SMG 1231.16

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF FOODS AND VETERINARY MEDICINE

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

OFFICE OF FOOD ADDITIVE SAFETY

Effective Date: October 1, 2012

1. OFFICE OF FOOD ADDITIVE SAFETY (DJJHG).

A. Serves as the Center focal point for scientific and policy support for the development of Agency-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 contract substances, and foods and food ingredients derived from recombinant DNA biotechnology. Evaluates safety information, compiles the administrative record supporting actions on petitions and other agency 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 Agency 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 contract 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 Agency's review and monitoring of identity, probable human exposure to, and toxicity information on food additives and color additives, food contract 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 Agency 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 Agency in accordance with good laboratory practices.

H. Serves as the Center’s focal point for scientific and policy support for the development of Agency-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 contract 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 Agency’s compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contract substances, color additives, GRAS substances, biotechnology derived foods, and prior sanctioned substances are consistent and based on sound science.

L. Ensures the Agency's review and monitoring of identity, probable human exposure to, and toxicity information on, food additives and color additives, food contract 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 Agency 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 Agency'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. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services, effective October 1, 2012.

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Organizations and Functions
Effective Date: October 1, 2012

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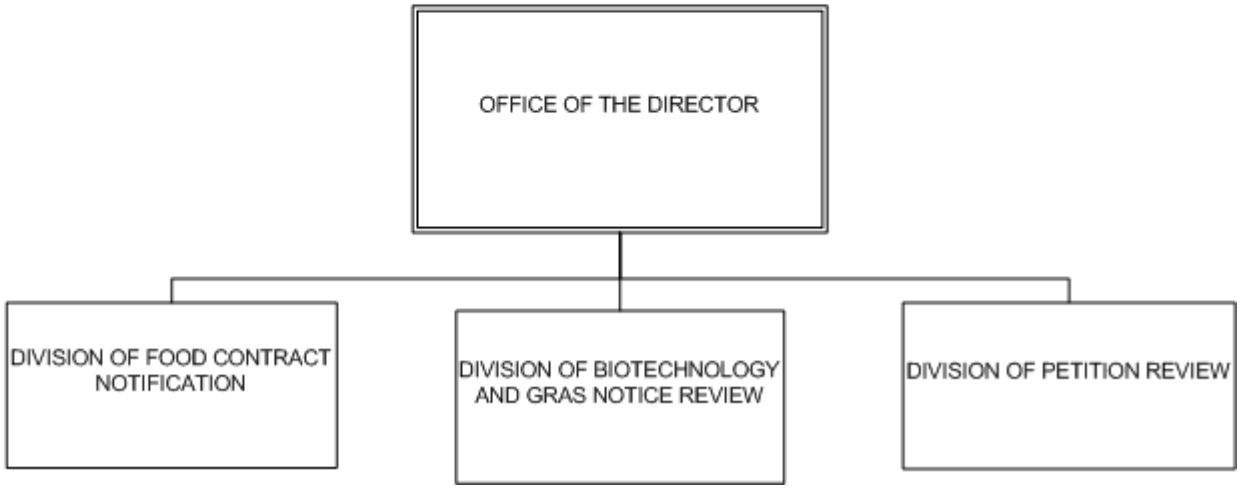

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The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Division of Food Contract Notification
- Division of Biotechnology and Gras Notice Review
- Division of Petition Review