SMG 1355.2

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

DIVISION OF REGULATORY PROJECT MANAGEMENT

Effective Date: 03/24/2014

1. DIVISION OF REGULATORY PROJECT MANAGEMENT (DKKIEA).

A. Directs the tobacco product review process from initial submission to the time of regulatory action.

B. Serves as the regulatory expert and primary point of contact for communications with regulated entities including industry and researchers related to product submissions.

C. Develops and implements policies and procedures governing the submission and review of applications and other regulatory submissions including substantial equivalence, pre-market tobacco applications, and modified risk tobacco product applications.

2. REGULATORY PROJECT MANAGEMENT BRANCH I (DKKIEA1).

A. Coordinates scientific projects including product review activities.

B. Performs administrative and regulatory screening of applications and other submissions.

C. Develops and implements policies and procedures governing the development of product standards and regulatory submissions not addressed by other branches.

3. REGULATORY PROJECT MANAGEMENT BRANCH II (DKKIEA2).

A. Coordinates scientific projects including product review activities.

B. Performs administrative and regulatory screening of applications and other submissions.

C. Develops and implements policies and procedures governing the submission and review of substantial equivalence and other regulatory submissions.

4. REGULATORY PROJECT MANAGEMENT BRANCH III (DKKIEA3).

A. Coordinates scientific projects including product review activities.

B. Performs administrative and regulatory screening of applications and other submissions.

C. Develops and implements policies and procedures governing the submission and review of pre-market tobacco applications and other regulatory submissions.

5. REGULATORY PROJECT MANAGEMENT BRANCH IV (DKKIEA4).

A. Coordinates scientific projects including product review activities.

B. Performs administrative and regulatory screening of applications and other submissions.

C. Develops and implements policies and procedures governing the submission and review of modified risk tobacco product applications and other regulatory submissions.

6. AUTHORITY AND EFFECTIVE DATE.

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

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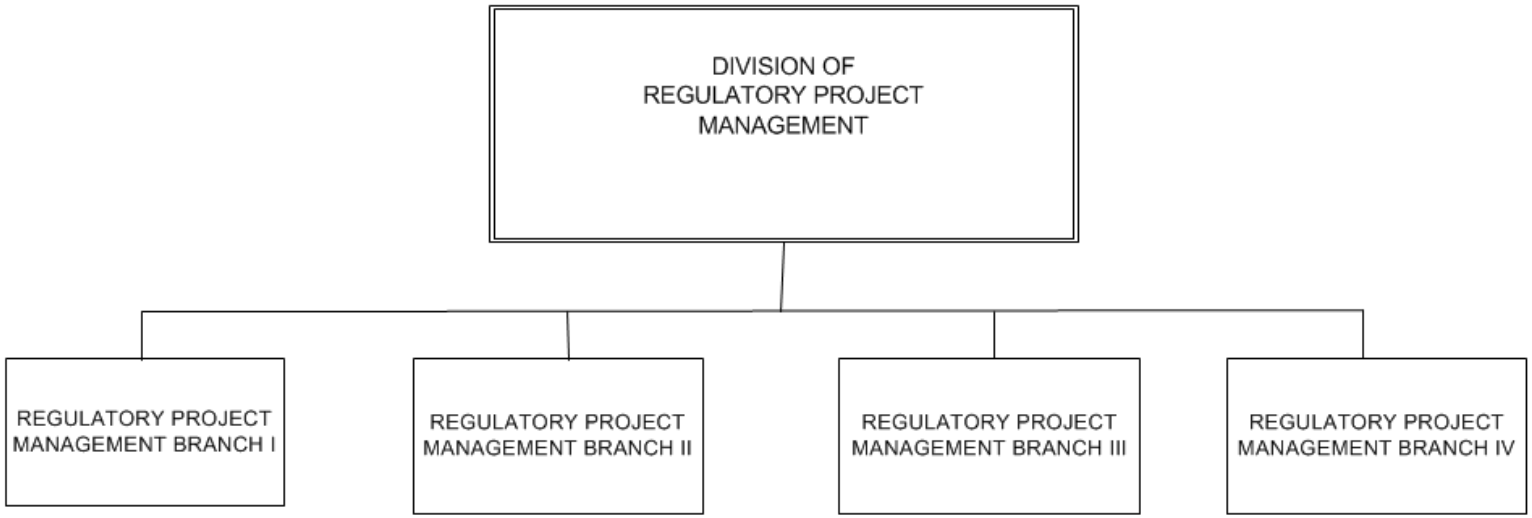

STAFF MANUAL GUIDE 1355.2
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: March 24, 2014

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

OFFICE OF THE DIRECTOR:

- REGULATORY PROJECT MANAGEMENT BRANCH I
- REGULATORY PROJECT MANAGEMENT BRANCH II
- REGULATORY PROJECT MANAGEMENT BRANCH III
- REGULATORY PROJECT MANAGEMENT BRANCH IV