OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

GOOD MANUFACTURING PRACTICE COMPLIANCE STATUS

I. PURPOSE

This document establishes policy concerning the approval of (abbreviated) new animal drug applications ((A)NADAs), (generic) investigational new animal drug ((J)INAD) files, Medicated Feed Mill Licenses, and CVM research projects for firms that are not in compliance with current Good Manufacturing Practices (cGMPs) in 21 CFR Parts 211, 225 and/or 226.

II. POLICY

No (A)NADA (original or supplement) 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 CVM personnel and Field District Offices concur.

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

III. PROCEDURES

Before recommending approval of an (A)NADA,[1] (J)INAD,[1] 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

(A)NADAs[1] and (J)INADs[1]

The reviewer should contact the cGMP Pre-Approval Program Manager in HFV-140, Office of New Animal Drug Evaluation (ONADE) for firms involved in the manufacture of pharmaceutical dosage forms or Type A medicated articles under an (A)NADAs[1] or (J)INADs[1], as described in P&P 1243.8500.

[1] Firms referenced in Drug Master Files (DMFs), which are in turn referenced by an (A)NADA or (J)INAD, are also subject to meeting the appropriate cGMPs.

Medicated *Feed Mill Licenses*

The reviewer should contact the Division of Animal Food Ingredients in the Office of Surveillance and Compliance (OSC) for firms involved in the manufacture of Type B and C medicated feeds.

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.

The ONADE manufacturing reviewer (Division of Manufacturing Technologies) or OSC reviewer (Divisions of Drug Compliance, Animal Food Ingredients, and Veterinary Product Safety) has the option of requesting an inspection of the proposed manufacturing facility to determine whether or not the firm complies with the cGMP commitments listed in the application.

Application of this policy requires confirmation of the cGMP status of each designated facility in each (A)NADAs, (J)INADs, or Medicated Feed Mill License submission. The facility status must also be determined prior to approval of a supplement to an (A)NADA or (J)INAD.

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

IV. RESPONSIBILITIES

The cGMP 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 (A)NADAs, (J)INADs, DMFs, and VMFs.

The Division of Animal Food Ingredients, OSC is responsible for maintaining access to the cGMP compliance status of medicated feed facilities.

The division reviewing the (A)NADA, (J)INAD, or Medicated Feed Mill License is responsible for ascertaining the current cGMP status before recommending approval of an application.

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 CVM research.

V. REFERENCES

CVM Program Policy and Procedures Manual – ONADE Reviewer's Chapter

1243.8500 cGMP status check

Compliance Program

7368.001 - Pre-NADA/ANADA Inspection Program

7371.004 - Feed Manufacturing Program

7371.005 – Type A Medicated Articles

VI. VERSION HISTORY

September 18, 1998 – Original version.

June 22, 2009 – Revised

June 17, 2022 – Updated to create a word version and format in the proper template.

August 5, 2022 – Quality systems review for minor formatting updates. Updated references to OSC due to office reorganization.

February 6, 2024 – Quality management review completed. No substantive updates needed. The document was put into the office's current template and format.