SMG 1113B.3

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Chief Medical Officer

Office of Combination Products

Effective Date: May 13, 2024

1. Office of Combination Products (DCJB).

A. Serves as the Food and Drug Administration (FDA) focal point for combination products (i.e., drug device, drug-biologic, device-biologic or drug-biologic-device products).

B. Serves as the FDA 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 FDA 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, guidance, 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 post market 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 post market regulation of such products including current good manufacturing practices (cGMP) and safety reporting.

H. Ensures timely and effective, and aligned premarket review of combination products by overseeing the timeliness of intercenter consultations and assisting reviews involving more than one FDA 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 the Office of Combination Products were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Medical Officer
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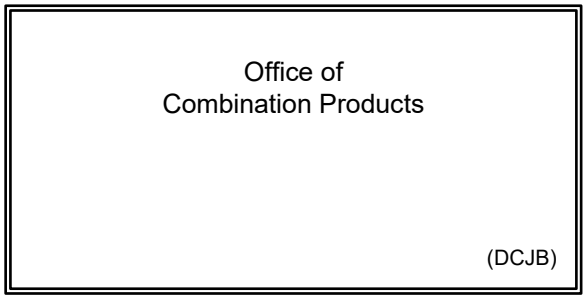

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Medical Officer, Office of Combination Products organization structure depicting all the organizational structures reporting to the Director: