SMG 1244.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine

Office of Surveillance and Compliance

Effective: September 30, 2022

1. Office of Surveillance and Compliance (DCGD).

- A. Advises the Center Director on surveillance and compliance policy concerning Food and Drug Administration (FDA) regulatory responsibility with respect to animal drugs, food, and devices.
- B. Oversees and coordinates (as necessary) the work of the Office's surveillance and monitoring programs to ensure the safety and effectiveness of animal drugs, food, and devices
- C. Coordinates the Office's animal drug, food, and device policy initiatives
- D. Provides scientific, policy, and regulatory expertise to the Center as needed
- E. Coordinates the Office's business process improvement and communication needs
- F. Serve as a focal point of coordination with other offices within CVM and across the Agency related to post-market animal drug, food, and device programs
- G. Monitors the animal drug and food supply chain and coordinates the Center's response to supply chain issues and animal drug shortages.

2. Regulatory Counsel Staff (DCGD1).

- A. Advises Center leadership and staff on legal, policy and regulatory issues affecting animal drugs, food, and devices.
- B. Develops evidence to support enforcement and regulatory actions; and procedures pertinent to implementing regulatory authorities and programs. Identifies issues needing resolution by the Office of the Chief Counsel.
- C. Drafts, and assists in the review and revision of, proposed regulations, guidance documents, and correspondence (e.g., responses to petitions or congressional inquiries), that state or interpret Office, Center, or FDA policy and typically involve industry-wide impact, broad public health implications, or precedent-setting interpretations of FDA policy, to ensure legal sufficiency and compliance with Good Guidance Practices or other requirements.

D. Represent the Office in crosscutting (affecting multiple offices or Centers) compliance and regulatory policy development initiatives (e.g., working groups, committees, etc.).

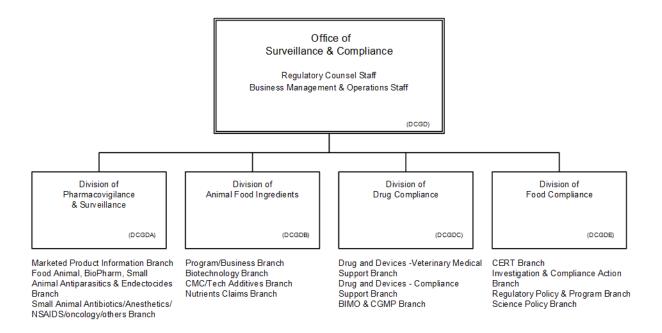
3. Business Management and Operations Staff (DCGD2).

- A. Manages payroll and operating budgets.
- B. Provides Human Resources support for the whole office.
- C. Provides general administrative support for the whole office.
- D. Manages acquisition contracts and supports the office with Contracting Officer Representatives (CORs).

4. Authority and Effective Date.

The functional statements for the Office of Surveillance and Compliance were approved by the Commissioner of Food and Drugs on August 11, 2022, and effective on September 30, 2022.

Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine Office of Surveillance and Compliance



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance organization structure depicting all the organizational structures reporting to the Director of Surveillance and Compliance:

Office of Surveillance and Compliance (DCGD).

These organizations report to the Office of Surveillance and Compliance:

Regulatory Counsel Staff

Business Management and Operations Staff

Division of Pharmacovigilance and Surveillance (DCGDA)

Division of Animal Food Ingredients (DCGDB)

Division of Drug Compliance (DCGDC)

Division of Food Compliance (DCGDE

These organizations report to the Division of Pharmacovigilance and Surveillance (DCGDA):

Marketed Product Information Branch

Food Animal, BioPharm, Small Animal Antiparasitics & Endectocides Branch Small Animal Antibiotics/Anesthectics/NSAIDS/oncology/others Branch

These organizations report to the Division of Animal Food Ingredients (DCGDB):

Program-Business Branch

Biotechnology Branch

Chemistry Manufacturing and Controls (CMC) Tech Additives Branch

Nutrients Claims Branch

These organizations report to the Division of Drug Compliance (DCGDC):

Drug and Devices-Veterinary Medical Support Branch

Drug and Devices-Compliance Support Branch

Bioresearch Monitoring (BIMO) & Current Good Manufacturing Practice (CGMP) Branch

These organizations report to the Division of Food Compliance (DCGDE):

Complaints, Emergencies, and Recall Team (CERT) Branch

Investigation & Compliance Action Branch

Regulatory Policy & Program Branch

Science Policy Branch