

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit input on program priorities in the Center for Food Safety and Applied Nutrition (CFSAN). CFSAN is currently conducting a comprehensive review of its programs to set priorities and establish work product expectations. This meeting is intended to give the public an opportunity to provide input into the priority-setting process.

Date and Time: The meeting will be held on June 24 and 25, 1998, 10 a.m. to 5 p.m.

Location: The meeting will be held in the auditorium at the Cohen Bldg., 330 Independence Ave. SW., Washington, DC.

Contact: Tracy S. Summers, Center for Food Safety and Applied Nutrition (HFS-1), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4850, FAX 202-205-5025, e-mail tsummings@bangate.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (name, title, firm name, address, telephone, and fax number) and requests to make oral presentations to the contact person by June 15, 1998. Written comments should be identified with the docket number found in brackets in the heading of this document and should be submitted by July 15, 1998, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: FDA's CFSAN is conducting a comprehensive

review of all its programs to set priorities and establish reasonable work product expectations. Although implementation of the President's Food Safety Initiative (FSI) is clearly CFSAN's top priority, CFSAN has responsibility for many other important programs as well. (The Presidential initiative is aimed at reducing foodborne microbial illness by strengthening food safety practices and policies.) This meeting is intended to provide the public with an opportunity to provide input into the priority-setting process. This meeting will also serve as one of many activities undertaken by the agency to solicit input in accordance with section 406(b) of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (Pub. L. 105-115) (codified at 21 U.S.C. 393(f)). Section 406 of FDAMA requires that FDA, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, develop and publish in the **Federal Register** a plan for meeting all statutory obligations of the Federal Food, Drug, and Cosmetic Act.

By way of example, in CFSAN's regulations program, work priorities are being assigned as follows: (1) The highest priority will be those regulations that enhance consumer safety, such as those issued to carry out the President's FSI; (2) those regulations that are mandated by statute; (3) health-related product labeling regulations; (4) regulations that will improve efficiency of operations; and (5) those additional regulations that have a major positive impact. The agency is interested in comments regarding the use of these criteria for setting priorities in CFSAN's other program areas. To facilitate comments on this issue, the appendix to this notice contains a list of major activities undertaken by FDA to ensure that foods are safe, wholesome, sanitary, and properly labeled, and that cosmetics are safe and properly labeled. Specific activities are listed in one of six general categories: Application review, injury reporting, product safety assurance, research, outreach, and enforcement.

The agency is most interested at this time in receiving comments regarding program priorities outside of FSI, as other venues are available for interested persons to provide input regarding implementation of FSI across the Federal Government. (Information regarding public meetings on the implementation of FSI can be obtained by contacting Camille E. Brewer at 202-260-1784.) Moreover, because many FSI-related activities require that FDA collaborate with one or more of the

other Federal agencies that have primary responsibility for food safety (e.g., the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Food Safety and Inspection Service, the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service in the Department of Agriculture; and the Environmental Protection Agency), comments on priorities in the FSI program at the meeting should be limited to those activities for which FDA has sole responsibility.

To help focus comments, FDA requests that oral and/or written input regarding CFSAN program priorities address the following questions:

1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

2. Beyond implementation of FSI, which program areas and/or activities do you believe should be top priorities for CFSAN, and why?

3. The criteria being used to set priorities for CFSAN's regulations are described above. Should these same criteria be used to set priorities for work in CFSAN's other program areas? If not, what criteria should be used?

4. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

5. Because so much of our nation's food supply is either imported or exported, international activities, such as Codex, appear to be growing in importance. What level of priority do you believe should be given in CFSAN to international activities? Please identify specific activities in your answer.

6. Finally, while not a public health issue, economic fraud affects both the industry and consumers. What level of priority do you believe should be given to addressing issues of economic fraud in the food supply?

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HF1-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after each meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Persons requiring a sign language interpreter or other special

accommodations should notify the listed contact person by June 15, 1998. This will be an informal meeting conducted in accordance with 21 CFR 10.65.

Appendix

Center for Food Safety and Applied Nutrition—List of Major Activities

(*Italics indicates FSI activity*)

I. Application Review

- Food and Color Additive Petitions
- GRAS Determinations
- Threshold of Regulation Determinations (food packaging)
 - Product Notification (consultation with biotechnology firms)
 - Food Additive Regulatory Management (FARM) System (automated workflow)
 - Review of Scientific Data and Research (nonlab) (to support petition review/biotech)
 - Notification Program for Infant Formula
 - Notification Program for Dietary Supplements
 - Notification for Nutrient Content and Health Claims Based on Authoritative Statements
 - Nutrient Content and Health Claim Petitions
 - Small Business Notifications
 - Approval of Data Bases for Nutrition Labeling
 - Temporary Marketing Permits
 - Certificates of Free Sale

II. Injury Reporting

- Adverse Event Reporting/Monitoring
 - *Foodborne Active Surveillance Network (FoodNet)*
 - *Coordination on Foodborne Disease Outbreaks*
 - *DNA Fingerprinting (PulseNet)*

III. Product Safety Assurance

- Monitoring
 - Good Laboratory Practices (GLP)/Bioresearch Monitoring
 - *Preventive Measures for Eggs*
 - Safety of Dietary Supplements/Herbal Products
 - Monitoring of Prohibited Ingredients (cosmetics) and Adherence to GMP's
 - Food Labeling and Packaging Survey (FLAPS)
 - Priority-Based Assessment of Food Additives (PAFA)
 - Monitoring the Safety of Imported Foods and Cosmetics
 - Monitoring of Adverse Reactions to Food Products Reported by the Field
 - *Produce Initiative*
 - Seafood Decomposition—Investigation of Problems

- Epidemiological Support
- Monitoring Pesticide Residues
- *Monitoring Microbial Pathogens*
- Monitoring Chemical and Industrial Contaminants
 - Monitoring Seafood Toxins
 - Safety of Medical Foods

Compliance

- Lab Accreditation (e.g., milk labs)
- Low-Acid Canned Food and Acidified Food Regulations and Establishment Registration
 - *Development of GAP's and GMP's for Fresh Produce*
 - Electronic Inspection System (EIS)
 - Import and Domestic Seafood Compliance Program Development and Evaluation
 - Economic Fraud
 - Regulation and Policy Development (centerwide)
 - Economic Cost Benefit Analysis Studies (regulations)
 - Nutrient Content Analyses
 - Food Standards (including petitions to modify or establish)

HACCP

- International Shellfish Program
 - *Implementation of Seafood HACCP*
 - *Juice HACCP and Warning Label Proposed Regulations*
 - HACCP at Retail (pilot)
- Product Testing**—This category includes laboratory testing of components/ingredients of foods and cosmetic products for safety.
- Indirect and Direct Food Additives
 - Sample Analyses
 - Infant Formula Samples
 - Testing for Harmful Ingredients and Contaminants in Cosmetic Products

IV. Research

• **Methods Development**—This is research to develop new analytical methods or investigate known analytical methods for detecting and identifying microbial pathogens, chemical contaminants, and toxins in foods and cosmetics that can be potentially harmful to the public's health. Most of the research conducted in CFSAN falls into this category.

— *Analytical Methods Development to Detect Microbial Pathogens*

• **Risk Assessment**—Developing or applying analytical methods to quantify exposure to or determine if a pathogen, chemical contaminant, or toxin poses a public health risk. This is the second largest category of research conducted in CFSAN.

— *Risk Assessment for the Food Safety Initiative: Interagency Consortium; Improve Modeling Techniques*

— Mathematical and Statistical Support

— Pathology Data Analyses
 — Pharmacokinetic and Pharmacodynamic Modeling

• **Other Research**— Laboratory studies to obtain knowledge/data necessary for application in methods development and/or risk assessment. This category also includes collaborative research efforts with academia and other food safety research concerns.

V. Outreach

- Technical Assistance and Education (consumers/industry/retail/foreign countries)
 - Codex Activities
 - Guideline Development
 - Voluntary Registration Program
 - Mutual Recognition Agreements
 - Federal/State Cooperative Programs (milk, shellfish, retail)
 - *Education on Food Safety*
 - *Develop educational messages and materials*
 - *Educate general public about safe food handling*
 - *Educate children about safe food handling*
 - *Educate vulnerable populations about safe food handling*

VI. Enforcement

- Case Processing
- Recalls of Foods and Cosmetics

Dated: May 28, 1998.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Nominations of Candidates to Serve on the National Vaccine Advisory Committee, Department of Health and Human Services

The Public Health Service (PHS) is soliciting nominations for possible membership on the National Vaccine Advisory Committee (NVAC). This committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States; recommends research priorities and other measures the Director of the National Vaccine Program should take to enhance the safety and efficacy of vaccines; advises the Director of the Program in the implementation of sections 2102, 2103, and 2104, of the PHS Act; and identifies annually, for the Director of the Program, the most