SMG 1140A.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

Effective Date: 07/08/2011

1. OFFICE OF MEDICAL PRODUCTS AND TOBACCO (DKK).

A. Provides executive leadership, management and policy direction to all FDA medical-product- and tobacco-related programs

B. Exercises, on behalf of the Commissioner, direct line authority over the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Tobacco Products (CTP)

C. Directs the activities of FDA's special medical programs, including the Office of Combination Products, the Office of Orphan Products Development, the Office of Good Clinical Practice, and the Office of Pediatric Therapeutics

D. Directs efforts to integrate the programs, as necessary, of CDER, CBER, CDRH, and CTP and thereby ensure the optimal use of all available FDA resources and tools to improve the safety and proper labeling of medical products and tobacco

E. Directs the development of integrated strategies, plans, policies and budgets to build FDA's medical product- and tobacco-related scientific and regulatory capacities and programs, including recruitment and training of key personnel and development of information systems

F. Represents FDA on medical product- and tobacco-related matters in dealing with the Office of the Secretary of Health and Human Services, the White House, other elements of the executive branch, and with the Congress

G. In conjunction with the Deputy Commissioner for Global Regulatory Operations and Policy, represents FDA on medical product- and tobacco-related matters in dealing with foreign governments and international organizations

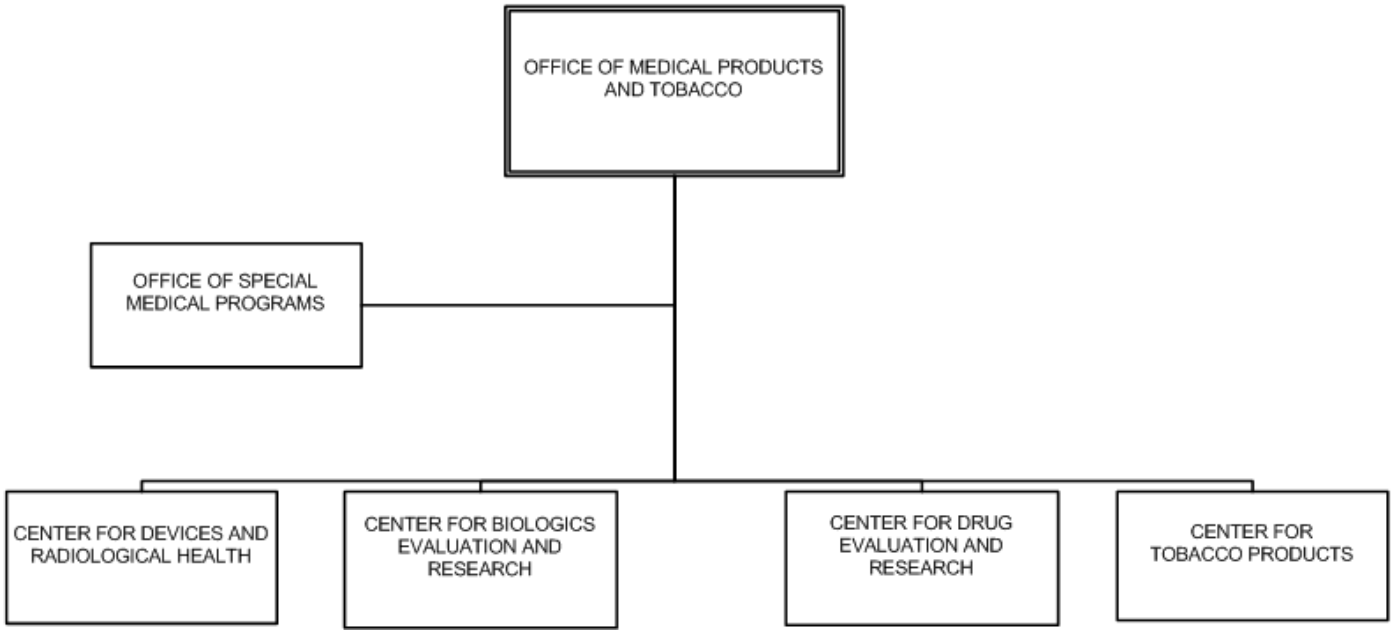
H. Directs FDA efforts to build consistency and uniformity in the evaluation for safety and efficacy of new medical products and new tobacco products

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.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/07/2009	N/a	OC/OA/OM/OBOH CP/OMP	Secretary of the Department of Health and Human Services
Revision	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO



STAFF MANUAL GUIDE 1140A.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: July 8, 2011

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

OFFICE OF MEDICAL PRODUCTS & TOBACCO:

- OFFICE OF SPECIAL MEDICAL PROGRAMS
- CENTER FOR DEVICES & RADIOLOGICAL HEALTH
- CENTER FOR BIOLOGICS EVALUATION & RESEARCH
- CENTER FOR DRUG EVALUATION & RESEARCH
- CENTER FOR TOBACCO PRODUCTS