OFFICE OF THE CENTER DIRECTOR

Consulting the Controlled Substance Staff on INDs and Protocols That Use Schedule I Controlled Substances and Drugs

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PURPOSE

- This MAPP establishes responsibilities and procedures for consulting the Controlled Substance Staff (CSS) in the Center for Drug Evaluation and Research (CDER) regarding Schedule I INDs and protocols submitted for review.

REGULATORY AUTHORITY

- Title 21 Code of Federal Regulations (CFR) part 1300 requires the Department of Health and Human Services (DHHS) to review and comment on the scientific merit of the studies and qualifications of the investigators conducting research with Schedule I controlled substances and drugs and to report this information to the Drug Enforcement Administration (DEA).

- 21 CFR part 5.10(a)(9) redelegates the function of determining the qualifications and competency of investigators wishing to conduct research with controlled substances and drugs listed in Schedule I, and the merits of the research protocol, to the FDA Commissioner. The Commissioner assigns this responsibility to CSS within CDER.

REFERENCES

- Controlled Substances Act (CSA) of 1970, as amended (primarily 21 U.S.C. 823(f))
- 21 CFR parts 5 and 1300

DEFINITIONS

- **Schedule I Substances and Drugs**: Drugs with high abuse potential and no accepted medical use in the United States. Examples of Schedule I drugs are heroin, marijuana,

lysergic acid diethylamide (LSD), and methaqualone. A complete list of current Schedule I substances and drugs maintained by the DEA can be found on the Internet at http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm.

RESPONSIBILITIES

The Controlled Substances Staff will:

- Represent the Food and Drug Administration (FDA) in interactions with other government agencies concerning controlled substances.
- Serve as the DHHS and FDA liaison to the DEA on Schedule I investigational new drug (IND) applications and protocols.
- Convey information, policy issues, and concerns from the DEA to the Office of New Drugs (OND) and CDER management.
- Review nonclinical studies (which may or may not be part of an IND) and IND clinical protocols using Schedule I substances and drugs to advise the DEA on Schedule I licensure.
- Communicate with DEA on CDER's behalf on the scientific merit of the Schedule I protocols and research and the qualifications of individuals who conduct such research, as required by the CSA. DEA makes the final determination on approving research using Schedule I substances and drugs (21 CFR 1301.18).

PROCEDURES

1. The Office of New Drugs (OND)/Review Divisions will:

Designate an appropriate individual to communicate the following information to CSS within 5 days of receipt of an IND or new protocol involving a Schedule I substance or drug:

- IND Number
- Drug or Controlled Substance Name (generic and trade names, if applicable)
- Sponsor of Application
- Date of Receipt of Application
- Indication for Use
- Dosage
- Route of Administration
- Status of the application or protocol within 24 hours of the final determination of its status (e.g., on hold, partial hold, allowed to proceed)
- Subsequent changes to an IND or protocols involving Schedule I substances and drugs

Notify CSS of the above information by e-mail at: CDER CSS CONSULTS

2. The Office of the Center Director/CSS will:

- Review the Schedule I application, incorporating the information from OND, and advise DEA on the "qualifications and competency of the applicant, as well as the merits of the protocol" (21 U.S.C. 823(f)(5) and 21 CFR 1301.32(c)).
- Convey information, policy issues, and concerns from DEA to OND and CDER management.
- Maintain correspondence with DEA regarding Schedule I researcher INDs and protocols.

EFFECTIVE DATE

This MAPP is effective upon date of publication.