



The United States Department of Justice

Drug Enforcement Administration



Research and the DEA Registration

*Researcher Conference
Anaheim, California
Wednesday, February 6, 2019*

Loren Miller
Chief, Policy Section
Diversion Control Division

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.



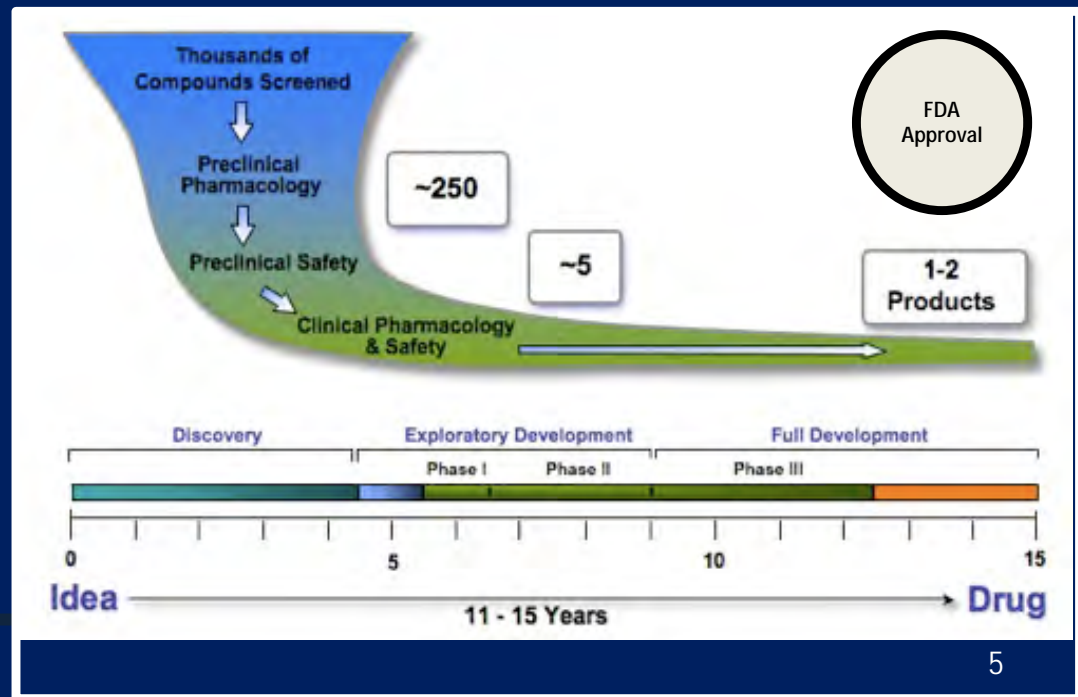
Objectives

- § 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.

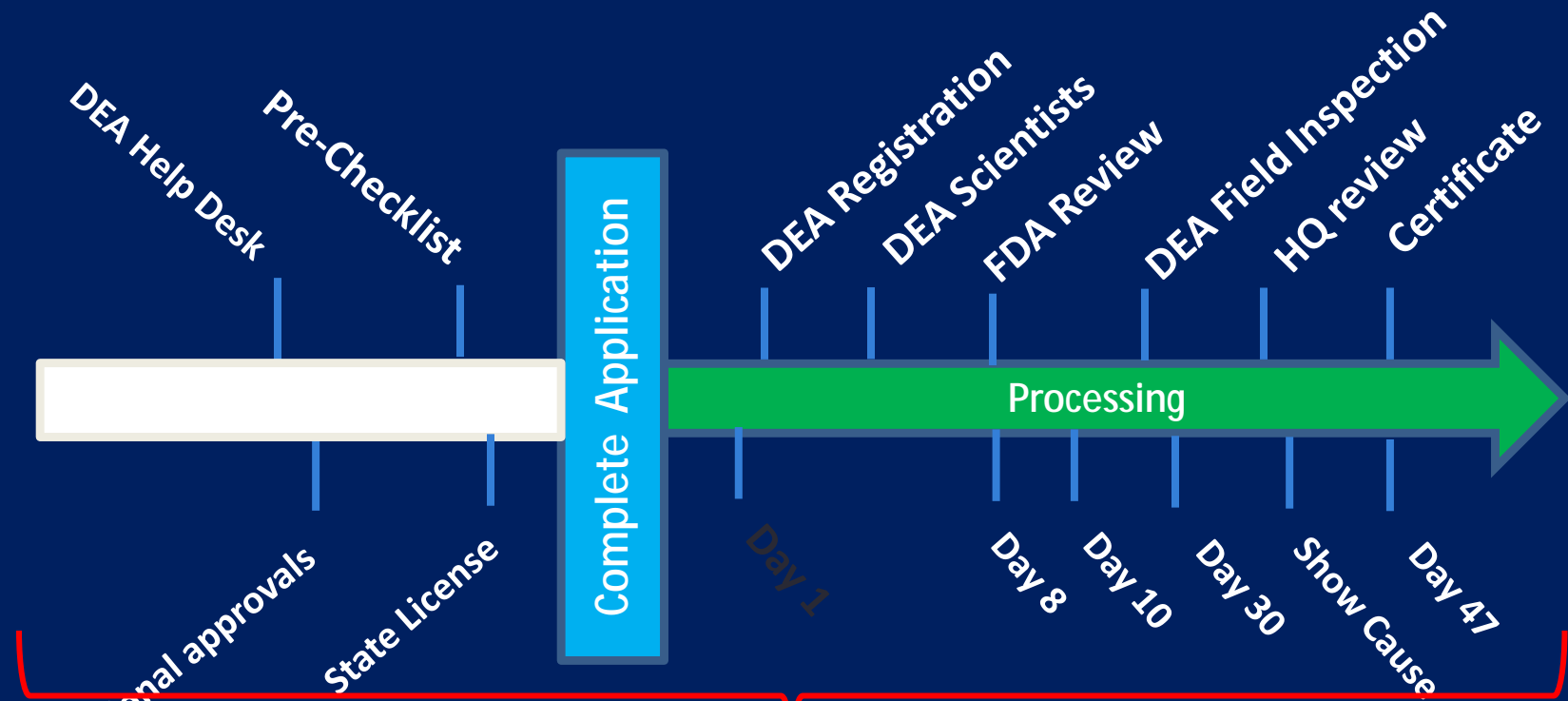


Misinformation

- 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



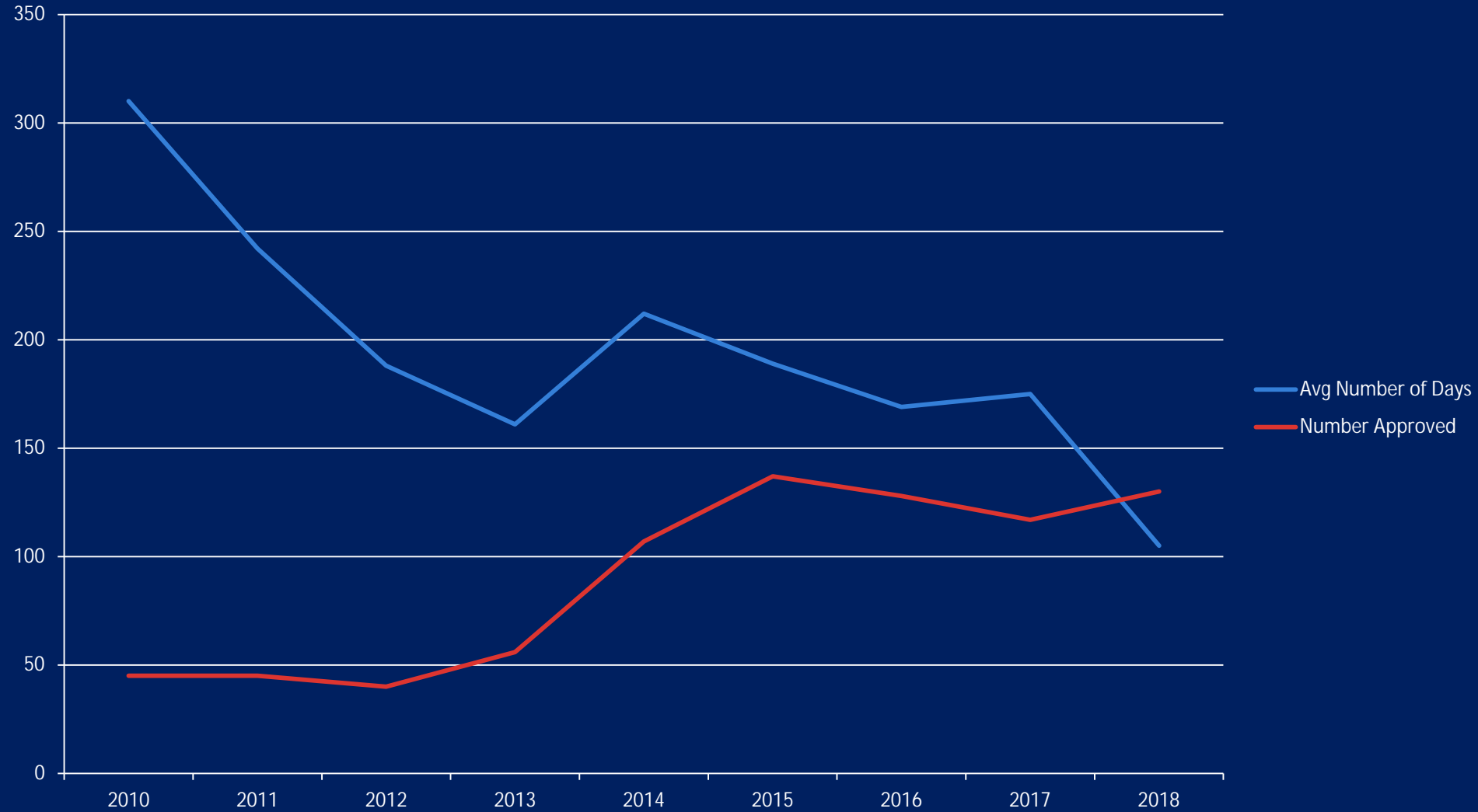
Regulatory Timeline



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



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.

Mission

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.

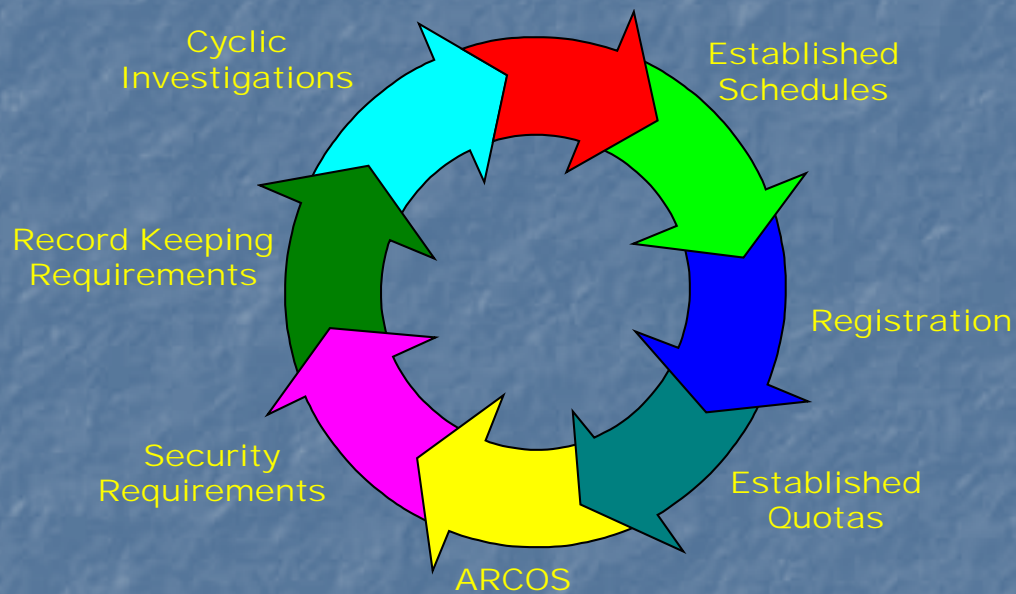
21 U.S.C. § 822 (a) (2)

Provided for:

A System of Registration



Closed System of Distribution



U.S. Drug Enforcement
Administration
Diversion Control Division



The Registrant Community

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

U.S. Drug Enforcement
Administration
Diversion Control Division



Registration Requirements

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



U.S. Drug Enforcement
Administration
Diversion Control Division



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
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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.





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

 Search

Due to the National Day of Mourning, the Call Center will be closed Wednesday, December 5, 2018. The Call Center will resume normal working hours on Thursday, November 6, 2018. This closure will affect responses to the email address as well.

HOME

REGISTRATION

REPORTING

RESOURCES

ABOUT US

EMERGENCY DISASTER RELIEF



Emergency Authorization
for Disaster Relief:
Domestic & International

See Details

Registration Support

Call: 1-800-882-9539 (8:30 am-5:50 pm ET)

Email: DEA.Registration.Help@usdoj.gov

Locate Field Registration Specialists

New Applications

Renewal Applications

Registration Changes (Address, Drug Code, Name, Schedule)

CMEA (Combat Meth Epidemic Act)

Registration for Disposal of Controlled Substances

Duplicate Certificate Request

Duplicate Receipt of Registration

Order Forms (DEA 222)

Registration Validation

Search and Collector Location

What's New

Exempt Chemical Preparations Under the Controlled Substances Act

(December 3, 2018)

Steve Fanto, M.D.; Decision and Order (November 30, 2018)

Narciso A. Reyes, M.D.; Decision and Order (November 30, 2018)

Final Order: Placement of Furanyl Fentanyl, 4-Fluoroisobutyryl Fentanyl, Acryl Fentanyl, Tetrahydrofuranyl Fentanyl, and Ocfentanil in Schedule I (November 29, 2018)

Importer of Controlled Substances Registration (November 27, 2018)

Bulk Manufacturer of Controlled Substances Registration (November 27, 2018)

Importer of Controlled Substances Registration (November 27, 2018)

Noramco Inc. (November 27, 2018)

In The News

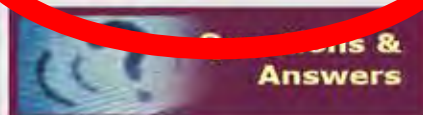
Get Email Updates:



DEA Forms & Applications



Publications & Manuals



Questions & Answers



Meetings & Events

Quick Links

ARCOS (Automation of Reports & Consolidated Orders System)

Cases Against Doctors

Chemical Control Program

Controlled Substance Schedules



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DEA Forms & Applications

DEA Forms & Applications

REGISTRATION APPLICATIONS AND TOOLS

Renewal Registration Applications	Apply Online	← Online Only	Form 224a, Form 225a, Form 363a, Form 510a
New Registration Applications	Apply Online	PDF Version	Form 225, Form 363, Form 510 (Form 224 unavailable in PDF)
Duplicate Receipt of Controlled Substances	Apply Online	← Online Only	Request an additional receipt for a previously submitted Renewal Application
Duplicate Certificate Request	Apply Online	← Online Only	Duplicate Certificates for misplaced, illegible, or destroyed originals
Online Pharmacy Modifications	Apply Online	← Online Only	Modify your existing Retail Online Pharmacy information
Registration Change Requests	Apply Online	← Online Only	Make changes to drug code, schedule, name, or address (<i>address change requires approved state license for the new address first</i>)
Registration Validation	Apply Online	← Online Only	Allows a current DEA registrant to check the validity of another DEA registrant
Registration for Disposal of Controlled Substances	Apply Online	← Online Only	Modify eligible DEA registration to collect pharmaceutical controlled substances from ultimate users (e.g., patients); Modify DEA registration to stop being a collector; Modify existing collector registration information
Search for an Authorized Collector Location	Search	← Online Only	A search utility for Controlled Substance Public Disposal Locations
DEA Form 222 – Official Order Forms	Apply Online	← Online Only	Request Official Order Forms (<i>Schedule I & II Registrants Only</i>)
CSOS (Controlled Substance Ordering System)	Apply Online	← Online Only	Allows electronic orders of controlled substances without the supporting paper Form 222

REPORTING FORMS



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

**Application for Registration Under Controlled Substances Act of 1970
(New Applicants Only)**

ON-LINE REGISTRATION CONSISTS OF SIX (6) SECTIONS. Please have the following information available before you begin the application:

Section 1. Personal/Business Information

If you are applying for an Individual Registration (Practitioner, MLP, Researcher) you are required to provide your Full Name, Address, Social Security Number, and Phone Number. If you are applying for a Business Registration, you are required to provide the Name of the Business, Address, Tax ID, and Phone Number.

Section 2. Activity

Business Activity and Drug Schedule information. **In addition** - Certain registrants for forms 225 and 510 will need to provide specific drug codes and/or chemical codes related to their operations.

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.

Section 4. Background Information

Information pertaining to controlled substances in the applicant's background.

Section 5. Payment

Payment, via this on-line application, must be made with a Visa or MasterCard, American Express, or Discover. **Application fees are not refundable.**

Section 6. Confirmation

Applicants will confirm the entered information, make corrections if needed, and electronically submit the application and a submission confirmation will be presented. Applicants will be able to print copies for their records.

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than \$250,000, or both.

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](#)
[Researcher](#)

Form 510

[Chemical Manufacturer](#)
[Chemical Importer](#)
[Chemical Exporter](#)
[Chemical Distributor](#)

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

- 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-

ADDITIONAL INFORMATION

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Welcome, New Applicant | [Logout](#) | Need Help? **Email Us:** DEA.Registration.Help@usdoj.gov **Call Us Toll Free:** 1-800-882-9539

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**

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 synthesis procedures, etc. 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.

→ Continue

⊗ Cancel



Schedule I Researchers

- **Required approvals**
 - **Human research**
 - Ø **Institutional Review Board (IRB)**
 - Ø **Notice of Claimed Investigational Exemption for a New Drug (IND)**
 - **Animal research**
 - Ø **Institutional Animal Care and Use Committee (IACUC)**
- **Schedule I controlled substances must be obtained from *lawful sources* (DEA registrants)**

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 synthesis procedures etc. 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**

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

→ Continue

⊗ Cancel

Personal Information

Last Name*	<input type="text"/>	
First Name*	<input type="text"/>	
Additional Company Information	<input type="text"/>	
Business Address Line 1*	<input type="text"/>	
Business Address Line 2	<input type="text"/>	
City*	<input type="text"/>	
State*	<input type="text" value="- State -"/>	
Zip*	<input type="text"/> (No dashes or spaces)	
Business Phone Number*	<input type="text"/> Ext. <input type="text"/>	
Business Email Address*	<input type="text"/>	
Contact Name	<input type="text"/>	
Contact Cell Phone Number*	<input type="text"/>	
Mailing Address	<input type="checkbox"/> (Same as Registered Address)	
Additional Company Information	<input type="text"/>	
Mailing Address Line 1*	<input type="text"/>	
Mailing Address Line 2	<input type="text"/>	
City*	<input type="text"/>	
State*	<input type="text" value="- State -"/>	
Zip*	<input type="text"/> (No dashes or spaces)	

→ Proceed

⊗ Cancel

Personal Information

Last Name*	<input type="text" value="ARNOLD"/>	?
First Name*	<input type="text" value="JAMES"/>	?
Additional Company Information	<input type="text" value="DRUG ENFORCEMENT ADMINISTRATION"/>	?
Business Address Line 1*	<input type="text" value="600 ARMY-NAVY DRIVE"/>	?
Business Address Line 2	<input type="text" value="EAST BUILDING"/>	?
City*	<input type="text" value="ARLINGTON"/>	?
State*	<input type="text" value="VIRGINIA"/> v	?
Zip*	<input type="text" value="22202"/> (No dashes or spaces)	?
Business Phone Number*	<input type="text" value="(202) 307-1000"/> Ext. <input type="text"/>	?
Business Email Address*	<input type="text" value="James.A.Arnold@usdoj.gov"/>	?
Contact Name	<input type="text"/>	?
Contact Cell Phone Number*	<input type="text"/>	?
Mailing Address <input checked="" type="checkbox"/> (Same as Registered Address)		
Additional Company Information	<input type="text" value="DRUG ENFORCEMENT ADMINISTRATION"/>	?
Mailing Address Line 1*	<input type="text" value="600 ARMY-NAVY DRIVE"/>	?
Mailing Address Line 2	<input type="text" value="EAST BUILDING"/>	?
City*	<input type="text" value="ARLINGTON"/>	?
State*	<input type="text" value="VIRGINIA"/> v	?
Zip*	<input type="text" value="22202"/> (No dashes or spaces)	?



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[See Checklist](#)

CSA Registration Online Mgmt Tools: Personal Information - Page 2

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 [?](#)

← Previous

→ Proceed

⊗ Cancel



Contacts for Researchers

- **Registration;**

DEA.Registraion.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.

The screenshot shows the website for the U.S. Department of Justice Drug Enforcement Administration, Diversion Control Division. The page features a search interface for field office contact information. The search results section displays the following information for the Los Angeles Division Office:

Location	Registration Assistance
LOS ANGELES DIVISION OFFICE 255 EAST TEMPLE ST. 17TH FLOOR LOS ANGELES, CA 90012	Phone 1: (800) 421-9822 Phone 2: (310) 833-8800

9001



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 NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
PB000 [REDACTED]	12-31-2016	Exempt
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N 3,3N,4,5	ANALYTICAL LAB	12-15-2015
DRUG ENFORCEMENT ADMIN MIAMI FIELD DIVISION 2100 N COMMERCE PKWY ATTN: DIVERSION GROUP WESTON, FL 33326		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) 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.

Form DEA-223 (9-2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
PB000 [REDACTED]	12-31-2016	Exempt
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N 3,3N,4,5	ANALYTICAL LAB	12-15-2015
DRUG ENFORCEMENT ADMIN MIAMI FIELD DIVISION 2100 N COMMERCE PKWY ATTN: DIVERSION GROUP WESTON, FL 33326		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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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.



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.



DEA Registration Limits

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.



DEA Registration Limits

Final Rule: Clarification of Registration Requirements for Individual Practitioners (December 1, 2006)

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.



DEA Registration Limits

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**.



DEA Registration Limits

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 Researcher 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.



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.



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

U.S. Drug Enforcement Administration
Diversion Control Division





Common Problems Encountered

Discontinuing Practice:

Permanently



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.



Review

- § 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.



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