

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 Cardiology, Hematology, Endocrinology & Nephrology

Division of Pharmacology Toxicology for Cardiology, Hematology,

Endocrinology & Nephrology

Effective Date: September 25, 2019

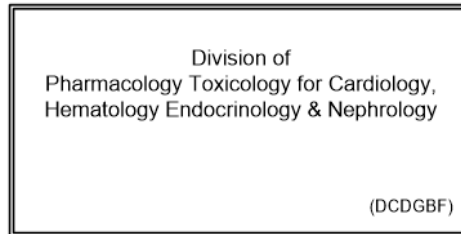
1. Division of Pharmacology Toxicology for Cardiology, Hematology, Endocrinology & Nephrology (DCDGBF).

- 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 the nonclinical pharmacology and toxicology data in 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 for cardiology, hematology, endocrinology, and nephrology products 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 cardiology, hematology, endocrinology, and nephrology products and provides recommendations for modifications.
- D. Develops, in coordination with other Food and Drug Administration (FDA) components, guidance for staff, sponsor and the public that describes the FDA's interpretation of or policy on regulatory issues that involve the Division and the pharmacology and toxicology discipline in general.

2. Authority and Effective Date.

The functional statements for the Division of Cardiology, Hematology, Endocrinology & Nephrology were approved by the Secretary of Health and Human Services on September 25, 2019.

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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 for Cardiology, Hematology, Endocrinology & Nephrology, Division of Pharmacology Toxicology for Cardiology, Hematology, Endocrinology & Nephrology organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacology Toxicology for Cardiology, Hematology, Endocrinology & Nephrology (DCDGBF).