SMG 1263.36

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 Cardiology, Hematology, Endocrinology & Nephrology

Division of Non-Malignant Hematology

Effective Date: September 25, 2019

1. Division of Non-Malignant Hematology (DCDGBE).

A. Reviews Investigational New Drugs (INDs) and requests for claimed investigational exemption regulated by this Division and decides on appropriate regulatory action. Develops policies and procedures pertinent to particular aspects of investigation of drugs and biologics.

B. Evaluates New Drug Applications (NDAs) and Biologics License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable regulations/statutes. Evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops regulatory and scientific policies and procedures applicable to the review and evaluation of drugs and biologics for non-malignant hematology products.

C. Evaluates adequacy of information in proposed labeling for non-malignant hematology products.

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for non malignant hematology products.

E. Provides advice and information to other components of the Center and to the Food and Drug Admniistration (FDA) on non-malignant hematology drug products with regard to medical and scientific issues, status of processing of drug and biologics applications, appropriate policy, and proposed regulatory actions.

F. Utilizes the advisory committee process to obtain advice on product safety and effectiveness. Also participates in FDA sponsored consumer and professional educational programs on drug standards..

G. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of or policy on regulatory issues that involve non malignant hematology products.

H. 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 Non-Malignant Hematology were approved by the Secretary of Health and Human Services on September 25, 2019.

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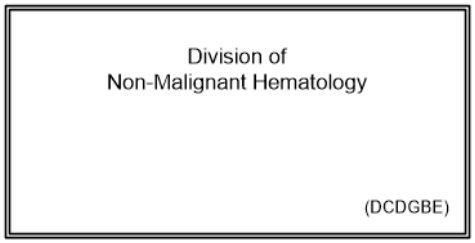

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of for Cardiology, Hematology, Endocrinology & Nephrology, Division of Non-Malignant Hematology organization structure depicting all the organizational structures reporting to the Director.

Division of Non-Malignant Hematology (DCDGBE).