

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 Oncologic Diseases

Division of Hematology Oncology Toxicology

Effective Date: September 25, 2019

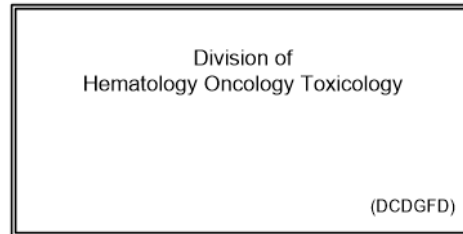
1. Division of Hematology Oncology Toxicology (DCDGFD).

- A. Reviews non-clinical pharmacology and toxicology data in Investigational New Drug applications and decides on appropriate action and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions. Develops policies and procedures pertinent to particular aspects of drug and biologics investigations.
- B. Evaluates New Drug Applications and Biological License Applications for nonclinical pharmacology and toxicology 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 and biologics related to hematology oncology toxicology.
- C. Evaluates adequacy of information in proposed labeling for products related to hematology oncology toxicology.
- 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.

2. Authority and Effective Date.

The functional statements for the Division of Hematology Oncology Toxicology 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 Hematology & Oncology Products, Division of Hematology Oncology Toxicology organization structure depicting all the organizational structures reporting to the Director.

Division of Hematology Oncology Toxicology (DCDGFDF).