

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 II

Effective Date: September 25, 2019

1. Division of Neurology II (DCDGAC).

- A. Reviews Investigational New Drugs and requests for claimed investigational exemption for treatment of migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular) 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 treatment of migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular).
- C. Evaluates adequacy of information in proposed labeling for treatment of migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular) products.
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for treatment of igraines, traumatic

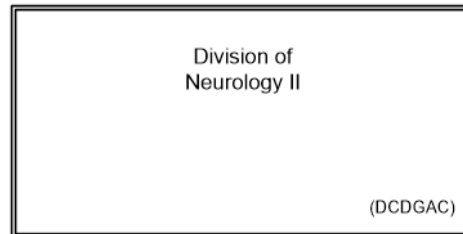
brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular) products.

- 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 migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular) 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 II were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
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Division of Neurology II**



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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 II organization structure depicting all the organizational structures reporting to the Director.

Division of Neurology II (DCDGAC).