

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 Pharmacovigilance and Surveillance

Effective: September 30, 2022

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. Marketed Product Information Branch (DCGDA1).

- A. Reviews and maintains drug listing and registration for approved and unapproved animal drugs.
- B. Reviews and tabulates reported amounts of animal drugs in commercial distribution, with particular attention to antimicrobials for food animals.
- C. Evaluates animal drug product labels and recommends actions to correct deficiencies.

3. Food Animal, BioPharm, Small Animal Antiparasitics and Endectocides Branch (DCGDA2).

- A. Evaluates adverse event reports for approved and unapproved animal drugs from consumers and industry, post market safety data from industry submissions, and other information available for marketed drugs in order to detect safety signals and evaluate risk; and develop strategies/recommend regulatory actions to mitigate identified risks.
- B. Reviews proposed proprietary trade names for their potential to result in medication errors.
- C. Reviews proposed product labeling for inappropriate promotional content and potential medication error (use error) risks.
- D. Reviews promotional materials for animal drug products and develops actions against false and misleading promotional materials.
- E. Participates in development and implementation of regulations, guidance and policies pertaining to branch functions.

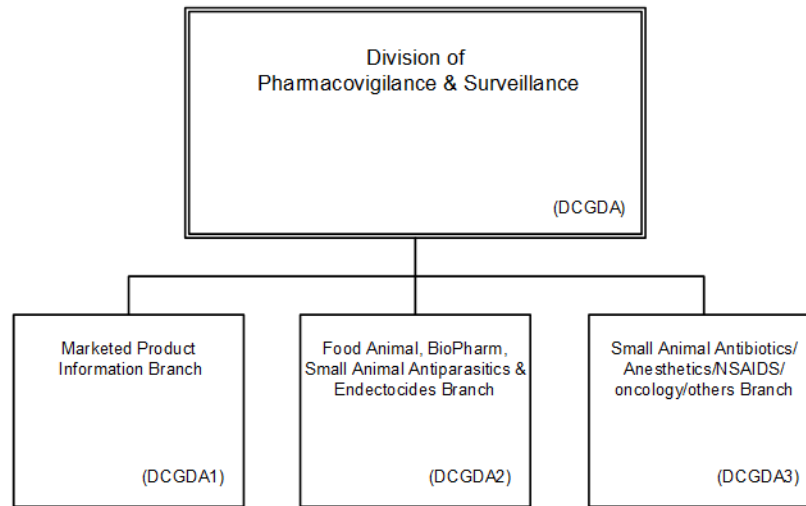
4. Small Animal Antibiotics/Anesthetics/NSAIDS/oncology/others Branch (DCGDA3).

- A. Evaluates adverse event reports for approved and unapproved animal drugs from consumers and industry, post market safety data from industry submissions, and other information available for marketed drugs in order to detect safety signals and evaluate risk; and develop strategies/recommend regulatory actions to mitigate identified risks.
- B. Reviews proposed proprietary trade names for their potential to result in medication errors.
- C. Reviews proposed product labeling for inappropriate promotional content and potential medication error (use error) risks.
- D. Reviews promotional materials for animal drug products and develops actions against false and misleading promotional materials.
- E. Participates in development and implementation of regulations, guidance and policies pertaining to branch functions.

5. Authority and Effective Date.

The functional statements for the Division of Pharmacovigilance and Surveillance 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
Division of Pharmacovigilance and Surveillance**



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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 Pharmacovigilance and Surveillance organization structure depicting all the organizational structures reporting to the Director of Pharmacovigilance and Surveillance:

Division of Pharmacovigilance and Surveillance (DCGDA)

Marketed Product Information Branch (DCGDA1)

Food Animal, BioPharm, Small Animal Antiparasitics and Endectocides Branch
(DCGDA2)

Small Animal Antibiotics/Anesthetics/NSAIDS/oncology/others Branch (DCGDA3)