SMG 1232A.211

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Food Chemical Safety, Dietary Supplements, and Innovation

Office of Pre-Market Additive Safety

Division of Food Ingredients

Effective Date: May 13, 2024

1. Division of Food Ingredients (DCRKAA).

A. Provides Food and Drug Administration (FDA) guidance and coordinates the technical evaluation of regulatory and scientific issues regarding direct food additives, food irradiation, color additives, and GRAS (Generally Recognized as Safe) substances, including industry actions.

B. Evaluates toxicological, nutritional and microbiological data and information, and chemical data (including data on probable human exposure) submitted to the FDA by petitioners/notifiers that pertain to the safety of direct food additives, food irradiation, GRAS substances, and color additives in foods, drugs, medical devices, or cosmetics.

C. Consults with prospective petitioners/notifiers prior to submission concerning proposed new uses of direct food additives, food irradiation, GRAS substances, and color additives, and advises on content of submissions and approaches to meet statutory standards. Advises petitioners/notifiers, and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division in collaboration with the Office.

D. Writes and amends, as needed, procedural regulations, direct food additive and color additive regulations, and guidelines to implement relevant provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act specific to direct food additives, color additives, food irradiation, and GRAS substances.

E. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with direct food additives, food irradiation, color additives, and GRAS substances.

F. Develops and maintains information for assessment and monitoring of direct food additives, color additives, food irradiation, and GRAS substances. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

2. Toxicology Review Branch (DCRKAA1).

A. Evaluates toxicological, nutritional, and microbiological data and information, (including data on probable human exposure) submitted to the FDA by petitioners, notifiers, or from other sources, that pertain to the safety of GRAS ingredients, direct food additives, irradiated food, and of color additives in foods, drugs, medical devices, or cosmetics.

B. Consults with prospective petitioners and notifiers as necessary prior to filing, concerning proposed new uses of direct food additives and color additives, and GRAS ingredients, advising on petition content and approaches to meet statutory standards. Advises petitioners, notifiers, and other interested parties of any inadequacies that may preclude requested action on petitions or notifications reviewed by this Division.

3. Chemistry Review Branch (DCRKAA2).

A. Evaluates chemistry data and information, (including data on probable human exposure) submitted to the Agency by petitioners, notifiers, or from other sources, that pertain to the safety of GRAS ingredients, direct food additives, irradiated food, and of color additives in foods, drugs, medical devices, or cosmetics.

B. Consults with prospective petitioners and notifiers as necessary prior to filing, concerning proposed new uses of direct food additives and color additives, and GRAS ingredients, advising on petition content and approaches to meet statutory standards. Advises petitioners, notifiers, and other interested parties of any inadequacies that may preclude requested action on petitions or notifications reviewed by this Division.

4. Regulatory Review Branch (DCRKAA3).

A. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding direct food additives, food irradiation, color additives, and GRAS.

B. Consults with prospective petitioners/notifiers prior to submission concerning proposed new uses of direct food additives, food irradiation, GRAS substances, and color additives, and advises on content of submissions and

approaches to meet statutory standards. Advises petitioners/notifiers, and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division.

C. Coordinates the technical evaluation of regulatory and scientific issues regarding direct food additives, GRAS ingredients, food irradiation, and color additives, including industry actions.

D. Writes and amends, as needed, direct food additive and color additive regulations, procedural regulations, and guidelines to implement the provisions of the FD&C Act specific to direct food additives, color additives, and GRAS ingredients.

E. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

5. Authority and Effective Date.

The functional statements for the Division of Food Ingredients were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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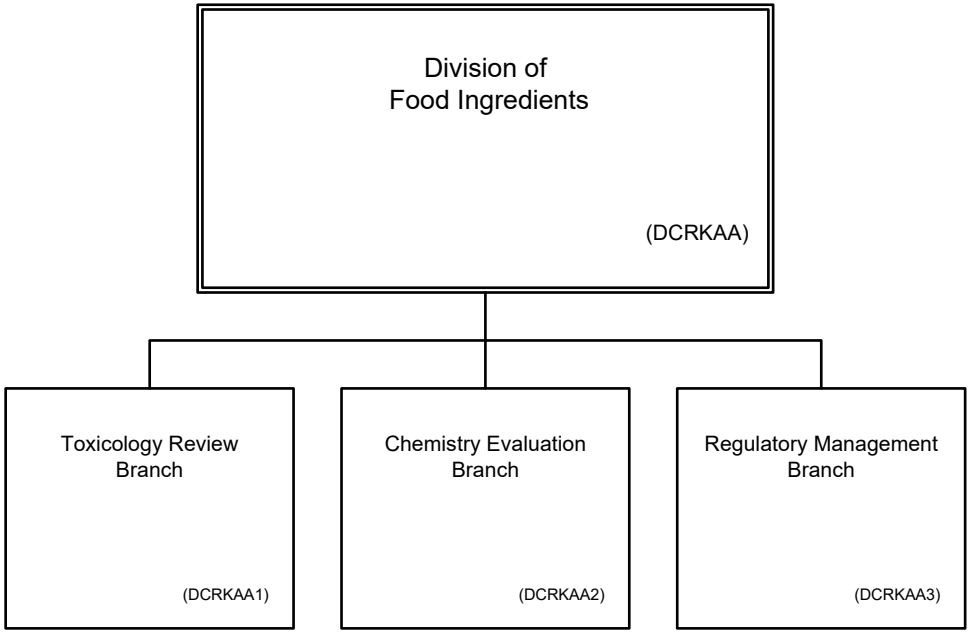

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Office of Pre-Market Additive Safety, Division of Food Ingredients organization structure depicting all the organizational structures reporting to the Director:

Toxicology Review Branch (DCRKAA1)

Chemistry Evaluation Branch (DCRKAA2)

Regulatory Management Branch (DCRKAA3)