

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 Date: October 1, 2012

1. OFFICE OF MINOR USE AND MINOR SPECIES ANIMAL DRUG DEVELOPMENT (DJJVF).

- 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 Section 573 of the Federal Food, Drug, and Cosmetic Act (FFDCA).
- B. Ensures appropriate indexing of new animal drugs for minor use or minor species in accordance with Section 573 of the FFDCA. 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 Section 571 of the FFDCA.
- 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 this office were approved by the Secretary for Health and Human Services, effective October 1, 2012.

FOOD AND DRUG ADMINISTRATION
OFFICE OF FOODS AND VETERINARY MEDICINE
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OFFICE OF THE DIRECTOR

STAFF MANUAL GUIDE 1246.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: October 1, 2012

The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, 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 Director.

OFFICE OF THE DIRECTOR