

**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 Scientist**

**Office of Cosmetics and Colors**

**Division of Cosmetics**

Effective Date: May 13, 2024

**1. Division of Cosmetics (DCPIB).**

- A. Administers the provisions of the Food, Drug and Cosmetics Act and other legislation relevant to cosmetics, including the provisions of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).
- B. Develops guidelines, regulations, and policies for cosmetics and color additives in cosmetics.
- C. Provides expert scientific and technical support for cosmetics and color additives in cosmetics.
- D. Provides technical assistance and management of compliance activities related to cosmetics and applicable color additives.
- E. Communicates policy, guidance, and information for cosmetics and color additives in cosmetics and supports other units in this area.

**2. Cosmetics Regulatory Activities Branch (DCPIB1).**

- A. Provides subject matter expertise related to cosmetics-related regulations.
- B. Develops policies for regulation of cosmetic products and ingredients as well as enforcement policy and guidance in association with the Office of the Chief Scientist (OCS).

- C. Reviews establishment inspection reports and investigation memoranda from the Food and Drug Administration (FDA) inspections and investigations program and evaluates for regulatory follow-up.
- D. Collaborates with and provides advice to FDA's inspections and investigations program for onsite inspections of cosmetics-related facilities to monitor compliance.
- E. Evaluates complaints and other issues to initiate for cause inspection assignments, as warranted.
- F. Evaluates corrective actions taken by cosmetics establishments.
- G. Works to ensure industry compliance with reporting requirements.
- H. Coordinates with the Cosmetics Regulatory Science Branch to identify and address emerging concerns related to cosmetics products.
- I. Administers the cosmetics product facility registration and listing program.
- J. Supports the helpdesk function for the cosmetics product facility registration and listing program and responds to complex issues that cannot be addressed by the helpdesk.
- K. Answers inquiries from other federal agencies, global regulatory partners, and industry regarding interpretations of FDA enforced laws and regulations related to cosmetics.
- L. Develops responses to press and congressional inquiries related to cosmetics.
- M. Provides advice and counsel on recall policy and procedures.

### **3. Cosmetics Regulatory Science Branch (DCPIB2).**

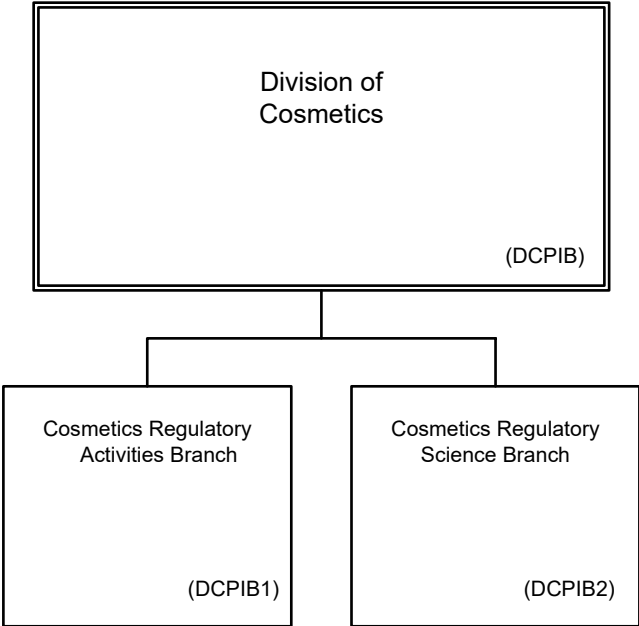
- A. Maintains scientific expertise and leadership within the global scientific community in issues related to cosmetics and cosmetic ingredients.
- B. Plans and supports research related to the oversight of cosmetics to develop a scientific base for establishing standards and informing regulatory decision-making needs.
- C. Monitors serious and non-serious adverse events and works with the Cosmetics Regulatory Activities Branch to respond to potential signals indicated through analysis of adverse event reports.

- D. Develops and utilizes data analytic approaches to monitor signals and trends related to cosmetics to identify areas of concern and works with the Cosmetics Regulatory Activities Branch to ensure public health protection.
- E. Works with research offices in the OCS and other FDA components on the development of analytical methods for detecting new emerging substances in cosmetics and to address necessary research activities to answer specific regulatory questions.

**4. Authority and Effective Date.**

The functional statements for the Division of Cosmetics 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 Scientist  
Office of Cosmetics and Colors  
Division of Cosmetics**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Division of Cosmetics organization structure depicting all the organizational structures reporting to the Director:

Cosmetics Regulatory Activities Branch (DCPIB1)

Cosmetics Regulatory Science Branch (DCPIB2)