SMG 1263.75

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 Hematologic Malignancies I

Effective Date: September 25, 2019

1. Division of Hematologic Malignancies I (DCDGFB).

A. Reviews Investigational New Drug applications and requests for claimed investigational exemption regulated by this Division 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. Also evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops policies and procedures applicable to the review and evaluation of drugs and biologics for hematologic malignancies.

C. Evaluates adequacy of information in proposed labeling for hematologic malignancy products.

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for hematologic malignancy drugs and biologics.

E. 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 hematologic

malignancy products. Participates in FDA sponsored consumer and professional educational programs on drug standards.

F. Performs 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, as applicable.

2. Authority and Effective Date.

The functional statements for the Division of Hematologic Malignancies I were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
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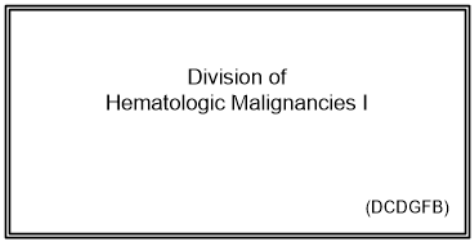
Division of Hematologic Malignancies I



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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 Oncologic Disease, Division of Hematologic Malignancies I organization structure depicting all the organizational structures reporting to the Director.

Division of Hematologic Malignancies I (DCDGFB).

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