

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 Specialty Medicine

Division of Imaging & Radiation Medicine

Effective Date: September 25, 2019

1. Division of Imaging & Radiation Medicine (DCDGJB).

- A. Reviews Investigational New Drugs 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 for medical imaging and radiation medicine.
- 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/statutes. Also 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 medical imaging and radiation medicine.
- C. Evaluates adequacy of information in proposed labeling for medical imaging and radiation medicine products.
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for medical imaging and radiation medicine products.
- E. Provides advice and information to other components of the Center and to the Food and Drug Administration (FDA) on imaging and radiation medicine 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 that involve medical imaging and radiation medicine.
- H. Provides advice and information to other components of the Center and to the FDA on drugs products and biologics used in the areas of medical imaging, including nuclear medicine, radiation safety and elimination as well as medical countermeasures for radiation exposure with regard to medical and scientific issues, status of processing of drug applications, appropriate policy and proposed regulatory actions.
- I. Reviews reports submitted to the radioactive drug research committee program and decides appropriate regulatory action.
- J. 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 Imaging & Radiation were approved by the Secretary of Health and Human Services on September 25, 2019.

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Division of Imaging & Radiation Medicine**

Division of
Imaging & Radiation
Medicine

(DCDGJB)

Staff Manual Guide 1263.132
Organizations and Functions
Effective Date: September 25, 2019

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 Specialty Medicine, Division of Imaging & Radiation Medicine organization structure depicting all the organizational structures reporting to the Director.

Division of Imaging & Radiation Medicine (DCDGJB).