



Guide to Ordering DEA-Listed, DEA-Scheduled and MDPH-Scheduled Substances

Purpose: This document clarifies some federal and Massachusetts restrictions that apply to certain chemicals that may be used in laboratories.

US Drug Enforcement Agency (DEA)

The federal DEA regulates substances in various ways to limit diversion, abuse, and illicit manufacturing and distribution. The following two DEA chemical categories are the ones that most often raise questions in our research laboratories:

DEA *Controlled* Substances: The federal Controlled Substances Act, enacted in 1970, lists approximately 200 drugs or chemicals that have the potential to be addictive or habit forming. The substances are categorized into five lists ranging from Schedule I (The substance has a high potential for abuse and no currently accepted medical use in treatment in the United States) to Schedule V (The drug or other substance has a low potential for abuse and dependency and has currently accepted medical use). Researchers electing to use these chemicals must obtain (and annually maintain) a registration from the DEA prior to purchasing or be listed as an authorized researcher under an existing registration. The Controlled Substances Researchers' Guide provides more information.

DEA *Listed* Chemicals: The federal Chemical Diversion and Trafficking Act (CDTA) lists approximately 40 chemicals as part of a system of regulatory controls intended to address the diversion of chemicals important for illegal manufacture of controlled substances. The CDTA created two categories (called List 1 and List 2) which are precursor chemicals for making illicit drugs and substances. Under the federal regulations for DEA "Listed" chemicals, Distributors and Manufacturers (among others) of List 1 and 2 chemicals must obtain a specific license from the DEA: Labs that order these DEA Listed chemicals are NOT required to obtain the license; however, they may find that some of their chemical distributors may request additional information (e.g.: a "sign off" from a responsible official knowledgeable about the intended work with the precursor; a statement of why a precursor chemical has a legitimate research purpose; a signed Authorized Purchaser Form). There is no strict or standard process for the distributors' due diligence so there are differing approaches used by precursor chemical distributors and manufacturers to satisfy themselves that they are not selling DEA Listed chemicals to clandestine drug labs or other improper actors. This additional scrutiny rarely occurs in the course of ordering by Harvard labs but, when it does, causes confusion with DEA Controlled Substance Requirements. There is no requirement for the lab to obtain a DEA Controlled Substance Registration to purchase, use or store DEA *Listed* Substances. It is prudent, however, for all labs to be attentive to use of chemicals and any potential for inappropriate chemical ordering or use activity (unusually high volume or a chemical not expected as part of the research) and to report any suspicious activity to the PI, department administrator, campus security, or Harvard University Police.

Massachusetts Department of Public Health (MDPH) Schedule VI Controlled Substances

Massachusetts regulations require researchers using DEA Schedule I through V to obtain a MDPH registration in addition to a DEA registration. Further, Massachusetts regulates another Schedule, Schedule VI, which includes all pharmaceutical grade prescription drugs not in DEA Controlled Substance Schedules II - V. Researchers electing to use these chemicals must obtain (and annually maintain) a registration from the MPDH prior to purchasing. The Controlled Substances Researchers' Guide provides more information.

There may be some Schedule VI substances that are chemically similar to prescription drugs (although not pharmaceutical grade) and not intended for use as a prescription drug, in either research animals or humans. These chemicals (e.g.; epinephrine and antibiotics used only *in vitro*) do NOT require a MDPH registration for purchase of the non-prescription version. Be aware that, in research animals, you must use USP pharmaceutical grade drugs (if they are available), unless you have obtained a special written exemption from the Institutional Animal Care and Use Committee (IACUC). It is **not acceptable** to order a non-pharmaceutical grade substance to bypass MDPH Schedule VI prescription drug registration requirements.

References and Resources:

<http://www.deadiversion.usdoj.gov/schedules/> Databases of DEA Controlled and Listed Chemicals

<http://www.ehs.harvard.edu/programs/controlled-substances> *Controlled Substances Researchers' Guide*