SMG 1231.210

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 Dietary Supplement Programs

Division of Research and Evaluation

Effective Date: October 9, 2020

1. Division of Research and Evaluation (DCELA).

A. Provides toxicology, chemistry, and pathology expertise on dietary ingredients and supplement to the Center, develops guidelines and establishes expectations for identity and safety of dietary ingredients.

B. Performs, manages, reviews, and coordinates risk assessments and 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 redirects, as necessary, current policies, compliance efforts, and research dealing with ingredients marketed in dietary supplements.

E. Manages the Center's review of new dietary ingredient notifications.

F. Manages the Office's scientific research agenda and coordinates with partners within the Center, FDA, and the federal government, as well as external stakeholders, to ensure that dietary supplement research needs are addressed.

2. Identity and Status Branch (DCELA1).

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 submitted to the FDA by notifiers 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 and otherwise provides expert support for ingredient analysis, policy, and action as appropriate.

3. Safety Evaluation Branch (DCELA2).

A. Evaluates toxicological and other data and information (including history of safe use) submitted to the FDA by notifiers that pertain to the safety and identity 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 Commissioner of Food and Drugs, FDA and effective on October 9, 2020.

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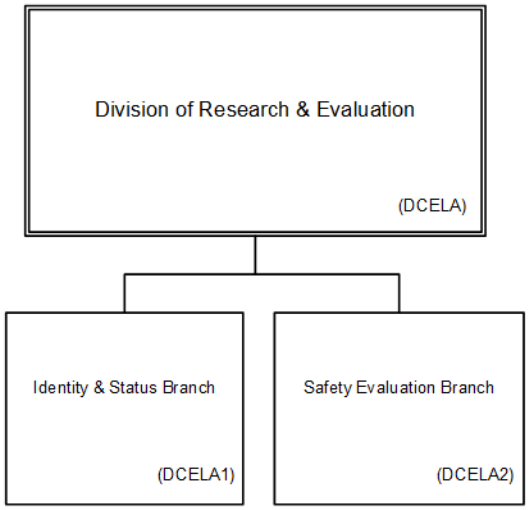

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Dietary Supplement Programs, Division of Research and Evaluation organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Research and Evaluation (DCELA):

Identity and Status Branch (DCELA1)

Safety Evaluation Branch (DCELA2)