1. Division of Drug Compliance (DCGDC)

A. Coordinates the preparation of evidence concerning withdrawal/refusal to approve animal drugs and the documentation for a formal evidentiary hearing. Coordinates the preparation of administrative and evidentiary records for a hearing.

B. Develops, monitors, and evaluates the Center’s bioresearch monitoring programs and their investigative and regulatory follow-up. Manages the application integrity policy.

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

D. Coordinates drug recall activities.

E. Coordinates and prepares compliance and enforcement-oriented replies to inquiries from consumers, State and Federal governments, Congress, industry, etc.

F. Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal drugs, medical devices, and other veterinary medical products. Prepares and issues guidance to the field offices.

G. Performs preliminarily reviews of Establishment Inspection Reports, investigations, complaints and other information on regulated products. Coordinates investigative and regulatory follow-up through consultation with management, legal, and scientific advisors. Reviews proposed regulatory actions submitted by the field offices and recommends whether such actions should be pursued further by the FDA.
H. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.

I. Reviews unapproved and compounded animal drugs and provides scientific support for enforcement actions; determines the jurisdictional classification of animal drugs, biologics and medical devices; participates in policy development; and evaluates scientific, compliance and regulatory issues related to health hazards and medically necessary veterinary products.

J. Conducts surveillance of illegal internet marketing and works closely with the Office of Regulatory Affairs / Office of Criminal Investigations (ORA/OCI) on cases of illegal marketing of unapproved and counterfeit drugs intended for use in animals.

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 Drug Compliance organization structure depicting all the organizational structures reporting to the Director of Drug Compliance:

Division of Drug Compliance (DCGDC)