

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 Neuroscience

Division of Pharmacology Toxicology for Neuroscience

Effective Date: September 25, 2019

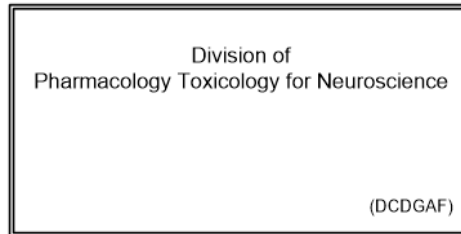
1. Division of Pharmacology Toxicology for Neuroscience (DCDGAF).

- A. Reviews and evaluates non-clinical pharmacology and toxicology data in Investigational New Drug applications (INDs) and formulates appropriate action and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions as needed.
- B. Reviews and evaluates New Drug Applications (NDAs) and Biological License Applications (BLAs) and formulates recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs and biologics regulated by the Division that are consistent with approaches across the pharmacology and toxicology discipline.
- C. Evaluates adequacy of information (e.g., Nonclinical Toxicology section) in proposed labeling for drug products used for the treatment of movement disorders, epilepsy, dementia, cognitive disorders migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular); anesthetics, analgesics, and addiction; and psychiatric products and provides recommendations for modifications.
- D. Develops, in coordination with other Food and Drug Administration components, guidance for staff, sponsor and the public that describes the Agency's interpretation of or policy on regulatory issues that involve drug products used for the treatment of movement disorders, epilepsy, dementia, cognitive disorders, migraines, traumatic brain injuries, ear disorders, neuromuscular disorders, multiple sclerosis, and stroke (vascular); anesthetics, analgesics, and addiction; and psychiatric products and provides recommendations for modifications and the pharmacology and toxicology discipline in general.

2. Authority and Effective Date.

The functional statements for the Division of Pharmacology Toxicology for Neuroscience 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
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Division of Pharmacology Toxicology for Neuroscience**



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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 Pharmacology Toxicology for Neuroscience organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacology Toxicology for Neuroscience (DCDGAF).