SMG 1244.12

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

Division of Drug Compliance

Effective: September 30, 2022

1. Division of Drug Compliance (DCGDC).

A. Evaluates the safety and effectiveness of marketed unapproved animal drugs, animal medical devices, and other animal health products and recommends action to correct deficiencies resulting from inadequate directions for use, warnings, and cautionary information.

B. Evaluates the safety and effectiveness of marketed unapproved animal drugs, animal medical devices, and other animal health products to establish medical risk as related to animal and public health.

C. Evaluates drugs products labels and other information to determine new animal drug status, regulatory priority, acceptable conditions of use, and need for regulatory activity. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.

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

E. 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.

F. Coordinates drug recall activities.

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

H. 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.

I. 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.

J. Coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities.

K. 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.

L. 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.

M. Coordinates activities related to the laws, regulations, and policies applicable to the import and export of animal drugs, animal medical devices, and other animal health products.

2. Drug and Devices-Veterinary Medical Support Branch (DCGDC1).

A. Reviews unapproved drugs, compounded animal drugs, and animal bioengineering and cellular therapies; provides scientific support for regulatory actions (including enforcement discretion).

B. Determines the jurisdictional classification of animal drugs, animal biologics and animal medical devices.

C. Evaluates scientific, compliance and regulatory issues related to recall-related health hazards and shortages of medically necessary veterinary products.

D. Provides scientific support and surveillance for illegal internet marketing and criminal investigations on cases involving illegal unapproved and counterfeit drugs intended for use in animals.

3. Drug and Devices-Compliance Support Branch (DCGDC2).

A. Oversees regulatory action (including enforcement discretion) involving unapproved drugs, compounded animal drugs, and animal bioengineering and cellular therapies.

B. Provides compliance support related to the jurisdictional classification of animal drugs, and animal medical devices.
C. Oversees regulatory actions involving illegal internet marketing and works closely with the Division of Compliance and the Office of Criminal Investigations on cases of illegal marketing of unapproved and counterfeit drugs intended for use in animal.
D. Provides support to activities related to drug and device recalls and imports.

4. BIMO and CGMP Branch (DCGDC3).

A. Provides expertise regarding BIMO inspections, approval support (GLP, CL, sponsor monitor), inventory and BIMO Compliance Program maintenance, and administrative action support.

B. Evaluates establishments, sterile and non-sterile finished dosage form animal drugs, drug components, and APIs through CGMP inspections.

C. Monitors the quality of drugs through surveillance activities and evaluating products via agency programs (including evaluating foreign regulator inspectional findings conducted under mutual recognition agreements, complaints, field alert reports, and drug experience reports).

D. Provides support to activities related export certificates.

5. Authority and Effective Date.

The functional statements for the Division of Drug 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
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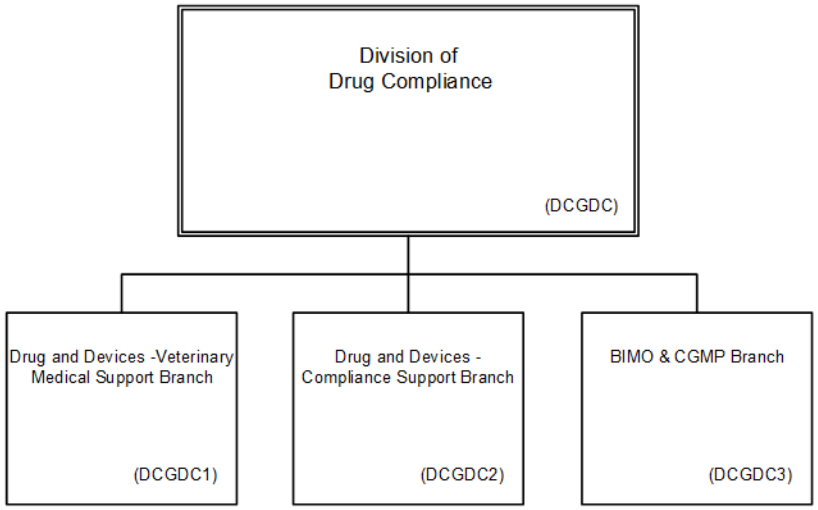

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Organizations and Functions
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance, Division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

Division of Drug Compliance (DCGDC)

Drug and Devices-Veterinary Medical Support Branch (DCGDC1)

Drug and Devices-Compliance Support Branch (DCGDC2)

BIMO and CGMP Branch (DCGDC3)