SMG 1354.1

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 REGULATIONS

Effective Date: 07/08/2011

1. OFFICE OF REGULATIONS (DKKID).

A. Provides Center's oversight and leadership in, and coordinates the development of regulations, policies, procedures, and guidance related to the regulation of tobacco products.

B. Reviews and clears draft regulations developed by the Center, other FDA Centers, and other agencies.

C. Provides Center-level leadership and coordination for briefings within FDA, and with DHHS, OMB and other Federal agencies related to regulations and guidance documents.

D. Serves as the Center's focal point for developing and maintaining communications, policies, and programs with regard to regulations development, review, clearance and publication.

E. Serves as the Center's primary liaison with the FDA's Office of Chief Counsel and the DHHS Office of General Counsel; and provides support for legal defense in litigation.

F. Manages the development and implementation of plans for the Center's regulation development activities.

G. Provides technical assistance on the development of legislative proposals related to FDA responsibilities of the Family Smoking Prevention and Tobacco Control Act.

H. Manages the Citizens' Petition process on behalf of the Center.

I. Supports Center in its regulatory litigation activities.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services effective July 8, 2011.

Staff Manual Guide 1354.1
Organizations and Functions
Effective Date: July 8, 2011

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STAFF MANUAL GUIDE 1354.1
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EFFECTIVE DATE: July 8, 2011

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

OFFICE OF THE DIRECTOR