This document is scheduled to be published in the
Federal Register on 07/27/2017 and available online at
https://federalregister.gov/d/2017-15443, and on **FDsys.gov**

Billing Code: 4160

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Office of the Commissioner

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Medical Products and Tobacco (OMPT), has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 22, 2016, and became effective on that date.

FOR FURTHER INFORMATION CONTACT: Rachel Sherman, M.D., Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco, Food and Drug Administration, White Oak Bldg. 1, HFD-40, Room 2307, Silver Spring, Maryland, 20993. Phone: 240-402-4474.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and

76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of Medical Products and Tobacco.

This reorganization establishes the Oncology Center of Excellence (OCE) to optimize an integrated cross-center regulatory approach and enhance the coordination of medical product development in oncology. Located within OMPT, OCE will work closely with the directors of the centers, the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and all FDA staff involved in oncology efforts. The OCE will be responsible, in accordance with an Inter-Center Agreement between OCE, CBER, CDER, and CDRH, for the clinical portion of medical oncology and malignant hematology applications involving drugs, biologics, and devices. Other functions of the OCE include: harmonization of cancer-specific regulatory approaches; coordination of oncology-specific regulatory science initiatives and outreach; implementation of cross-center oncology-focused meetings; stakeholder engagement to the external community of other government agencies, industry, academia, professional societies, and patient advocacy groups; and communication with international regulatory agencies.

The Food and Drug Administration (FDA), Office of Medical Products and Tobacco (OMPT), has been restructured as follows:

DKK. ORGANIZATION. The Office of Medical Products and Tobacco is headed by the Deputy Commissioner for Medical Products and Tobacco and includes the following organizational units and FDA Centers that, under the current structure, officially report to OMPT:

Office of Medical Products and Tobacco (DKK)

Office of Special Medical Products (DKKA)

Office of Pediatric Therapeutics (DKKAA)

Office of Orphan Products Development (DKKAB)

Office of Combination Products (DKKAD)

Center for Biologics Evaluation and Research (DKKB)

Center for Tobacco Products (DKKI)

Center for Drug Evaluation and Research (DKKN)

Center for Devices and Radiological Health (DKKW)

Oncology Center of Excellence (DKKX)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm

(Authority: 44 U.S.C. 3101)

Dated: July 17, 2017.

_____

Thomas E. Price,
Secretary of Health and Human Services
[FR Doc. 2017-15443 Filed: 7/26/2017 8:45 am; Publication Date: 7/27/2017]