GOOD MANUFACTURING PRACTICE COMPLIANCE STATUS

1. Purpose:

This guide establishes policy concerning the approval of NADAs, ANADAs, Medicated Feed Mill Licenses, and Center research projects for firms that are not in compliance with current good manufacturing practices (CGMPs) in 21 CFR Parts 211, 225 and/or 226.

2. Policy:

a. No new animal drug application (original, abbreviated or supplement to either) or medicated feed mill license will be approved for firms that are not in compliance with cGMPs. Exceptions based on the degree of non-compliance will be determined on a case-by-case basis. An example of an exception is where existing GMP violations at a firm involve a process or area not relevant to the product under consideration, e.g., an NADA for a tablet when the firm may have GMP problems only in its sterile production area. Approval for the application may be granted if Center personnel and Field District Offices concur.

b. Drug products manufactured by firms with significant cGMP violations will not be used in Center intramural or contract research projects.

3. Procedures.

a. Before recommending approval of an NADA,* an ANADA,* or a Medicated Feed Mill License, the reviewer must contact the appropriate CVM or FDA unit to determine if an applicant or designated firm is in compliance with cGMPs.

Domestic (U.S.) and Foreign Facilities

NADAs* or ANADAs*

The reviewer should contact the GMP Program Manager in HFV-140, ONADE for firms involved in the manufacture of pharmaceutical dosage forms or Type A medicated articles under an NADA* or ANADA*.

* NOTE: Firms referenced in Drug Master Files (DMFs) which are in turn referenced to an NADA or ANADA are also subject to meeting the appropriate cGMPs.

Medicated Feed Mill Licenses

The reviewer should contact the Division of Animal Feeds, Medicated Feeds Team (HFV-226) for firms involved in the manufacture of Type B and C medicated feeds.

b. If the proposed facility manufactures human drugs, the Division of Manufacturing and Product Quality, CDER, (HFD-320) may be contacted to determine if there are any existing regulatory actions related to cGMP violations.

c. The NADE manufacturing reviewer (Division of Manufacturing Technologies) or S&C reviewer (Division of Epidemiology and Surveillance, Division of Compliance or Division of Animal Feeds) has the option of requesting an inspection of the proposed manufacturing facility to determine whether or not the firm can comply with the cGMP commitments listed in the application.

References: CVM P&P Manual Guide 1240.3620

Compliance Program 7368.001 - Pre-NADA/ANADA Inspection Program

Compliance Program 7371.004 - Medicated Feeds Program

Compliance Policy Guide Manual, Chapters 7155a and 56c (MOUs).

d. Application of this policy requires confirmation of the cGMP status of each designated facility in each NADA, ANADA, or Medicated Feed Mill License submission. The status of a facility must also be determined prior to approval of a supplement to an NADA or ANADA.

e. Before using any animal drug or medicated feed in a Center-sponsored research project, the study director or project officer should determine the manufacturer's compliance status with the cGMPs as described above.

4. Responsibility:

a. The Pre-Approval Program Manager, HFV-140, ONADE, is responsible for maintaining access to the cGMP status of domestic, Canadian, and other foreign facilities designated in NADAs, ANADAs, DMFs, and VMFs.

b. The Division of Animal Feeds, Medicated Feeds Team, (HFV-226), S&C is responsible for maintaining access to the cGMP compliance status of medicated feed facilities.

c. The Division reviewing the NADA, ANADA or Medicated Feed Mill License is responsible for ascertaining the current cGMP status before recommending approval of an application.

d. The study director or project officer is responsible for ascertaining the current GMP status of a manufacturer for a drug product to be used in Center research.