SMG 1232A.21

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

Effective Date: May 13, 2024

1. Office of Pre-Market Additive Safety (DCRKA).

A. Serves as the Food and Drug Administration (FDA) lead for scientific, policy, and regulatory review support for the development of FDA-initiated regulations as well as regulations related to stakeholder pre-market and new use petitions, notices and consultations on matters pertaining to the provisions of the food additive, color additive sections, GRAS (Generally Recognized As Safe) substances, food contact substances of the Federal Food, Drug, and Cosmetic Act including foods and food ingredients derived from innovative technologies including recombinant DNA biotechnology and cell culture technology.

B. Provides expert advice to inquiries from throughout the Human Foods Program (HFP), the FDA, other federal entities, U.S. and foreign government officials and external stakeholders including Congress, as well as industry, international and other organizations on pre-market food safety programs and policies.

C. Develops policy, authorizing and procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contact substances, color additives, GRAS substances, foods derived through innovative technologies, and prior sanctioned substances.

D. Provides toxicology, chemistry, and pathology expertise to the HFP, and contributes to the FDA's overall safety assessment of foods derived through innovative technologies, food additives, color additives, food ingredients, food contact substances.

2. Authority and Effective Date.

The functional statements for the Office of Pre-Market Additive Safety 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
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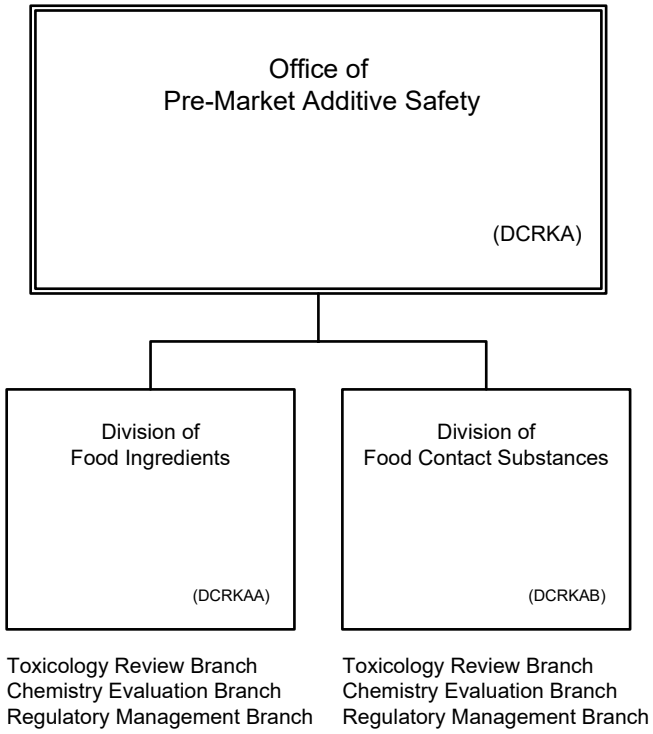

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Office of Pre-Market Additive Safety organization structure depicting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

Division of Food Ingredients (DCRKAA)

Division of Food Contact Substances (DCRKAB)

These organizations report to the Division of Food Ingredients (DCRKAA):

Toxicology Review Branch (DCRKAA1)

Chemistry Evaluation Branch (DCRKAA2)

Regulatory Management Branch (DCRKAA3)

These organizations report to the Division of Food Contact Substances (DCRKAB):

Toxicology Review Branch (DCRKAB1)

Chemistry Evaluation Branch (DCRKAB2)

Regulatory Management Branch (DCRKAB3)