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CENTER FOR VETERINARY MEDICINE

OFFICE OF NEW ANIMAL DRUG EVALUATION

DIVISION OF BIOMETRICS & PRODUCTION DRUGS

1. Division of Biometrics & Production Drugs
2. Authority and Effective Date

1. DIVISION OF BIOMETRICS & PRODUCTION DRUGS (HFV-120).

- a. Evaluates, for animal safety and effectiveness, applications for new animal drugs used for production purposes in food animals, and recommends procedures to establish the safety and effectiveness of drugs for production use in food animals and provides such information to investigators, drug sponsors, and manufacturers.
- b. Determines the adequacy of information submitted to support proposed use of investigational drugs for production purposes in food animals; evaluates proposed labeling to assure that it clearly indicates the use and limitations of the product and provides other required information.
- c. Evaluates statistical validity and adequacy of ongoing and proposed experiments and studies submitted by sponsors in support of both proposed and marketed animal drugs, medicated feeds, food additives, veterinary medical devices, and other veterinary medical products; designs, develops, and applies new mathematical and statistical methods when existing techniques are inadequate; provides Center-wide biometrical, statistical, mathematical, and scientific computational support to the regulatory and research activities of the Center; and serves as a consultant to the Agency and Federal and State organizations regarding biometrical issues.
- d. Provides technical and scientific support and expert testimony in legal proceedings relative to the approval or withdrawal of approval of new animal drugs for production purposes.
- e. Recommends, and may participate in, intramural and extramural research projects to be conducted or coordinated with other Center

components to gain further information on production drugs for food animals.

- f. Participates in the development and implementation of regulations and policies pertaining to drugs intended for production use in food animals.
- g. Evaluates division activities to ensure compliance with the National Environmental Policy Act (NEPA).

2. AUTHORITY AND EFFECTIVE DATE: The functional statements for this Division were approved by the Deputy Commissioner for Operations on January 23, 1997.