GENERAL PROCEDURAL POLICIES

CONFIDENTIALITY OF CENTER FILES

All CVM employees are responsible for complying with the laws, regulations, and policies governing the release of official files containing data and information that are not available for public disclosure.

Departmental and Agency regulations govern the public disclosure of official records in response to requests for information under the Freedom of Information (FOI) Act.

The Center has specific policies concerning confidentiality of data and information relating to New Animal Drug Applications, Investigational New Animal Drug Applications, Food Additive Petitions, and related files.

1. **Purpose:**

   This guide provides general procedures relating to the maintenance of the confidentiality of data and information in Center files.

2. **Confidentiality of Center Files:**

   All data and information submitted to the Center for Veterinary Medicine should be treated as confidential by CVM employees because submissions may contain trade secrets and commercial or financial information. Revealing such information is a prohibited act (Sec. 301(j) of the Federal Food, Drug, and Cosmetic Act). Supervisors will ensure that all employees are adequately informed of the parts of Sec. 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 20, and related regulations that govern the disclosure of CVM records.

   a. Confidentiality of Data and Information in a New Animal Drug Application and related files (Investigational New Animal Drug Application, Veterinary Master File, Drug Experience Report)

      "NADA file," as used in this section, includes all data and information submitted with or incorporated by reference in the NADA, INADs incorporated into the NADA, supplemental NADAs, reports under 21 CFR 510.300 and 510.301, abbreviated new animal drug applications, master files, and other related submissions. The availability for public disclosure of any record in the NADA file shall be handled

in accordance with the provisions of 21 CFR 514.11 and 514.12.

(1) The existence of an NADA file will not be disclosed by the Food and Drug Administration before approval has been granted, unless it has previously been publicly disclosed or acknowledged.

(2) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure until approval is granted.

b. Confidentiality of Data and Information in a Food Additive Petition

Most information contained in a food additive petition is available for public disclosure as stated in 21 CFR 571.1(h). Procedures to be followed for making such data and information available for public disclosure are described in Policy and Procedures Guide 1240.2501.

c. Confidentiality of Research Data in the Office of Research

Release of information related to research conducted by FDA shall be handled in accordance with the provisions of 21 CFR 20.105. Data and research reports are not releasable until the Division Quality Assurance review of the final report is complete and the final report is accepted by the responsible FDA official.

3. Maintaining Confidentiality of Records in CVM:

a. General procedures for information security relating to industry conferences are stated in Policy and Procedures Guide 1240.2600.

b. Supervisors of CVM units providing correspondence and reviews relating to NADA files (as defined above) are responsible for the physical security of the files.

In units where correspondence that may contain confidential data or information is processed, supervisors will establish, at the team or division level, a secure method for disposing, e.g., shredding of secondary records, such as extra copies, discards, carbon copies, computer printouts, and so forth, to ensure that such records do not go into the general trash disposal.

c. Each individual user of a computer system has a responsibility to ensure that his/her system and the information contained in it are adequately safeguarded from loss, damage, and unauthorized access or alteration. (See CVM Security Review Manual.)

4. **References:**

a. Title 18, United States Code, Section 1905.

b. Federal Food, Drug, and Cosmetic Act, Section 301(j) (21 U.S.C. 331(j)). This section prohibits FDA staff from revealing information concerning a method or process which is entitled to protection as a trade secret.

c. Code of Federal Regulations, Title 21.

(1) Commissioner's Delegation of Authority to disclose official records and information, 21 CFR 5.23 and FDA Staff Manual Guide FDA 1410.7.

(2) Public Information, 21 CFR Part 20.

(3) Food Additive Petitions, 21 CFR 571.1(h).

(4) New Animal Drug Applications, 21 CFR 514.11 and 514.12.

d. FDA Staff Manual Guides:

(1) FDA h:2280.3, Physical Security in Headquarters Activities.

(2) FDA h:2280.4, Removal of Privileged Information from Headquarters Facilities.

(3) FDA h:2280.5, Reports of Loss, Theft, Vandalism or Suspicious Actions Within Headquarters Activities.

(4) FDA h:2280.6, Protection of Privileged Information at Headquarters.