SMG 1263.70

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

Effective Date: 05/20/2011

1. OFFICE OF HEMATOLOGY AND ONCOLOGY PRODUCTS (DKKNRM).

A. Reviews notices of claimed investigational exemptions for new drugs and biologics (INDs) within hematology and oncology products regulated by the Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

B. Evaluates for safety and effectiveness and approves new drug applications (NDAs) and biological license applications (BLAs) for hematology and oncology products regulated by the Office, and evaluates supplements that propose changes in the conditions upon which NDA and BLA approvals are based.

C. Develops policy and procedures governing the review and evaluation of drug and biologics investigations.

D. Evaluates and takes appropriate action on recommendations concerning recalls and withdrawal of approval of NDA, BLAs and other products regulated by the Office.

E. Coordinates and directs a cross cutting Food and Drug Administration (FDA) Oncology Program, including an Agency-wide Oncology Coordinating Committee to insure proactive and consistent policies and approaches to the development of anticancer therapies.

F. Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs, and BLAs for oncology products regulated by the Office.

G. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by IND sponsors, NDA applicants, BLA applicants and from other sources.

H. Performs consulting medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

I. Develops, in coordination with other Agency components, guidance for staff, sponsors and the public that describes the Agency's interpretation of or policy on regulatory issues that involve the Office.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were 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	05/20/2011	N/a	CDER/OM	Director, Center for Drug Evaluation and Research

FOOD AND DRUG ADMINISTRATION
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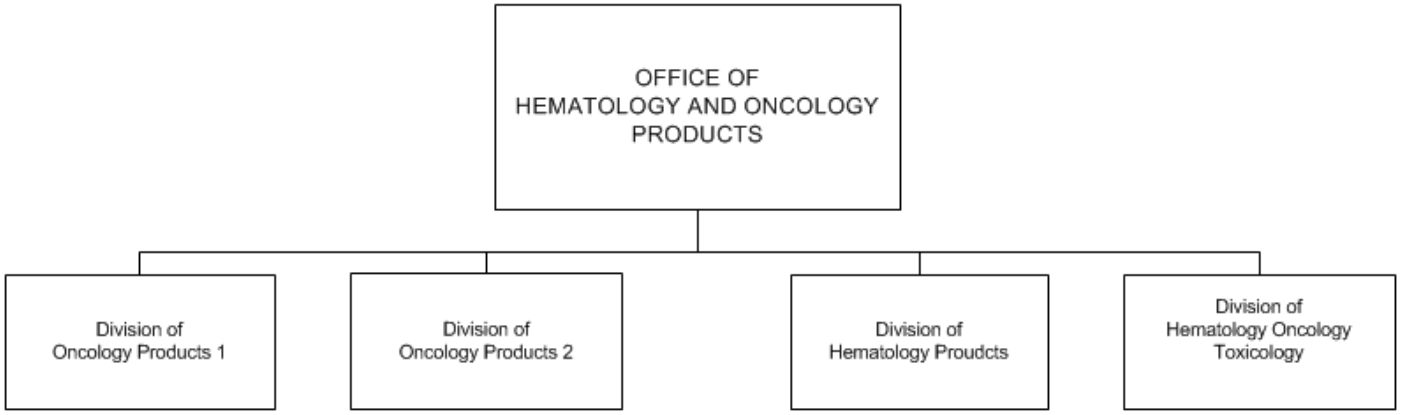

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The following is the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Hematology and Oncology Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF HEMATOLOGY AND ONCOLOGY PRODUCTS:

- Division of Oncology Products 1
- Division of Oncology Products 2
- Division of Hematology Products
- Division of Hematology Oncology Toxicology