

ORDERING GUIDELINES FOR U.S. RESEARCH INVESTIGATORS/USERS

The NIDA Drug Supply Program provides various controlled drugs, other chemical substances, and marijuana and nicotine research cigarettes for research purposes to research investigators working in the area of drug abuse, drug and addiction, and related disciplines in various academic institutions, and research laboratories within this Country and anywhere in the world. The availability of controlled substances is regulated by the United States Drug Enforcement Administration (DEA), Department of Justice under the Control Substances Act (CSA), and Psychotropic Convention. These controlled drugs include hallucinogens, stimulants, sedatives and hypnotics, narcotics, designer drugs, cannabinoids, marijuana, as well as several other essential chemical substances. The NIDA Drug Supply Program maintains an inventory of such drugs and other chemical substances. In addition, continuous efforts are made to synthesize new compounds and add them to the inventory. The stability and purity of all such compounds are periodically monitored and maintained. Upon request, research investigators are provided with pure drugs/compounds along with their respective analytical data sheets.

Marijuana is a plant material which is grown, harvested, processed and analyzed for delta-9-THC and other cannabinoids concentrations, stored under controlled conditions to preserve its purity and stability, and distributed for approved research purposes. The aforesaid entire process for marijuana is subject to control under Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq), the most restrictive of the five federally regulated classes of controlled substances. Persons who wish to conduct research using marijuana, and marijuana cigarettes and/or plan to use it for purposes other than research such as forensic analytical standard, dog training, or any other law enforcement purposes must first obtain a special DEA registration under the CSA and then submit a request to NIDA along with the required documents for consideration. The NIDA marijuana is of research grade quality and if a person wishes to use as an analytical standard it is the responsibility of the user to establish its purity before use.

In order to obtain controlled drugs, other research chemicals, marijuana, marijuana and nicotine research cigarettes from NIDA, research investigators and users other than researchers are required to submit their requests along with necessary documents to the NIDA drug supply program for consideration.

THE DRUG SUPPLY REQUEST PROCESS

1. A request for the supply of drugs or other chemicals should include (1) a cover letter including the name(s) and quantities of compounds being requested, grant number, and name, phone number and e-mail address of your

program officer (for a NIDA/NIH grantee), (2) a research protocol that should clearly specify the purpose of your study, the number of experiments, number of animals, dosages or concentration of drugs that will be used, (3) justification for quantities of drug(s) requested, (4) DEA Order Form 222, (5) a copy of your current DEA registration Form DEA-223 (for controlled substances), (6) IND number (for a clinical study), (7) a copy of NRC license (for radioactive compounds), (8) a copy of the document demonstrating that the research is approved by the Animal Care & Use Committee and that adequate care in conducting the animal research will be exercised, (9) curriculum vitae of the principal investigator, and (10) a commitment that NIDA will be acknowledged in publications.

2. The request should be sent to the Drug Supply & Analytical Services Staff at the Division of Basic Neuroscience & Behavioral Research, NIDA who will review it for completeness and notify the investigator in case the package is incomplete.

3. Once a complete request is received, it is assigned to a NIDA scientific officer for preliminary review. If this request is related to a research proposal that has already undergone the NIH peer review process, it is forwarded to the assigned NIDA scientific officer for further review and necessary action. If the request has not undergone the NIH peer review process (i.e., where the request is from a non-grantee, a potential grantee, or a foreign investigator), the research protocol is forwarded to a NIDA scientific officer for review. After its preliminary review the request is submitted to external experts for further scientific reviews. These external reviewers are advised to keep contents of the protocol confidential.

4. After these initial reviews, the NIDA Drug Supply Program official reviews all documents and makes the final decision.

The step-by-step guidelines for U.S. Research Investigators are given below:

GUIDELINES FOR U.S. RESEARCH INVESTIGATORS

1. Calculate required amount of drugs, chemical substances, or drug formulations for your project and submit your request well in advance of your planned experiments or tasks, or 6-8 weeks prior to depletion of stock on hand for ongoing studies/tasks. If multiple studies/tasks are planned, combine projected needs into a single order rather than placing several separate requests in a short time interval.
2. The request should generally be limited to no more than four items or drugs/compounds per order to avoid delay.

3. Send a cover letter including name, quantity, or number of each drug/compound, or formulated item being requested along with a commitment to acknowledge NIDA in publications resulting from the use of supplies obtained from NIDA. The letter should also include the following:
 - A. Your current and complete address that would allow shipment by Federal Express (i.e. street address, building name or number, room number, city and state) - This address should coincide with the address on the DEA order form. For radio-labeled drugs or chemical substances, indicate the address to which such materials are to be shipped. In case the shipping address is different from the researcher's address, a current copy of the radioactive materials license must be submitted.
 - B. Names of co-investigator (s), if any
 - C. Your grant number, and name and contact number of your NIDA/NIH program official, if applicable
 - D. IND number and a copy of your approved IND letter from FDA (for clinical studies only)
4. A detailed research protocol with justification for the quantity or number of drugs/chemicals, or formulated drugs or substances being requested.
 - a. If the request is related to a previously submitted protocol, reference to this protocol and a brief statement of progress should be provided along with references to resulting publications
 - b. In case of a request from a non-NIH grantee, the research protocol is subject to external review for scientific merit before approval. External review is conducted by Federal and/or non-Federal experts.
 - c. Requests for marijuana for purposes other than research should be accompanied by a justification of the quantity requested.
5. Requests from a non-NIH grantee must include the investigator's curriculum vitae and bibliography.
6. *A copy of your current DEA registration along with your request for controlled substances must be submitted. It is the research investigator's responsibility to keep his/her registration current and verify the drug code (number) of drug (s) being requested. For those investigators who request Schedule I drug(s) and/or Etorphine HCl and Diprenorphine must provide

documentation from the DEA that the requested drug(s) is/are covered under their current DEA registration.

7. *Enclose an accurately completed DEA order Form 222 for controlled substances with your request. Note that a DEA Form-222 is not necessary for drugs in Schedules III-V, but a valid registration for the appropriate schedule is.

A. Avoid drug abbreviations, and include specifications such as (+), (-), (dl), base, or salt, if appropriate.

B. Under the third column of DEA Form 222 (Size of Package), list quantities as bulk weight. The total radioactivity (preferred units of measurement, mg per vial, etc.) should be stated in the cover letter, not on the order form). Radio labeled compounds must be listed by weight and NOT by units of activity.

C. Supplier name and address should be filled in as follows:

Division of Basic Neuroscience & Behavioral Research,
National Institute on Drug Abuse
National Institutes of Health
6001 Executive Boulevard, Room # 4262, MSC 9555
Bethesda, MD 20892-9555

Note (1): ETORPHINE AND DIPRENORPHINE - Request for either of these two compounds should be made on separate order forms when ordering additional compounds at the same time. Please note that etorphine hydrochloride and diprenorphine (free base or hydrochloride) are Schedule II drugs, however etorphine free base is Schedule I drug. Therefore etorphine free base should be ordered using DEA Form-222 for Schedule I drugs.

Note (2): CARFENTANIL, ETORPHINE AND DIPRENORPHINE - The DEA registration of a research investigator requesting these compounds must show the proper registration for such compounds.

*Note (3): RESEARCH NICOTINE CIGARETTES - The requirement for DEA Form 222, and DEA registration is not applicable.

8. All requests should be addressed to:

Hari H. Singh, Ph.D.
Phone: (301) 435-1310, or

Paul S. Hillery, Ph.D.

Phone: (301) 435-1306, or

Kevin Gormley (RTI)
Drug Supply Specialist
Phone: (301) 435-0264

Chemistry & Physiological Systems Research Branch
Division of Basic Neuroscience & Behavioral Research
National Institute on Drug Abuse, NIH
6001 Executive Boulevard, Room # 4262, MSC 9555
Bethesda, MD 20892-9555
Fax: (301) 594-6043

9. Enclose a completed Drug Request Checklist with each order. Examples of a properly completed DEA order form and Drug Request Checklist follow.

Failure to comply with aforesaid guidelines may delay the processing of your request.

DRUG REQUEST CHECKLIST

1. *Cover letter* including the name and quantity of compounds being requested, grant number, name, phone number and e-mail address of your program officer (for a NIDA/NIH grantee), your shipping address, e-mail address, and phone and fax numbers
2. *Recommendation letter* from your program officer in support of your request, if you are not a NIDA grantee
3. *Research protocol*, including *justification* for quantities of drug(s) being requested
4. *DEA Form- 222* (for controlled substances)
5. *Copy of your current DEA registration* (for controlled substances)
6. *Approved FDA letter and IND number* (for a clinical study)
7. *Copy of NRC license* for radioactive compounds
8. *Curriculum vitae* of the principal investigator, and
9. *Statement of commitment* that NIDA will be acknowledged in publications.

Name: _____ Date: _____

Telephone no.: _____ E-Mail address: _____

(Principal Investigator)