SMG 1231.16

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Food Additive Safety

Effective Date: December 14, 2018

1. Office of Food Additive Safety (DCEG).

A. Serves as the Center focal point for scientific and policy support for the development of Food and Drug Administration (FDA)-initiated regulations on matters pertaining to the provisions of the food and color additive sections of the Federal Food, Drug, and Cosmetic Act.

B. Manages the Center's petition review processes (both those conducted in- house and under extramural contract) for food additives and color additives, and consultation/notification processes for GRAS (Generally Recognized As Safe) substances, food contact substances, and foods and food ingredients derived from recombinant DNA biotechnology. Evaluates safety information, compiles the administrative record supporting actions on petitions and other FDA actions, and prepares Federal Register documents relating to petitions.

C. Prepares and/or reviews documentation required by the Center to implement the National Environmental Policy Act (NEPA). Coordinates the Center review of documents prepared under NEPA by other Federal agencies.

D. Serves as the principal FDA liaison on safety testing methodologies and protocol standards needed to evaluate the safety of food ingredients and on other aspects of regulatory decisions.

E. Develops compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contact substances, color additives, GRAS substances, biotechnology derived foods, and prior sanctioned substances. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely

and efficient manner. Consults with FDA laboratories regarding research relevant to the regulation of food and color additives and food ingredients

F. Manages the FDA's review and monitoring of identity, probable human exposure to, and toxicity information on food additives and color additives, food contact substances, and GRAS substances in current use. Recommends enforcement action or regulatory change as needed. Provides expert scientific and technical advice to other Office, Center, and FDA components as needed.

G. Provides evaluation and participates in bioresearch monitoring of non- clinical laboratory studies and facilities to assure quality and integrity of data submitted to the FDA in accordance with good laboratory practices.

H. Serves as the Center’s focal point for scientific and policy support for the development of FDA-initiated regulations on matters pertaining to the provisions of the food additive and color additive sections of the Federal Food, Drug, and Cosmetic Act.

I. Ensures the scientific integrity and consistency of the Center's petition review processes (both those conducted in house and under extramural contract) for food additives and color additives, and consultation/notification processes for generally recognized as safe (GRAS) substances, food contact substances, and foods and food ingredients derived from recombinant DNA biotechnology.

J. Consults with FDA laboratories regarding research relevant to the regulation of food and color additives and food ingredients.

K. Ensures that the FDAs compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contact substances, color additives, GRAS substances, biotechnology derived foods, and prior sanctioned substances are consistent and based on sound science.

L. Ensures the FDA's review and monitoring of identity, probable human exposure to, and toxicity information on, food additives and color additives, food contact substances, and GRAS substances in current use. Recommends enforcement or regulatory change as needed. Provides expert scientific and technical advice to other Office, Center, and FDA components as needed.

M. Provides toxicology, chemistry, and pathology expertise to the Center, develops guidelines for toxicological studies and establishing specifications of identity and purity of food additives and estimating dietary exposure, and monitors newly developed testing methodologies that may prove useful in toxicological

assessments of novel food additives and other food ingredients and contributes to the FDA's overall safety assessment of food ingredients.

N. Provides evaluation and participates in bioresearch monitoring of non- clinical laboratory studies and facilities to assure quality and integrity of data submitted in accordance with good laboratory practices.

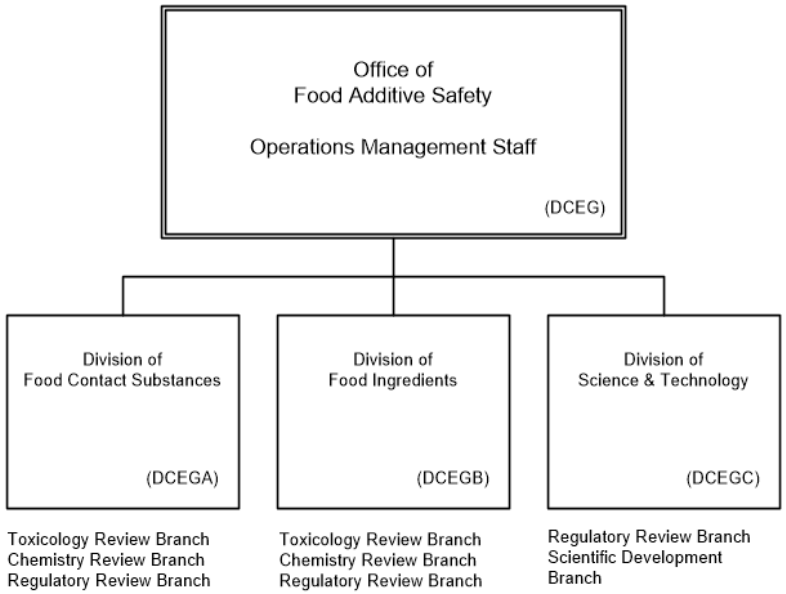
2. Operations Management Staff (DCEG1)

A. Provides oversight of the Office's budget, contracting, travel, records management, facilities management, property management, human resources, correspondence, and requests for information under the Freedom of Information Act.

3. Authority and Effective Date.

The functional statements for the Office of Food Additive Safety 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 Food Safety and Applied Nutrition
Office of Food Additive Safety



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety organization structure depicting all the organizational structures in the immediate office reporting to the Director.

The staff and divisions report to the Office of Food Additive Safety (DCEG)

- Operations Management Staff

These branches report to the Division of Food Contact Substances (DCEGA)

- Toxicology Review Branch
- Chemistry Review Branch
- Regulatory Review Branch

These branches report to the Division of Food Ingredients (DCEGB)

- Toxicology Review Branch
- Chemistry Review Branch
- Regulatory Review Branch

These branches report to the Division of Science and Technology (DCEGC)

- Regulatory Review Branch
- Scientific Development Branch

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