

**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 HEMATOLOGY AND ONCOLOGY PRODUCTS**

**DIVISION OF HEMATOLOGY ONCOLOGY TOXICOLOGY**

Effective Date: 05/20/2011

**1. DIVISION OF HEMATOLOGY ONCOLOGY TOXICOLOGY (DKKNRMD).**

- A. Reviews non-clinical pharmacology and toxicology data in investigational new drug applications (INDs) 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 (NDAs) and biological license applications (BLAs) 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 regulated by the division.
- C. Evaluates adequacy of directions for use, warnings, and other information (e.g., Nonclinical Toxicology section) in proposed labeling for products regulated by the division.
- D. Develops, in coordination with other Agency components, guidance for staff, sponsor and the public that describes the Agency's interpretation of or policy on regulatory issues that involve the Division.

## 2. AUTHORITY AND EFFECTIVE DATE.

This functional statement was approved by the Director, Center for Drug Evaluation and Research, effective May 20, 2011.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	05/20/2011	N/a	CDER/OM	Director, Center for Drug Evaluation and Research

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DIRECTOR

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The following is the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Hematology and Oncology Products, Division of Hematology Oncology Toxicology organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR