

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

DIVISION OF BIOTECHNOLOGY AND GRAS NOTICE REVIEW

Effective Date: October 1, 2012

1. DIVISION OF BIOTECHNOLOGY AND GRAS NOTICE REVIEW (DJJHGB).

- A. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding food additives, GRAS (Generally Recognized as Safe) substances and bioengineered food, including industry actions.
- B. Evaluates toxicological, nutritional and microbiological data and information, and chemical data (including data on probable human exposure) and information, submitted to the Agency that pertain to the safety of food ingredients, GRAS substances and bioengineered food. Develops guidelines for and monitors newly developed techniques pertaining to the safety assessment of food additives, GRAS substances, and bioengineered food.
- C. Consults with prospective notifiers prior to submission, concerning proposed uses of food additives, GRAS substances and bioengineered food, advising on content of submissions and approaches to meet statutory standards. Advises notifiers, and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division.
- D. Writes and amends, as needed, procedural regulations, food ingredient regulations, and guidelines to implement relevant provisions of the Federal Food, Drug, and Cosmetic Act.
- E. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with food additives, GRAS substances and bioengineered food matters.
- F. Develops and maintains information for assessment and monitoring of food additives, GRAS substances and bioengineered food. Responds to stakeholder

inquiries and processes Freedom of Information requests in a timely and efficient manner.

2. AUTHORITY AND EFFECTIVE DATE.

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

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OFFICE OF THE DIRECTOR

STAFF MANUAL GUIDE 1231.162
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: October 1, 2012

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, Division of Biotechnology and GRAS Notice Review organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR