

SMG 1267.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF EXECUTIVE PROGRAMS

Effective Date: 11/20/2013

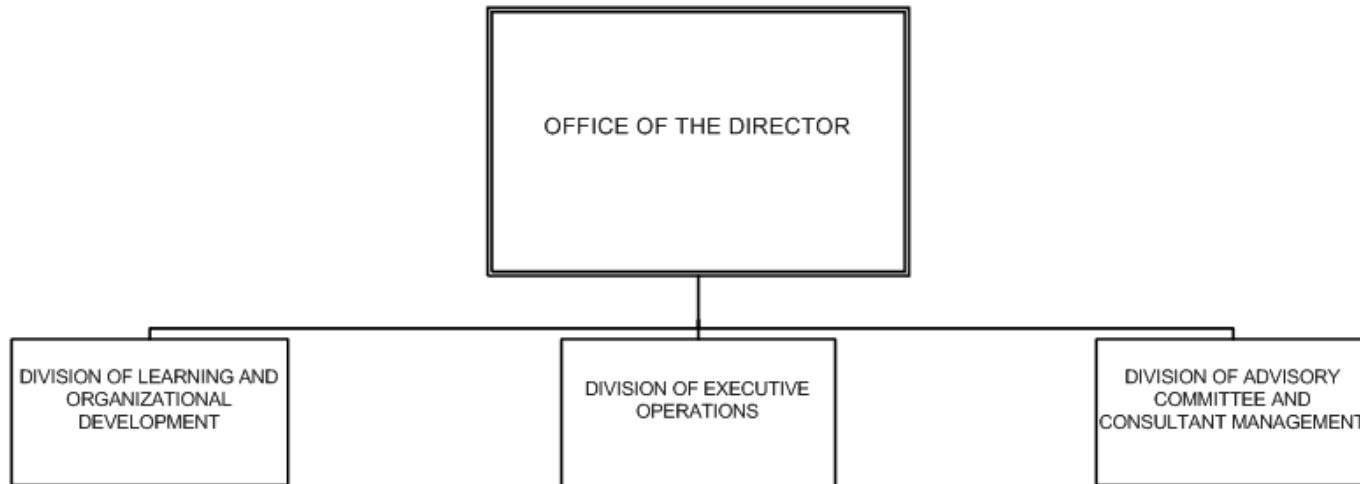
1. OFFICE OF THE DIRECTOR (DKKNH).

- A. Coordinates the operations of the Office of the Center Director, insuring that the goals and priorities of the Center Director are carried out.
- B. Advises and assists the Center Director and other key officials on center programmatic matters.
- C. Oversees the administrative management program for the Office of the Center Director, Office of Regulatory Policy, and the Office of Executive Programs.
- D. Coordinates Ombudsman activities, including managing informal dispute resolution between regulated industry and CDER, managing informal dispute resolution within CDER for scientific and review issues, responding to consumer and industry inquiries and investigating complaints, receiving and assessing feedback on CDER programs and advising CDER Director about problems and proposes solutions.
- E. Coordinates inter-center product jurisdiction activities, including establishing and representing CDER's position on which FDA center is most appropriate for reviewing a combination product, responding to formal and informal requests for assignment of combination and non-combination products, and serve as the point of contact and information source regarding product jurisdiction.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this division were approved by the Director, Center for Drug Evaluation and Research on November 20, 2013.

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Executive Programs organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF LEARNING AND ORGANIZATIONAL DEVELOPMENT
- DIVISION OF EXECUTIVE OPERATIONS
- DIVISION OF ADVISORY COMMITTEE AND CONSULTANT MANAGEMENT