

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 Neuroscience

Division of Neurology I

Effective Date: September 25, 2019

1. Division of Neurology I (DCDGAB).

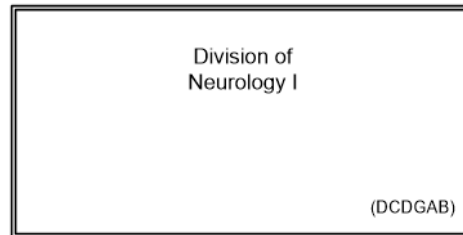
- A. Reviews Investigational New Drugs and requests for claimed investigational exemption for the treatment of movement disorders, epilepsy, dementia, and cognitive disorders and decides on appropriate regulatory action. Develops policies and procedures pertinent to particular aspects of investigation 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. 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 the treatment of movement disorders, epilepsy, dementia, and cognitive disorders.
- C. Evaluates adequacy of information in proposed labeling for drug products for the treatment of movement disorders, epilepsy, dementia, and cognitive disorders .
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for drug products for the treatment of movement disorders, epilepsy, dementia, and cognitive disorders.

- E. Provides advice and information to other components of the Center and to the Food and Drug Administration (FDA) on drug products for the treatment of movement disorders, epilepsy, dementia, and cognitive disorders with respect 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 the Division.
- 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 Neurology I were approved by the Secretary of the Health and Human Services on September 25, 2019.

**Department of Health and Human Services
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Division of Neurology I**



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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 Neuroscience, Division of Neurology I organization structure depicting all the organizational structures reporting to the Director.

Division of Neurology I (DCDGAB).