

**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 PRODUCTS

Effective Date: 05/20/2011

1. DIVISION OF HEMATOLOGY PRODUCTS (DKKNRMB).

- A. Reviews investigational new drug applications (INDs) and decides on appropriate action, including 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 safety and effectiveness 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 in proposed labeling for products regulated by the division.
- D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for drugs and biologics regulated by the division.
- E. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical experience and reports submitted by IND sponsors, by NDA and BLA applicants and from other sources.
- F. 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 for this Division was approved by the Director, Center for Drug Evaluation and Research, effective May 20, 2011.

| STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|-----------------------------|--------------------------|-------------------------------------------|------------------|-------------------------------------------------------------|
| Initial | 05/01/2005 | N/a | OC/OO/OM /OMP | Acting Director, Center for Drug Evaluation and Research |
| Revision | 01/12/2010 | N/a | OC/OA/OM /OMP | Commissioner of Food and Drugs |
| Revision | 05/20/2011 | N/a | CDER/OM | Commissioner of Food and Drugs |

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OFFICE OF
THE DIRECTOR

STAFF MANUAL GUIDE 1263.75
ORGANIZATIONS AND FUNCTIONS
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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 Products organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR