CENTER FOR VETERINARY MEDICINE

OFFICE OF SURVEILLANCE AND COMPLIANCE

DIVISION OF SURVEILLANCE

1. DIVISION OF SURVEILLANCE (HFV-210).

a. Evaluates the safety and effectiveness of marketed animal drugs, special dietary feeds, veterinary medical devices, and other veterinary medical products and recommends action to correct deficiencies resulting from inadequate directions for use, warnings, and cautionary information.

b. Evaluates drug product labels and other information to determine new animal drug status, regulatory priority, acceptable conditions of use, and need for regulatory activity. Maintains and makes available inventory listing of all marketed animal drugs to ensure adequate information is available for regulatory activity and customer support. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.

c. Reviews marketed product labeling and makes recommendations concerning label revisions, regulatory supplements, suspension of manufacturing, and withdrawal of approval of new animal drugs to ensure marketed products are safe and effective.

d. Monitors and evaluates promotion of marketed veterinary drugs to ensure promoted claims are consistent with approved claims.

e. Evaluates reports of product adverse experiences to ensure labeling contains a current accurate safety profile, identify unsafe products, and unsafe product uses. Maintains liaison with other agencies and organizations engaged in similar activities to identify product interactions and coordinate activities. Participates in outreach programs to encourage veterinarians to participate in the pharmacovigilance program.

f. Manages compliance programs covering regulated industries in animal drugs, veterinary medical devices, and other veterinary medical products to ensure the effectiveness of the programs. Reviews establishment inspection reports, labeling, and other findings to determine whether regulated products are being marketed in accordance with the Act and

Agency regulations and policy.

2. AUTHORITY AND EFFECTIVE DATE. The functional statements for this Division were approved by the Deputy Commissioner for Operations on December 2, 2005**.**