

**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 Antivirals**

Effective Date: September 25, 2019

**1. Division of Antivirals (DCDGDB).**

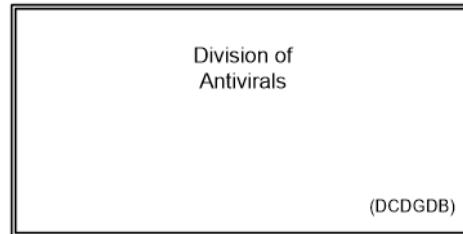
- A. Reviews Investigational New Drugs (INDs) and requests for claimed investigational exemption regulated by this Division and decides on appropriate regulatory action. Develops policies and procedures pertinent to particular aspects of investigation of drugs and biologics.
- B. Evaluates New Drug Applications (NDAs) and Biologics License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable regulations/statute. Evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops regulatory and scientific policies and procedures applicable to the review and evaluation of drugs and biologics for antiviral products.
- C. Evaluates adequacy of information in proposed labeling for antiviral products.
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal or approval of NDAs and BLAs for antiviral products.
- E. Provides advice and information to other components of the Center and to the Food and Drug Administration (FDA) on anti-viral and other specific antimicrobial drug products with regard to medical and scientific issues, status of drug and biologics applications, appropriate policy, and proposed regulatory actions.

- F. Utilizes the advisory committee process to obtain advice on product safety and effectiveness. Participates in FDA sponsored consumer and professional educational programs on drug standards.
- G. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy on regulatory issues for antiviral products.
- H. Provides advice and information on issues related to bioterrorism and emerging infections to other components of the Center, FDA, Department and other relevant parties, in coordination with the Office of Infectious Diseases, Immediate Office staff.

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

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

**Department of Health and Human Services  
Food and Drug Administration  
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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 Anti-viral organization structure depicting all the organizational structures reporting to the Director.

Division of Anti-Viral (DCDGDB).