service at 1-800-882-0570.

- Please Select -

Please do not use your browser’s BACK and FORWARD buttons while navigating this form.

Begin
- Cancel -

ADDITIONAL INFORMATION

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

2. 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 (See Above). Public reporting burden for this collection of information is estimated to average (See Above) per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.

3. 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.

4. 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.
Select Your Business Category

Form 224
Practitioner (MD, DO, DDS, DMD, DVM, DPM)
Mid Level Practitioner (NP, PA, OD, etc.)
Pharmacy
Hospital/Clinic
Teaching Institution

Form 225
Manufacturer
Importer
Exporter
Distributor
Rev. Distributor
Researcher
Canine Handler
Analytical Lab

Form 510
Chemical Manufacturer
Chemical Importer
Chemical Exporter
Chemical Distributor

Form 363
Narcotic Treatment Clinics

Select One Business Activity
Applying for a registration with the wrong Business Category/Activity will cause either delay in processing your application or the withdrawal of your application. If you are not certain of your Business Category/Activity, please contact DEA Customer Service at 1-800-882-9539.

RESEARCHER (I) ($244 / 1 YRS) 

Please do not use your browser’s BACK and FORWARD buttons while navigating this form.

Begin

- Cancel -

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Schedule 1 Researcher Pre-application Checklist

1. This form is for NEW applicants only who intend to handle Schedule I controlled substances for research purposes. If you need to renew your DEA registration, please navigate to the registration renewal application.

2. If your application is found to involve manufacturing activities not permitted under a researcher registration, your application may be denied. Some examples of manufacturing activities include the following:
   a. Activities to satisfy regulatory requirements such as FDA submissions or good manufacturing practice
   b. Activities related to production of material used for pilot, scale-up, and reformulation studies
   c. Activities related to product development including bioavailability, dosage formulation, stability, and validation studies

For additional questions or clarification related to manufacturing activities please email ODESchedule@dea.usdoj.gov

3. Registering as a researcher requires a NON-REFUNDABLE fee of $244. There is no prorated application fee and THE SUBSEQUENT WITHDRAWAL OF AN APPLICATION DOES NOT QUALIFY FOR A RETURN OF THE APPLICATION FEE.

4. The applicant must be the only individual completing and certifying by E-signature that the information provided is accurate for purposes of this DEA application. There is an exception if the applicant files a power of attorney with DEA (Title 21 CFR § 1301.13(j)).

5. You must currently possess all required state authority to handle controlled substances for the state of your registered business/office address. It is recommended you contact the local Diversion Field Office for clarification on state law/regulations before you complete the application. A LACK OF STATE AUTHORIZATION DOES NOT ENTITLE YOU TO A RETURN OF THE APPLICATION FEE

6. You must currently possess appropriate institutional authority to conduct research with schedule I controlled substances.

7. You must separately identify each of the studies/projects, by Project Name, that are covered by this application. If your research involves one or multiple studies/projects you will need to provide information specific for each of these studies/projects. For a given Study/Project:
   A. Are you conducting human research? If YES:
      i. You must have Institutional Review Board (IRB) approval for clinical studies PDF FILE UPLOAD REQUIRED
      ii. You must have an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number) for clinical studies PDF FILE UPLOAD REQUIRED
C. Are you conducting research that does not use animals or humans? Examples of such research are: In-Vitro laboratory research that doesn’t require institutional approval, research to develop analytical methods, and research to develop chemical syntheses protocols. If Yes:
   i. You must have a protocol*, See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements. PDF FILE UPLOAD REQUIRED

*Protocols: If a given study/project has a consolidated research protocol, that covers all of the types of research being performed, then you only need to upload the consolidated research protocol once for that study/project. If study/project’s research protocols have not been consolidated, then you will have to upload a dedicated research protocol for each type of research being performed.

Note: Size limit for upload documentation is 10 MB

8. You must submit a Curriculum Vitae for each of the investigator(s) working on each of the studies/projects as part of the application process. See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements.
   a. Curriculum Vitae of investigator(s) PDF FILE UPLOAD REQUIRED

Note: Size limit for upload documentation is 10 MB

9. Are you obtaining the Schedule I controlled substances that are mentioned in the research protocol from external sources?
   a. If YES, you will need to provide the DEA registration number(s) of the source(s) and validate their name and address. REQUIRED

10. You may be exempt from the application fee if you are a direct hire employee for a federal, state, or local government institution, or of a public university. The exemption will restrict the use of a DEA registration to government or university duties only. In accordance with Title 21 CFR § 1301.21(b), you must certify your status on the application. You may forfeit the fee exemption by not complying with this regulation. You may be required to provide evidence of government or public university employment.

11. Do not use this form if you have already mailed a paper application. Duplicate submissions may result in a duplicate collection of NON-REFUNDABLE application fees.

12. For additional questions or clarification, the following services are available:
   a. Contact a customer service representative at 1-800-882-9539
   b. Email DEA Registration Help@usdoj.gov
   c. Contact a Registration Program Specialist specific to your state

☐ I have read and understood the information and agree to the terms outlined above.
Schedule I Researchers

• Required approvals
  o Human research
    Ÿ Institutional Review Board (IRB)
    Ÿ Notice of Claimed Investigational Exemption for a New Drug (IND)
  o Animal research
    Ÿ Institutional Animal Care and Use Committee (IACUC)

• Schedule I controlled substances must be obtained from *lawful sources* (DEA registrants)
C. Are you conducting research that does not use animals or humans? Examples of such research are: In-Vitro laboratory research that doesn’t require institutional approval, research to develop analytical methods, and research to develop chemical synthesis procedures etc. If Yes:

- You must have a protocol*, See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements. **PDF FILE UPLOAD REQUIRED**

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- Contact a **Registration Program Specialist** specific to your state

☐ I have read and understood the information and agree to the terms outlined above.

[submit button]
Enter a Social Security Number or Taxpayer Identifying Number

If you are Fee Exempt, check the Fee Exempt box below and supply the required information.

Tax ID: [ ] (No dashes or spaces)

SSN: [ ] (No dashes or spaces)

For Fee Exempt Applicants ONLY:
By checking this box, the applicant hereby CERTIFIES that they are a Government employee (not a contractor) of a federal, state, or local government agency, or if an institution, it is OPERATED by a government agency and is exempt from the payment of the application fee.

☐ CERTIFICATION FOR FEE EXEMPTION - Government Only
Contacts for Researchers

- **Registration:**
  
  DEA.Registration.Help@usdoj.gov
  
  1-800-882-9539

- **Protocol:**
  
  DPEScheduleIREsearch@dea.usdoj.gov
  
  202-307-7183

- **Policy:**
  
  ODLP@usdoj.gov
  
  202-307-7297
Contacts for Researchers

Contact the DEA Registration Specialist in your area. To find their contact information go to the above website and look under “About Us.”

For example, using this method the Registration Specialist’s contact information for Los Angeles California is Phone – (888) 415-9822.
Contacts for Researchers

The Registration Specialist for your area can be located on the Diversion Control Division web-site.

You can search by zip code, city, county, or state.

U.S. Drug Enforcement Administration
Diversion Control Division
Required Information

The DEA cannot consider an application unless you first have state controlled substance authority, or are specifically exempt from registration, and each state is different:

- State Researcher License
- State controlled substance registration (if required)
- Other state licensure (if required)
- Certificates of advanced training (if required)
Practice Address vs Mailing Address

During the application process you are asked for your Practice Address, and you are asked for your Mail-to Address if different.

Your Practice Address is your principal place of business or professional practice pursuant to Title 21, C.F.R. 1301.12(a). This is the address on your DEA certificate.

Your mail-to address is for correspondence.
### DEA Certificate

**Dea Registration**
- PB000

**Registration Expire**
- 12-31-2016

**Schedule**
- 1, 2, 3, 4, 5

**Business Activity**
- Analytical Lab

**Issue Date**
- 12-15-2015

**Drug Enforcement Admin**
- Miami Field Division
- 2100 N Commerce Pkwy
- Attn: Diversion Group
- Weston, FL 33326

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**Section 304 and 1008 (21 USC 824 and 965) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.**

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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**Form DEA-23 (9/2016)**
Public Access

The DEA is required to turn over the practice address to the U.S. Department of Commerce.

The Department of Commerce sells this information through the National Technical Information Service (NTIS) to registrants and others.

Other companies then legally resell this information.

U.S. Drug Enforcement Administration
Diversion Control Division
Registration Duration

Federal regulation places researcher applicants into twelve groups.

Your expiration date is based on the group in which you were placed.

The first registration can be as short as 3 months, or as long as 14. All others are for a 12 month period.
Drug Class

Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration.

A statement listing the quantity of each such basic class of controlled substance to be imported or manufactured during the registration period for which application is being made shall be included with each such application.
A DEA registration cannot authorize you to do something that is otherwise prohibited by state law.

For Example: If you are registered by your state to conduct research in only schedules III-V the DEA cannot authorize you to handle schedule II.

For Example: If state law says you can procure only certain controlled substances, the DEA cannot authorize you to do otherwise.
A practitioner can only administer, dispense, procure, or store controlled substances in a state if they first hold a DEA registration in that state. The authority granted under this registration ends at that state’s border.

A practitioner can only administer, dispense, procure, or store a controlled substance at a location where he or she is registered with the DEA.
When more than one DEA registration number is needed:

- If a researcher plans to administer, dispense, procure or store controlled substances at more than one location in a state.

- If a researcher plans to administer, dispense, procure, or store controlled substances in more than one state.
A Researcher planning to use a schedule I controlled substance must submit a protocol with each application. 21 C.F.R. 1308.18(a)

A Researcher planning to use a schedule I controlled substance can request an amendment to their protocol to increase the amount of a schedule I controlled substance used in their approved research. 21 C.F.R. 1308.18(b)

A Research planning to conduct research beyond the variations provided in the registrant's approved protocol can submit a supplemental protocol for review. A supplemental protocol will be handled by the DEA in the same way as a new protocol.

U.S. Drug Enforcement Administration
Diversion Control Division
DEA Registration Limits

Coincident Activities allowed for Researcher in Schedule I
21 C.F.R. 1301. § 13(c)(1)(v)

A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in 21 C.F.R. § 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
DEA Registration Limits

Coincident Activities allowed for Researcher in Schedules II-V

21 C.F.R. 1301. § 13(c)(1)(vi)

May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to 21 C.F.R. § 1301.24; and conduct instructional activities with controlled substances.

U.S. Drug Enforcement Administration
Diversion Control Division
Common Problems Encountered

The applicant does not have appropriate state authority.

The registrant assumes their first registration will be for 12 months.

The applicant, or renewing registrant, fails to mark all appropriate schedules.

The registrant fails to renew their registration in a timely manner.
Common Problems Encountered

Failure to maintain state licensure once achieved.

Failure to notify the DEA of an email address change.

Renewals submitted simultaneously by both the researcher and the researcher’s employer.
Common Problems Encountered

Applying or renewing using an expired credit card or using a check from a closed account.

Relying upon an human resources department to renew their registration on their behalf, but they do not.

Applying for a new DEA # due to a name change.
Common Problems Encountered

Changing practice address:

- In same state
- To another state

Failure to update the protocol
Common Problems Encountered

Going inactive, and what to do with the registration:

Semi-retired

Health Issues

Sabbatical
Common Problems Encountered

Discontinuing Practice:

Permanently

U.S. Drug Enforcement Administration
Diversion Control Division
Fee Exempt Registrations

Conditions under which it is granted

Limits of this registration

Conversion to a fee paid registration
Steps to Reduce Diversion

- Monitor the use of your credit card and checking account.

- Have all controlled substances you purchase be checked in upon delivery by two employees.
Steps to Reduce Diversion

Conduct random audits to ensure they are not getting diverted.

Do not create an atmosphere of sloppiness in your practice by you or your staff.
Steps to Reduce Diversion

SCAM!!!

Criminals posing as DEA employees are targeting DEA registrants using an extortion scam. They use a disguised telephone number that appears on a practitioners' caller ID as the “DEA’s 800 registration support number”. The criminals then demand money and threaten to suspend a registrant’s DEA registration if they do not comply.
We looked at why the DEA issues registrations, the type of registrations that the DEA issues, and how such registrations fit into the closed system of distribution.

We addressed how a researcher obtains a DEA registration, what is required, and what to expect as part of this process.

We explain the limits of a DEA registration, and the coincident activities that a researcher can perform.

U.S. Drug Enforcement Administration
Diversion Control Division
Review

- We outline when a researcher would need more than one DEA registration.

- Finally, we reviewed some common problems researchers have encountered regarding their DEA registration and how they were resolved.
Thank you for your time and attention!

U.S. Drug Enforcement Administration
Diversion Control Division