

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of New Drugs

Office of Infectious Diseases

Division of Pharmacology Toxicology for Infectious Diseases

Effective Date: September 25, 2019

1. Division of Pharmacology Toxicology for Infectious Diseases (DCDGDC).

- A. Reviews and evaluates non-clinical pharmacology and toxicology data in Investigational New Drug Applications (INDs) and formulates appropriate action; and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions as needed.
- B. Reviews and evaluates the nonclinical pharmacology and toxicology data in New Drug Applications (NDAs) and Biological License Applications (BLAs) and formulates recommendations regarding approvability in accord with applicable delegations of authority.
- C. Develops policies and procedures applicable to the review and evaluation of drugs and biologics for infectious disease products that are consistent with approaches across the pharmacology and toxicology discipline.
- D. Evaluates adequacy of information (e.g., Nonclinical Toxicology section) in proposed labeling for infectious disease products and provides recommendations for modifications.
- E. Develops, in coordination with other Food and Drug Administration (FDA) components, guidance for staff, sponsor and the public that describes the FDA's interpretation of or policy on regulatory issues that involve the Division and the pharmacology and toxicology discipline in general.

2. Authority and Effective Date.

The functional statements for the Division of Pharmacology Toxicology for Infectious Diseases were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services
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Division of
Pharmacology Toxicology for Infectious
Diseases

(DCDGDC)

Staff Manual Guide 1263.53a
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Infectious Diseases, Division of Pharmacology Toxicology for Infectious Diseases organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacology Toxicology for Infectious Diseases (DCDGDC).