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GENERAL REVIEW AND ENFORCEMENT POLICIES

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**CENTER FOR VETERINARY MEDICINE RESEARCH ACTIVITIES**

1. Purpose:

This guide defines the objectives of CVM research activities, the types of research supported and responsibilities for its implementation.

2. Research Objectives:

All research activities supported by the Center are directly associated with the responsibilities of the Agency to insure the safety and efficacy of animal drugs and devices, and the safety of animal derived human food products. Studies designed to determine the safety of a compound are carried out in compliance with Good Laboratory Practice Regulations (21 CFR Part 58).

a. The primary objectives of the research activities are to provide:

- (1) Data necessary to establish Agency policies in regulatory veterinary medicine.
- (2) Data to minimize the level of pathogens in food from food-producing animals.
- (3) Timely and definitive scientific support to the Center Director and Divisions within the Center.
- (4) Responses to immediate and well-defined Center problems, e.g., confirmation of NADA data.
- (5) An insight to long range, less well-defined problems affecting regulatory policy and activities of the Center.

b. An additional objective is the continued development of scientific expertise in specialized fields and disciplines needed to support the Center's operation.

3. Categories of Research Activities Include:

- a. Development, improvement, and validation of analytical methods and techniques for drug residues, additives, and contaminants in animal tissues and feeds.
  - b. Development of research methodology, procedures, models, and data useful for the evaluation of the safety and efficacy of animal drugs.
  - c. Projects involving immediate or potential problems of public health associated with contamination by drugs, chemicals, or microbiological sources directly involving animal health or indirectly human health through foods from animals.
  - d. Studies initiated by other FDA Centers involving specialized animal experimentation.
4. Responsibility for Research Activities:
- a. The Director, Office of Research has the primary responsibility for implementation of all research undertaken by the Center. All research activities conducted by CVM, both intramural and extramural projects, shall be coordinated through the Director, Office of Research.
  - b. Additionally, the Director, Office of Research is responsible for:
    - (1) Providing current scientific information, when necessary, to support the Center's regulatory policies and decisions.
    - (2) Developing and monitoring the Center's research program.
    - (3) Evaluating research results in terms of Center policy and activities.
    - (4) Managing MOD II to support Agency needs for non-rodent animal support.