1. Division of Pharmacovigilance and Surveillance (DCGDA)

A. Evaluates the safety and effectiveness of marketed animal drugs, 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. Maintains and makes available inventory listings of all marketed animal drugs to ensure adequate information is available for regulatory activity and customer support.

C. Reviews marketed product labeling to make 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 the safety and effectiveness of marketed unapproved animal drugs, veterinary medical devices, and other veterinary medical products to establish medical risk as related to animal and public health. Coordinates with the Division of Drug Compliance and other CVM Divisions to determine enforcement priorities and risk mitigation strategies.

F. Monitors adverse drug event database to identify safety signals and effectiveness issues of concern.

G. Evaluates adverse event reports to ensure labeling contains a current accurate safety profile, identifies unsafe products, and unsafe product uses.

H. Coordinates with FDA District Offices to receive and evaluate product defect reports for the identification of product safety issues. Interacts with other FDA centers to ensure appropriate investigatory and risk mitigation measures are taken by the FDA. Analyzes data and relevant information to assess the need for product recalls.
I. Maintains liaison with other government entities and organizations engaged in similar activities to identify product interactions and coordinate activities.

J. Provides pre-market and post-market surveillance of drug product medication errors to CVM review divisions.

K. Participates in outreach programs to encourage veterinarians to participate in the pharmacovigilance program and to educate veterinarians, animal owners, and the public regarding the medical risk and benefits of veterinary products.

L. Provides consulting reviews to the Office of New Animal Drug Evaluation as part of the pre-market new animal drug evaluation process, including review of medicated feed labels.

2. Authority and Effective Date

The functional statements for the Office were approved by the Acting Commissioner of Food and Drugs on December 7, 2021 and effective on February 9, 2022.
The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Pharmacovigilance and Surveillance organization structure depicting all the organizational structures reporting to the Director of Pharmacovigilance and Surveillance:

Division of Pharmacovigilance and Surveillance (DCGDA)