

**SMG 1246.1**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Food and Drug Administration**

**Office of Foods and Veterinary Medicine**

**Center for Veterinary Medicine**

**Office of Minor Use and Minor Species Animal Drug Development**

Effective: December 14, 2018

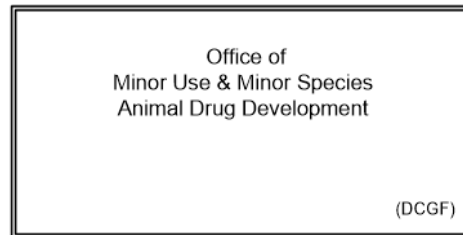
**1. Office of Minor Use and Minor Species Animal Drug Development (DCGF).**

- A. Evaluates requests for designation of new animal drugs intended for minor use or minor species and evaluates requests for grants subsequent to designation in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 573.
- B. Ensures appropriate indexing of new animal drugs for minor use or minor species in accordance with the FFDCA Section 573. Evaluates requests for determination of the eligibility for indexing of new animal drugs for minor use or minor species. If eligible, assures appropriate review by expert panel. Evaluates expert panel reports and recommendations and, if acceptable, ensures appropriate indexing and publication. Monitors the marketing of indexed products for adverse consequences and continued compliance with the FFDCA.
- C. Monitors animal requests for extension of conditional approval of new animal drugs for minor use and minor species and takes appropriate action in accordance with the FFDCA Section 571.
- D. Coordinates the development and implementation of regulations and policies pertaining to the conditional approval, indexing, or designation of new animal drugs intended for minor use or minor species.
- E. Evaluates office activities to ensure compliance with the National Environmental Policy Act (NEPA).
- F. Provides technical support and expert testimony in legal proceedings relative to the conditional approval, indexing or designation of new animal drugs intended for minor use or minor species.
- G. Participates in international activities designed to harmonize the process of conditionally approving, indexing or designating new animal drugs intended for minor use or minor species.

## **2. Authority and Effective Date**

The functional statements for the Office of Minor Use and Minor Species Animal Drug Development were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
Office of Minor Use and Minor Species  
Animal Drug Development**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Minor Use and Minor Species Animal Drug Development organization structure depicting all the organizational structures reporting to the Office of Minor Use and Minor Species Animal Drug Development:

Office of Minor Use and Minor Species Animal Drug Development (DCGF)