SMG 1141.11

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

OFFICE OF SPECIAL MEDICAL PROGRAMS

OFFICE OF COMBINATION PRODUCTS

Effective Date: 07/08/2011

1. OFFICE OF COMBINATION PRODUCTS (DKKAD)

A. Serves as the Agency focal point for combination products (i.e., drug device, drug-biologic, device-biologic or drug-biologic-device products)

B. Serves as the Agency Product Jurisdiction Office and administers 21 CFR Part 3. (i.e., when classification or assignment is unclear or in dispute, classifies products as biologics, devices, drugs or combination products and assigns them to the agency centers with primary jurisdiction)

C. Advises the Commissioner and other key agency officials on policy formulation, execution, cross-cutting and precedent setting issues involving combination products and involving the classification of products as biologics, devices, drugs, or combination products

D. Develops regulations, guidances, policies, procedures, and processes to facilitate classification and assignment of biologics, devices, drugs, and combination products, and to facilitate the agency's regulation, review, and oversight of combination products

E. Reviews and updates agreements, guidance or practices specific to classification or assignment of products as biologics, devices, drugs, or combination products

F. Serves as the focal point for employees and stakeholders to resolve issues arising during assignment and premarket review of combination products

G. Ensures consistency and appropriateness of postmarket regulation of like products to the extent permitted by law and serves as the focal point for

employees and stakeholders to resolve issues relating to postmarket regulation of such products

H. Ensures timely and effective premarket review of combination products by overseeing the timeliness of intercenter consultations and assisting reviews involving more than one agency center when necessary

I. Prepares annual reports to Congress on the activities and impact of the Office

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	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: July 8, 2011

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

OFFICE OF COMBINATION PRODUCTS