FactSheet

Drug Enforcement Administration (DEA) Registration & Renewal



rincipal Investigators (PI) at USC whose research involves use of controlled substances are required to apply for an individual DEA registration. This enables the PI to purchase, store, and use controlled substances (CS) at USC. Registration renewal is either annual or every three years depending on the <u>business activity</u> of the individual.

Only DEA <u>Schedule II-V drugs</u> are permitted at USC. Use of DEA schedule I drugs [e.g., Cannabis, Cocaine] is prohibited without special permission from the DEA and USC Office of Compliance.

HOW DO I REGISTER WITH THE DEA?

- 1. Go to the <u>DEA website</u> and access <u>Forms 224 or 225</u>. This distinction will depend on your business activity.
 - Follow the menu sequence: Registration → Applications → New Applications Online.
 - Form 224 Practitioner; Mid-Level Practitioner; Pharmacy: Valid for three years with paid registration.
 - ii. Form 225 Researcher; Analytical Lab: Valid for one year with paid registration.

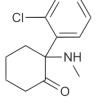
NOTE: Per the <u>Controlled Substances Act</u>, a separate registration must be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed.

The State of California requires pre-review and authorization of proposed research projects involving any schedule I CS and human research using any:

- Schedule I or II CS, and/or
- Research for the treatment of drug abuse using any drug, scheduled or not.
 - If your research falls in any of these categories, you must attain authorization from the <u>Research</u> Advisory Panel of California.
- 2. Complete the online DEA Registration Form 224 or 225.
 - Once registered, a DEA Investigator will be assigned to you. The investigator will provide you with a DEA questionnaire to complete and schedule an upcoming visit to approve security and storage of your CS.
- 3. Notify EH&S at ehs-cs@usc.edu of appointment time and schedule a preview of storage site.
 - EH&S will assist you with the pre-registration audit questions and requests from the DEA.
- 4. To use CS in animals, submit protocols via <u>iStar</u> application to the Institutional Animal Care and Use Committee (IACUC) for approval.

WHAT I NEED TO KNOW

- Medical practitioners are permitted to use their existing DEA registration for research in a USC lab if the address on their DEA license matches the storage and use location of the CS used for research.
- In addition to acquiring a DEA registration, researchers and practitioners who use CS for research are also required to enroll in USC's Controlled Substances Use Authorization (CSUA).
 - Refer to the USC EH&S <u>Controlled Substances</u> <u>Use Authorization (CSUA) Program Guide Sheet</u> for more detailed information.
- DEA registrations must be renewed prior to their expiration date.
- Working with controlled substances under a lapsed (expired) DEA registration may result in serious consequences that include fines.
- Contact ehs-cs@usc.edu for the following:
 - DEA registration is no longer needed. Complete <u>CS Form G - CS Waste Disposal Request</u> for CS in your possession (i.e., expired or unused) and forward a copy to <u>ehs-cs@usc.edu</u>.
 - ♦ More information on DEA registration.
- To use CS in vitro, consult with Biosafety (323) 442-2200 biosafety@ usc.edu to see if IBC registration is required.
- DEA agents, DEA Registrant, and EH&S
 CS personnel will meet at the location listed on the application.
- 7. Following approval of submitted documentation, a DEA registration will be granted.



Ketamine

HOW OFTEN DO I RENEW MY DEA REGISTRATION?

- Registration is renewed annually if you originally filed Form 225 or every three years if you originally filed Form 224.
- The DEA will notify the DEA registrant electronically or by US Mail of the upcoming expiration. EH&S will also dispatch frequent reminders to the DEA registrant as a courtesy to ensure continuance of the registration.
 - Renewal/reinstatement of a registration by the DEA is usually a four to six week process and is contingent upon the following criteria:
 - Renewal application submitted PRIOR to expiration date. The registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
 - Renewal application submitted AFTER expiration date. The DEA will allow the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.



NOTE: Federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration. It is the responsibility of the DEA Registrant to renew his/her registration prior to its expiration and provide EH&S with a copy.

HOW DO I RENEW MY DEA REGISTRATION?

- 1. Access the DEA Registration Renewal Form Login online.
- 2. Complete all required fields and click the "Login" button.
- 3. Complete per instructions provided by the DEA.
 - a. California does not have a state controlled substance registration program. Therefore, complete section 3 as follows:
 - State License Number "Not Applicable".
 - ii. State License State "California".
 - iii. State Controlled Substance Number "Not Applicable".
 - iv. Expire Date Select an expiration date after the date of your renewal registration application submittal.
- 4. Forward a copy of your updated DEA registration to ehs-cs@usc.edu.

NOTE: If your original certificate is misplaced, illegible, or destroyed, you may obtain a Duplicate Certificate.



REFERENCES

- Title 21 United States Code (USC) Controlled Substances Act
- Title 21 Code of Federal Regulations, Part 1300
- <u>Title 21 Code of Federal Regulations PART 1301</u> Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances
- §1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities

