SMG 1263.70

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

Effective Date: September 25, 2019

1. Office of Oncologic Diseases (DCDGF).

A. Reviews notices of claimed investigational exemptions for Investigational New Drugs (INDs) and biologics within hematology and oncology products 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 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 hematology and oncology products.

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

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

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 FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of or policy on regulatory issues.

2. Authority and Effective Date.

The functional statements for the Office of Oncologic Diseases were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
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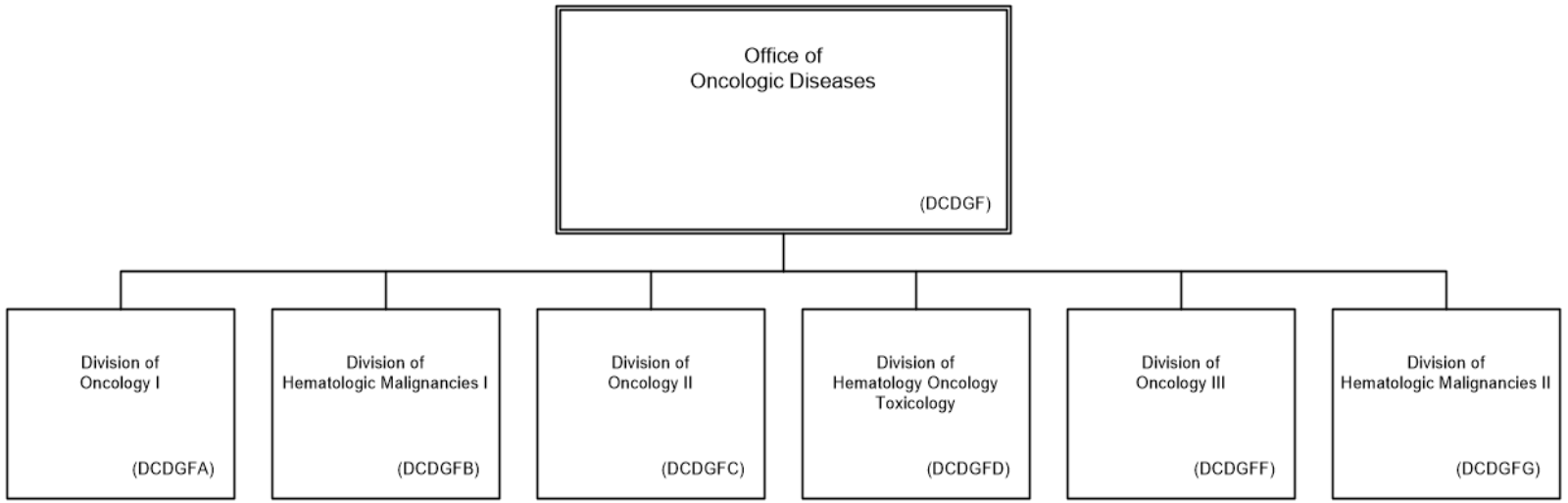

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Oncologic Diseases organization structure depicting all the organizational structures reporting to the Director.

Office of Oncologic Diseases (DCDGF).

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