

**SMG 1354.1**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Tobacco Products**

**Office of Regulations**

Effective Date: December 14, 2018

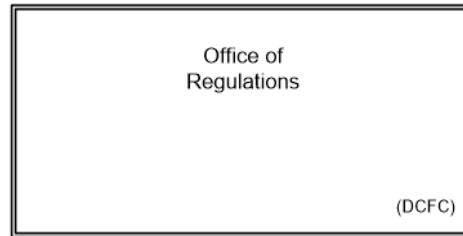
**1. Office of Regulations (DCFC).**

- A. Provides Center 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 Federal 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 Center 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 the Center in its regulatory litigation activities.

## **2. Authority and Effective Date.**

The functional statements for the Office of Regulations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products  
Office of Regulations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Office of Regulations organization structure depicting all the organizational structures reporting to the Office Director:

Office of Regulations (DCFC)