

**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 Dietary Supplement Programs**

**Division of Research and Evaluation**

Effective Date: May 13, 2024

- 1. Division of Research and Evaluation (DCRKCB).**
  - A. Provides toxicology, chemistry, pathology, microbiology, and clinical expertise on dietary ingredients and supplements to the Food and Drug Administration (FDA), develops guidelines and establishes expectations for identity, regulatory status, and safety of dietary ingredients.
  - B. Performs, manages, reviews, and coordinates risk assessments and regulatory science evaluations of dietary ingredients and supplements for policy decisions regarding the safe consumption of dietary supplements.
  - C. Provides subject matter expertise for dietary supplement specific guidelines, regulations, position papers, and educational aids.
  - D. Develops and directs current policies, compliance efforts, and research dealing with ingredients marketed in dietary supplements.
  - E. Manages the FDA's review of new dietary ingredient notifications and related inquiries.
  - F. Manages the Office's scientific research and regulatory science agenda and coordinates with partners within FDA's inspections and investigations programs, FDA, and the federal government, as well as external stakeholders, to guide the scope of dietary supplement research.

**2. Identity and Status Branch (DCRKCB1).**

- A. Coordinates the technical evaluation of regulatory and scientific issues regarding dietary ingredients and other ingredients in dietary supplements.
- B. Evaluates chemistry data and other information available to the FDA that pertains to the identity of dietary ingredients and dietary supplements.
- C. Evaluates data and information related to dietary ingredients and other ingredients marketed in dietary supplements to determine their regulatory status and responds to inquiries from other FDA components.
- D. Provides chemistry and related support for ingredient analysis, policy, and action as appropriate.

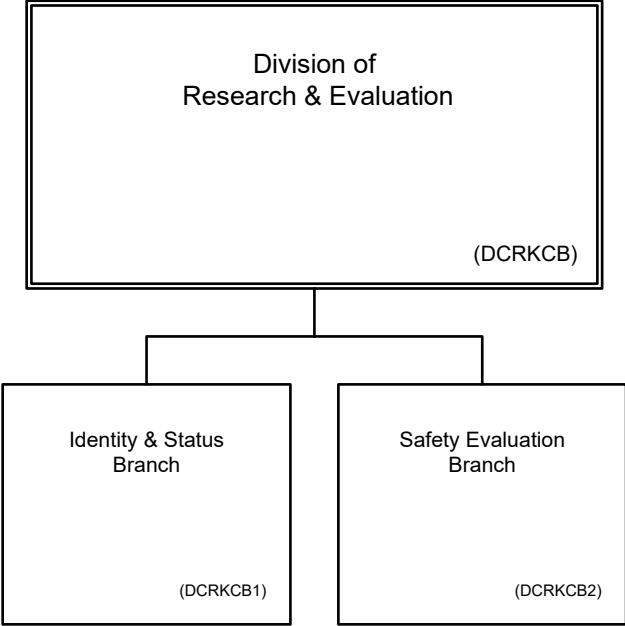
**3. Safety Evaluation Branch (DCRKCB2).**

- A. Evaluates toxicological and other data and information (including history of safe use) available to the FDA that pertain to the safety use of dietary ingredients and dietary supplements.
- B. Monitors and reviews, in coordination with other Center offices, all post-marketing surveillance adverse events reports on dietary supplements
- C. Provides clinical perspective on and expert support for dietary supplement and dietary ingredient analysis, policy, and action.
- D. Reviews and analyzes all available information on the safety of dietary ingredients and dietary supplements and provides advice on and support for regulatory and public health action to promote consumer safety.

**4. Authority and Effective Date.**

The functional statements for the Division of Research and Evaluation 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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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 Dietary Supplement Programs, Division of Research and Evaluation organization structure depicting all the organizational structures reporting to the Director:

Identity and Status Branch (DCRKCB1)

Safety Evaluation Branch (DCRKCB2)