CENTER FOR VETERINARY MEDICINE

OFFICE OF NEW ANIMAL DRUG EVALUATION

DIVISION OF MANUFACTURING TECHNOLOGIES

1. DIVISION OF MANUFACTURING TECHNOLOGIES (HFV-140).

a. Evaluates raw material specifications to determine that the ingredients are adequate to insure the identity, strength, quality, and purity of the drug product; reviews the drug product formulation for composition, characteristics, and accuracy.

b. Evaluates specifications and methods of analysis for the drug product and its components in its dosage forms; recommends product expiration dates from stability data.

c. Evaluates the total manufacturing and control operations of a drug product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an NADA and ANADA.

d. Coordinates laboratory trials of methods of analysis for drug dosage forms and medicated feed preparations; recommends regulatory methods, and provides technical support when requested by FDA field laboratories.

e. Participates in the development and implementation of regulations, guidance and policies pertaining to manufacturing issues for drugs and feed additives intended for animal use.

f. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved animal drug products.

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.