

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 Immunology & Inflammation

Division of Gastroenterology

Effective Date: September 25, 2019

1. Division of Gastroenterology (DCDGCA).

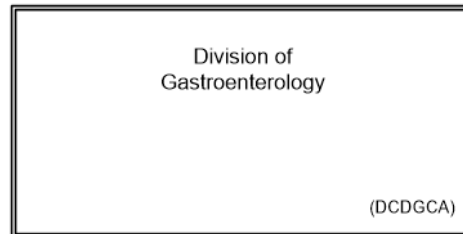
- A. Reviews Investigational New Drugs and requests for claimed investigational exemption for gastroenterology products and decides on appropriate regulatory action. Develops policies and procedures pertinent to particular aspects of investigation of drugs and biologics.
- B. Evaluates New Drug Applications (NDAs) and Biologic License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable regulations/statutes. 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 gastroenterology products.
- C. Evaluates adequacy of information in proposed labeling for gastroenterology products.
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for gastroenterology products.
- E. Provides advice and information to other components of the Center and to the Food and Drug Administration (FDA) on gastroenterological 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 or policy on regulatory issues for gastroenterology products.
- H. Performs medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and Over-the-Counter drug products regulated by other offices in the Center, as applicable.

2. Authority and Effective Date.

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

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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 Immunology & Inflammation, Division of Gastroenterology organization structure depicting all the organizational structures reporting to the Director.

Division of Gastroenterology (DCDGCA).