

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF NEW DRUGS

OFFICE OF DRUG EVALUATION IV

DIVISION OF MEDICAL IMAGING PRODUCTS

Effective Date: 01/12/2010

1. DIVISION OF MEDICAL IMAGING PRODUCTS (DBNREF)

- A. Reviews investigational new drugs (INDs) and decides on appropriate action, including approval or disapproval of research plans and protocols, modifications, and restrictions. Develops policies and procedures pertinent to particular aspects of drug investigation
- B. Evaluates new drug applications (NDAs) and biological license applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs regulated by the division
- C. Evaluates adequacy of directions for use, warnings, and other information in proposed labeling for products regulated by the division
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for drugs and biologics regulated by the division
- E. Works collaborate with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical experience and reports submitted by IND sponsors, by NDA applicants and from other sources
- F. Provides advice and information to other components of the Center and to the Agency 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

- G. Develops, in coordination with other Agency components, guidance for staff, sponsors and the public that describes the Agency's interpretation of or policy on regulatory issues that involve the division

2. AUTHORITY AND EFFECTIVE DATE

This functional statement was approved by the Commissioner of Food and Drugs on January 12, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/12/2010	N/a	OC/OA/ OM/OMP	Commissioner of Food and Drugs

**FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF OF NEW DRUGS
OFFICE OF DRUG EVALUATION IV
DIVISION OF MEDICAL IMAGING PRODUCTS**



OFFICE OF THE DIRECTOR

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Organizations and Functions
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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluation IV, Division of Medical Imaging Products depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR