CENTER FOR VETERINARY MEDICINE

OFFICE OF NEW ANIMAL DRUG EVALUATION

1. Office of New Animal Drug Evaluation
2. Authority and Effective Date

1. OFFICE OF NEW ANIMAL DRUG EVALUATION (HFV-100).

a. Evaluates for animal safety and effectiveness new animal drugs in pharmaceutical dosage forms or for use in animal feed, and the safety aspects of drug and food additive residues remaining in food produced for human consumption from animals, intentionally or otherwise, administered drugs or food additives.

b. Reviews and determines the adequacy of information submitted in support of proposed use of investigational new animal drugs, and recommends to the Center Director appropriate action on New Animal Drug Applications (NADA) and acts on Investigational New Animal Drug (INAD) notices of exemption and authorization requests.

c. Evaluates manufacturing methods and procedures for new animal drug products.

d. Coordinates the development and implementation of regulations and policies pertaining to new drugs intended for animal use.

e. Evaluates Office activities to ensure compliance with the National Environmental Policy Act (NEPA).

f. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs.

g. Participates in international activities designed to harmonize the drug approval process.

2. AUTHORITY AND EFFECTIVE DATE: The functional statements for this

Office were approved by the Deputy Commissioner for Operations on January 23, 1997.