



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street Baltimore, MD 21201

Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary

Division of Drug Control
4201 Patterson Avenue, Baltimore, MD 21215
410-764-2890, Fax 410-358-1793

Controlled Dangerous Substances (CDS)
Researcher Questionnaire

Applicant Name

Facility Name

Address

Telephone Fax

Current Md CDS Registration Number Exp. Date
(write "pending" if initial application)

Current DEA Registration Number Exp. Date
(write "pending" if initial application)

Business Hours: M-F _____ Sat. _____ Sun. _____ Hol. _____

1. Brief description of the research/testing that will be conducted and list of controlled dangerous substances ("CDS") that will be used to conduct research/testing and approximate quantities per year.

2. Who is the primary responsible person that supervises use of controlled substances at the facility?

The "Responsible Person" must be a principal investigator or have faculty-rank appointment (i.e., faculty or administrative professional). This person is ultimately responsible for obtaining approval to use a controlled substance, and is responsible for the safe use, secure storage, and recordkeeping requirements of that controlled substance. The Responsible Person certifies that the legally required records of receipts and disbursements of the controlled substances listed on this application will be maintained for inspection, and that drug security measures will meet those required by federal and state law.

3. Who are "individuals with access"?

The "Responsible Person" must be a principal investigator or have faculty-rank appointment (i.e., faculty or administrative professional). This person is ultimately responsible for obtaining approval to use a controlled substance, and is responsible for the safe use, secure storage, and recordkeeping requirements of that controlled substance. The Responsible Person certifies that the legally required records of receipts and disbursements of the controlled substances listed on this application will be maintained for inspection, and that drug security measures will meet those required by federal and state law.

4. What is the exact location where CDS will be stored? (Location/Name of Building, room number)

5. How will CDS for research be obtained? (Name, Address, Phone Number, and DES Number of Supplier)

6. What are the policies and procedures for disposal of outdated/unwanted CDS?

INSTRUCTIONS: Review acceptable disposal options at <http://www.des.umd.edu/hw/pickup/dea.pdf> and check appropriate box.

- Reverse Distribution* to authorized processor
- Witness Destruction* through the UM Dept of Environmental Safety

Comments:

7. Are there procedures for delivery and receipt of CDS?

Will items be hand-delivered to the person responsible for the order or an individual designated by the responsible person.

8. What kind of recordkeeping will be maintained for controlled substances?

RECOMMENDED - Complete recordkeeping is required at the site of storage for controlled substances. This includes an inventory logbook showing:

- Dates, quantity, and description of each controlled substance received, total quantity ON HAND along with initials of receiving individual.
- Dates, quantity, and description of each controlled substance removed from inventory with description of use, total quantity ON HAND and initials of individual removing from inventory.
- Logbook will show total quantity of each controlled substance ON HAND before removal from inventory and quantity of each controlled substance ON HAND following removal from inventory.
- Logbook to be maintained under security (lock and key) with the controlled substances and made available for responsible person and regulatory officials.

9. How will controlled substances be stored?

Controlled substances, by DES Regulations, are to be kept under secure conditions at all times and are to be accessible to approved users ONLY. Secure conditions include "under lock and key at all times except when receiving inventory or removing inventory for use":

- In a locked safe,
- In a locked drawer or cabinet within a room behind a locked door,
- Key or combination to safe, cabinet, or drawer lock accessible to approved users ONLY.
- In regard to FIELD USE: The responsible person must be notified in advance and approve if controlled substances are to be used in a location away from primary location listed in the application.

PLEASE READ AND INITIAL THE FOLLOWING REQUIREMENTS AND RECOMMENDATIONS

- Take an inventory of all CDS items prior to the opening of the business. If no CDS products are present, state "No CDS products at opening of business". [21 CFR 1304.11] (Initial_____)
- You are required to take a biennial CDS inventory, which is a physical inventory of all controlled substances on hand that is taken at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial or opening inventory date. [21 CFR 1304.11] (Initial_____)
- It is recommended that you keep a perpetual inventory of CDS products, which serves as an up to date record of all CDS products on hand. (Initial_____)
- Invoices for schedule III-V products must be dated upon receipt. It is recommended that these invoices be filed separately. [21 CFR 1304.21] (Initial_____)
- DEA Form 222, which must be used to order Schedule I-II products, must be signed by the DES Registrant. Power of Attorney may be executed by the registrant to allow others to sign the DEA 222 form. [21 CFR 1304.05] (Initial_____)
- When schedule I-II orders are received, the quantity and date received must be recorded for each line item on DEA Form 222. [21 CFR 1304.13(e)] (Initial_____)
- Executed DEA 222 Forms must be maintained separately from other records and kept readily available for 2 years. [21 CFR 1304.17] (Initial_____)
- Any significant loss or theft of CDS product must be reported immediately upon discovery, within one business day, in writing to DEA and the Division of Drug Control. A DEA Form 106 must be completed for any unresolved loss, with the original sent to DEA and a copy to DDC. [COMAR 10.19.03.12A(1)] (Initial_____)

Signature of Applicant _____ Date _____

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