

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR TOBACCO PRODUCTS

OFFICE OF SCIENCE

Effective Date: 03/24/2014

1. OFFICE OF SCIENCE (DKKIE).

- A. Conducts scientific research and product review programs to support the Center's goals for implementing the Family Smoking Prevention and Tobacco Control Act, as part of a comprehensive effort to reduce the toll of disease, disability, and death caused by tobacco products.
- B. Serves as the focal point for overall management of Center activities related to science priorities and resources. Advises and assists the Center Director, Commissioner of Food and Drugs, and other key officials on scientific issues related to tobacco product regulation that have an impact on public health, policy, direction, and long-range goals, and on the functions, capabilities, and management of scientific research facilities; and participates with other agency components in planning such facilities.
- C. Represents the Center in interactions with other government agencies, state and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on tobacco science and regulation issues.

2. REGULATORY SCIENCE AND MANAGEMENT STAFF (DKKIE1).

- A. Coordinates and provides guidance on regulatory science policy in program areas that cross major agency component lines, and on scientific aspects of critical or controversial issues.
- B. Coordinates scientific workshops and the Tobacco Products Scientific Advisory Committee which advises the Center Director, Commissioner of Food and Drugs, Secretary of Health and Human Services, and other key officials on certain issues related to the public health impact of tobacco products.
- C. Conducts and ensures product reviews.

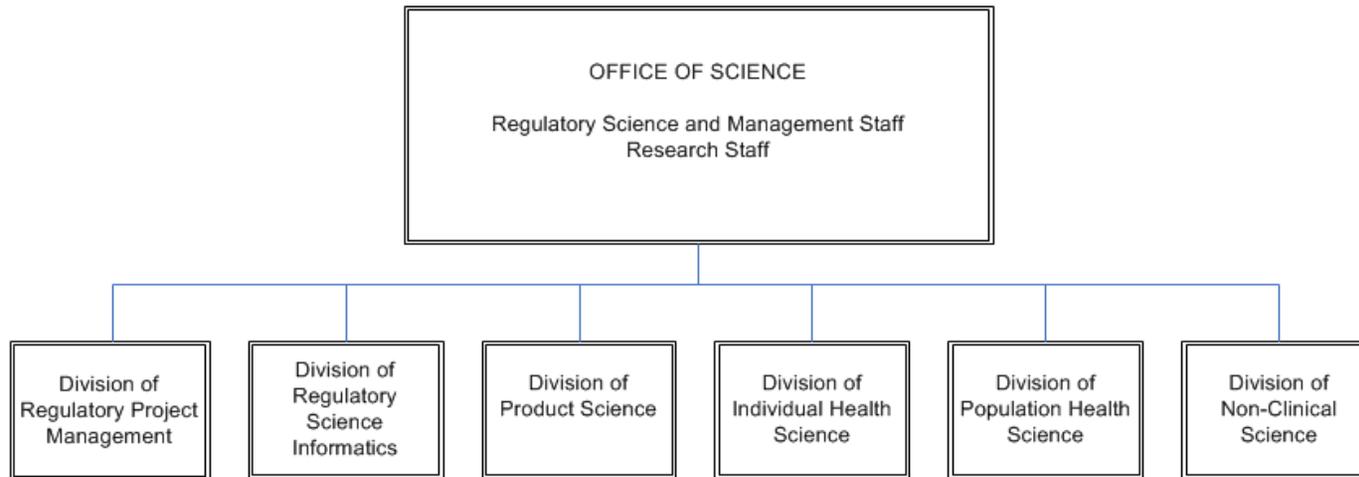
3. RESEARCH STAFF (DKKIE2).

- A. Identifies the gaps in scientific knowledge related to tobacco regulatory science and coordinates targeted research to address Center priorities in collaboration with leading scientists in other segments of Food and Drug Administration (FDA), other Federal agencies, and the scientific community at large.
- B. Provides scientific expertise for making regulatory decisions.
- C. Oversees human subjects' protections reviews for Center research.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office of Science were approved by the Deputy Commissioner for Operations/Chief Operating Officer and effective on 03/24/2014.

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STAFF MANUAL GUIDE 1355.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: March 24, 2014

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

OFFICE OF THE DIRECTOR:

- REGULATORY SCIENCE AND MANAGEMENT STAFF
- RESEARCH STAFF
- DIVISION OF REGULATORY PROJECT MANAGEMENT
- DIVISION OF REGULATORY SCIENCE INFORMATICS
- DIVISION OF PRODUCT SCIENCE
- DIVISION OF INDIVIDUAL HEALTH SCIENCE
- DIVISION OF POPULATION HEALTH SCIENCE
- DIVISION OF NON-CLINICAL SCIENCE