Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of ''National Institute for Occupational Safety and Health (NIOSH): Occupational Safety and Health Training Project Grants, PA PAR06–484.''

Contact Person for More Information: Charles N. Rafferty, PhD, Assistant Director for Review and Policy, Office of Extramural Programs, Office of Extramural Coordination and Special Projects, NIOSH, CDC, 1600 Clifton Road, NE., Mailstop E74, Atlanta, GA 30333 Telephone: (404) 498–2530.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 21, 2007.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–25544 Filed 12–31–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee (MSHRAC): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date:
8:45 a.m.—5:15 p.m., January 22, 2008.
8:30 a.m.—3:45 p.m., January 23, 2008.

Place: Hilton Garden Inn Pittsburgh/Southpointe, 1000 Corporate Drive, Canonsburg, PA 15317, telephone (724) 743–5000, fax (724) 743–5010.

Status: The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

Matters To Be Discussed: The meeting will focus on Communications and Tracking, update on Refuge Alternatives Activities, Mine Ground Control Research, Dynamic Failures Proposal, NAS Review and Planned Actions, Safety Culture Pilot Project and Coal Workers Pneumoconiosis Research. The agenda will also include an update report from the Associate Director for Mining. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jeffery L. Kohler, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, 626 Cochrans Mill Road, Pittsburgh, PA 15236, telephone (412) 386–5301, fax (412) 386–5300. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 21, 2007.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E7–25509 Filed 12–31–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Center for Food Safety and Applied Nutrition; Statement of Organization, Functions, and Delegations of Authority

Part D, Food and Drug Administration, Chapter DB, Office of Operations, Center for Food Safety and Applied Nutrition (DBF), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56005, November 9, 1995; 64 FR 36361, July 6, 1999; and in pertinent part at 57 FR 54239) is amended to reflect the restructuring of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Operations (OO), Food and Drug Administration (FDA) as follows:

I. Under Chapter DB, Office of Operations, delete in its entirety, the ''Center for Food Safety and Applied Nutrition (DBF).

II. Establish a new Chapter DH, Center for Food Safety and Applied Nutrition (DH), under Part D to read as follows:

DF.10 Organization. The Center for Food Safety and Applied Nutrition, FDA is headed by the Director, Food Safety and Applied Nutrition, and includes the following organizational units:

Office of the Center Director (DHA)
Office of Management Systems (DHB)
Office of Food Defense, Communication and Emergency Response (DHC)
Office of Food Safety (DHD)
Office of Cosmetics and Colors (DHE)
Office of Regulatory Science (DHF)
Office of Food Additive Safety (DHG)
Office of Compliance (DHH)
Office of Applied Research and Safety Assessment (DHI)
Office of Regulations, Policy and Social Sciences (DHJ)
Office of Nutrition, Labeling, and Dietary Supplements (DHK)

DF.20 Functions.

A. OFFICE OF THE CENTER DIRECTOR (DHA). The Office of the Center Director (OCD):

Provides leadership and direction for all Center activities and coordinates programs with other Agency, Department and government agencies.

Plans, administers, coordinates, evaluates and promulgates overall Center scientific, regulatory, compliance, enforcement and management programs, policies and plans.

Provides leadership and direction for Center management, planning, and evaluation systems to ensure optimum utilization of personnel, financial resources, and facilities.

Establishes and manages a program to maintain the highest level of quality and integrity for all Center laboratory studies and the processing of regulatory samples, and ensures that all Center laboratory studies subject to FDA's Good Laboratory Practice regulations are conducted in compliance with them.

Coordinates and monitors the Center's overall research portfolio, including all research-related activities and inquiries and the development of strategic research program plans.

B. SENIOR SCIENCE ADVISOR STAFF (DHA1). The Senior Science Advisor Staff (SSAS):

Provides advice to the Center Director and Deputy Directors on issues related to the Center's research portfolio, facilities and equipment.

Represents the Center and Agency in scientific and other professional forums, including international forums, on issues related to food laws, regulations, standards and science and policies.

Provides leadership for the development of short-, medium- and long-term strategic research program plans.

Provides advice, consultation, and management oversight to appropriate representatives associated with partnerships with academia and other consortia.

Fosters partnerships and effective communication with academia, private industry, trade associations, public sector groups, governmental agencies, commodity groups, and professional organizations.

C. INTERNATIONAL AFFAIRS STAFF (DHA2). The International Affairs Staff (IAS):

Provides advice to the Center Director and Deputy Directors on issues related to international policy and direction.

Provides leadership on development of the Center's policies that impact on international and/or trade issues.

Represents the Center and Agency in international forums on issues related to international harmonization of food laws, regulations, standards and science, and policies.

Provides expertise and oversight over international trade negotiations pertaining to foods and cosmetics and the implementation of the agreements that emerge from those negotiations, including management of any trade disputes.

Coordinates activities between the Center and other Federal agencies, foreign competent authorities, and relevant stakeholders on issues having international components.

Coordinates international technical assistance and training programs.

D. EXECUTIVE OPERATIONS STAFF (DHA3). The Executive Operations Staff (EOS):

Provides support to the Center Director and Deputy Directors, including the coordination and preparation of briefing materials and background information for meetings, responses to outside inquiries, and maintenance and control of the Center Director's working files.

Manages the Center's Freedom of Information Act activities, coordinating responses with other Center technical, regulatory, and policy units as well as developing direct responses. Provides correspondence control for the Center and controls and processes all agency public correspondence directed to the Center Director. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

Coordinates the Center's communications with the Agency, Department, and the other federal government agencies.

Manages all Congressional activities including hearings, briefings, and inquiries (except for legislation).

Acts as the focal point for all activities with respect to the Government Accountability Office (GAO) and the Office of the Inspector General.

E. OFFICE OF MANAGEMENT SYSTEMS (DHB). The Office of Management Systems (OMS):

Advises the Center Director on administrative policies and guidelines and scientific and technical information systems.

Plans and directs all Center operations related to program planning, budget, financial, and security management, and laboratory safety and health.

Performs management studies and evaluations, as necessary, throughout the Center.

Provides technical support and building operations support management to the Center in the areas of supply, equipment, space, communications, printing, reproduction, mail, contracts and grants, and awards.

Represents the Center's information technology (IT) needs to Shared Services and the Chief Information Officer (CIO). Provides support to critical in-house data systems.

F. OFFICE OF FOOD DEFENSE, COMMUNICATION AND EMERGENCY REPONSE (DHC). The Office of Food Defense, Communication and Emergency Response (OFDCER):

Provides Center leadership for food defense and counterterrorism activities in relation to that segment of the U.S. food supply that is regulated by the Food and Drug Administration (FDA). Serves as FDA's lead for directing, developing, and coordinating high quality outreach and education activities (in collaboration with Center Program offices) and as a resource to all stakeholders (e.g., consumers, industry, states, and other Federal partners) in relation to food safety, food labeling, and food defense.

Leads the Center in coordinating, directing, and assisting other agency units with foodborne outbreak investigations and coordination of other emergency activities involving food, dietary supplements, and cosmetics.

Provides direction for strengthening systems for conduct and coordination of risk analysis activities and related research associated with national and international food safety and food defense issues.

Assists the Center's Chief Medical Officer (CMO) as an expert for the Center in public health medicine, including Human Subject Protection (HSP) and Health Hazard Evaluations (HHE's).

Provides statistical and epidemiological support for Center and field research, extramural and regulatory programs.

G. OFFICE OF FOOD SAFETY (DHD). The Office of Food Safety (OFS):

Develops and implements policies, regulations, and guidelines related to food safety. Conducts food safety research related to chemical or microbial contamination.

Administers the federal portion of the Federal/State cooperative programs. Provides toxicological evaluations and quantitative risk assessments related to the presence of industrial chemicals, process induced toxicants and toxic elements in food.

Serves as the principal Agency liaison on food programs and policies with industry, Federal, State, foreign, and other organizations.

Provides expertise in acidified and low acid food technologies, including the registration and evaluation of filed processes.

Maintains the Interstate Certified Shellfish Shippers List and the Interstate Milk Shippers List.

Serves as Agency liaison with State partners in administering the Federal portion of the federal/state cooperative retail food program.

Develops and promotes the adoption and implementation of the FDA Food Code, the National Retail Food Regulatory Program Standards and related agency policy for sound public health practices.

Provides technical support and outreach to FDA staff and other Federal, State and local officials on the Food Code and other agency guidance on retail food protection.

H. OFFICE OF COSMETICS AND COLORS (DHE). The Office of Cosmetics and Colors (OCAC):

Develops guidelines, regulations, and policies for cosmetics and color additives. Communicates policy, guidance, and other information on cosmetics and color additives to the public, affected industry, and other stakeholders including international regulatory bodies.

Provides expert scientific and technical advice and support on cosmetic products and ingredients and color additives to other FDA units and other Federal, State, and local authorities.

Administers the Color Certification program, including laboratory testing and methods research.

Administers the Voluntary Cosmetic Registration Program.

Provides leadership and works closely with other Agency units in the area of nanotechnology.

I. OFFICE OF REGULATORY SCIENCE (DHF). The Office of Regulatory Science (ORS):

Conducts laboratory science and research that support the FDA regulatory agenda.

Develops laboratory-based methods to support regulations and related policy developments.

Provides technical support and expert advice on scientific issues related to policy and regulations.

Originates, plans, and conducts research in the areas of food processing and packaging, food chemistry, food toxicants, food microbiology and cosmetics.

Reviews regulatory actions for adequacy of evidence and accuracy of the science and technical procedures and findings.

Provides technical information and assistance with laboratory-based methods and procedures to foreign governments and visitors.

J. OFFICE OF FOOD ADDITIVE SAFETY (DHG). The Office of Food Additive Safety (OFAS):

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.

Manages the Center's petition review processes (both those conducted in-house and under extramural contract) for food and color additives, and consultation/notification processes for GRAS (Generally Recognized As Safe) substances, food contact 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.

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.

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.

Develops compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contact 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 Center and other FDA laboratories regarding research relevant to the regulation of food and color additives and food ingredients.

Manages the Agency's review and monitoring of identity, probable human exposure to, and toxicity information on food and color additives, food contact 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.

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

K. OFFICE OF COMPLIANCE (DHH). The Office of Compliance (OC):

Serves as the primary contact between the Center and FDA's field organization, including the Field Food Committee.

Has primary responsibility for management of compliance programs, field assignments, and work plans and maintains the center-wide compliance management and reference systems.

Initiates and/or coordinates the planning, development, publication and promotion of field guidance documents for CFSAN-regulated food and cosmetic products to implement sound public health practices, food safety/security interventions, compliance/enforcement strategies, and regulatory programs; provides information, training and technical assistance to implement development of Center guidance and regulations.

Reviews proposed regulatory actions and recalls for adequacy of evidence and consistency across programs. Oversees the development of compliance and enforcement strategies for emerging compliance challenges.

Monitors and mines information from internal and external sources to identify trends or emerging compliance and enforcement-related issues that may influence the Center's area of regulatory responsibility. Provides data and other information on field accomplishments to support the Center's evaluation of programs and assignments, development of new assignments, assessment of the industry or any other relevant Agency purpose.

Oversees, monitors and evaluates the food facility registration data base.

Plans and develops approaches to administer regulatory responsibilities in the Interstate Travel Program and provides information, problem-solving and technical assistance to Agency and external organizations within this program.

L. OFFICE OF APPLIED RESEARCH AND SAFETY ASSESSMENT (DHI). The Office of Applied Research and Safety Assessment (OARSA):

Establishes and conducts a cohesive mission-relevant research program in the areas of toxicology, microbiology and molecular biology that will ensure the safety of the U.S. food supply and the establishment of sound counterterrorism measures.

Provides Center and Agency leadership in reproductive toxicology, neuro/behavioral toxicology, immunotoxicology, in vitro toxicology with special emphasis on hepatotoxicity, virulence assessment, immunobiology, microbial genetics and molecular virology.

Recommends, develops, and conducts the Center's research program goals and priorities on food safety threat agents, safety and health hazards to foods, nutritional supplements, chemical contaminants, natural toxicants, and metabolities.

Serves as the Center's principal research liaison with other Agency units and with other organizations outside the Agency. Initiates and coordinates collaborative studies with Center stakeholders and coordinates development of long-term collaborative research planning with the Center, other Agency units, academic, and research components to achieve food safety and food defense.

Provides support to the national toxicological program with planning and implementation of sub-chronic and chronic toxicological evaluations emphasizing dose response relationships. Provides expert scientific direction, guidance and support to the Center's regulatory and compliance programs and provides expertise in both food safety and food defense.

M. OFFICE OF REGULATIONS, POLICY, AND SOCIAL SCIENCES (DHJ). Office of Regulations, Policy, and Social Sciences (ORPSS):

Coordinates the development of all CFSAN regulations and guidance documents, and reviews and clears for CFSAN draft regulations and guidance documents developed by CFSAN, other Centers in FDA, or by other agencies.

Resolves policy issues involving Center-regulated food or cosmetic products in collaboration with the Center Director, Deputy Directors and other senior managers.

Provides economic analyses and conducts consumer studies to provide information about the impact and/or effectiveness of various options; these analyses and studies are used by CFSAN managers throughout the decision-making and evaluation processes.

Serves as the Center focal point and provides a centralized monitoring, coordinating, and advisory function for the Center and U.S. government on policies involving sensitive, controversial, and complex food issues,

including policies involving food derived from biotechnology.

Advises Center officials on regulatory approaches and manages the development of periodic plans for the Center's regulation development activities.

Develops legislative proposals related to food and cosmetic safety and defense; coordinates the Center's review of bills and proposed legislation, upon request; and coordinates the Center's technical assistance to Congressional or FDA Office of Legislation staff developing bills related to food and cosmetics, upon request.

Manages the Center's compliance with the Information Quality Act, including responses to request for correction and reconsideration submitted under the Act.

Advises Center staff concerning the administrative procedures for rulemaking, guidelines, guidance documents, and other policy documents, hearings and delegations of authority.

Leads the Center's evaluation of existing regulations to determine whether they are efficiently or effectively accomplishing their intended purpose.

Provides Center-level leadership and coordination regarding briefings with other parts of the Agency or Federal Government with clearance responsibility regarding CFSAN regulations and guidance documents, and other CFSAN documents subject to the Paperwork Reduction Act, in coordination with the Executive Operations Staff.

Directs and manages Center programs involving the use of external scientific advisors, consultants, and committees.

Counsels and coordinates with Center managers on the use of external scientific experts and resources.

N. OFFICE OF NUTRITION, LABELING, AND DIETARY SUPPLEMENTS (DHK). The Office of Nutrition, Labeling, and Dietary Supplements (ONLDS):

Primary responsibility for policy development and management of food and nutrition labeling, food standards, conventional foods, dietary supplements, and special nutritional (including infant formula and medical foods) food.

Provides expert advice to the Center Director, other Deputy Directors, and other senior managers, and directs major Agency and Department nutrition and labeling initiatives and is the Delegate to national and international forums and conferences.

Primary responsibility for policy and regulatory development and management of the food labeling program, including Nutrition Labeling and Education Act, Food Allergen Labeling and Consumer Protection Act and other Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act labeling requirements.

Provides scientific and technical review of and response to petitions and notifications related to all aspects of conventional food labeling. With the Office of Compliance, determines compliance with existing food standards and common or usual name regulations and issues temporary marketing permits to allow manufacturers to test market new foods. In addition, conducts scientific and technical review of enforcement and compliance materials including inspection reports, analytical reports and other pertinent records, and provides policy decisions on misbranding charges for all domestic and import actions, including infant formula and medical food manufacturers.

Provides expert guidance for other Agency units and Federal and State officials and industry concerning regulatory requirements and compliance policies on food labeling (including infant formula and medical foods) and reviews proposed enforcement/compliance actions referred by other agency units.

Provides expert technical advice for participation in international forums.

Reviews food product labeling (including infant formula, medical foods and nutrition labels) for adherence to regulations and appropriateness of claims and manages the Small Business Nutrition Labeling Exemption Notification Program.

Provides scientific review and analysis of policies, regulations, research priorities, position papers, and advisory opinions on issues related to nutrition and nutrition labeling, and dietary guidance recommendations, and related nutrition science issues.

Responsible for scientific and regulatory review of health claim petitions, qualified health claim petitions, nutrient content claim petitions, and FDA Modernization Act notifications for health claims and nutrient content claims.

Provides expert advice and assistance to key officials and coordinates with other domestic and international scientific bodies on efforts related to nutrition and health.

Identifies program priorities for, provides content design input to, and analysis of large-scale databases of food consumption, food composition, food ingredients, sales of processed packaged food products and product label information. Develops methods for monitoring US populations and special subgroups relative to use and safety of conventional foods and dietary supplements.

Provides management and scientific review on issues related to infant formula, medical foods, and dietary supplements including petitions and notifications, and provides advice to key Agency components as well as international bodies.

Responsible for the development of regulations, guidance, policy, programs, position papers and advisory opinions, and recommends research priorities for the management of the dietary supplement program, which includes safety assessments for the New Dietary Ingredient Notification Program, structure-function notifications, Certificates of Export, safety assessment for dietary supplement policy, responses to petitions and industry-related notifications, post-market adverse event evaluations, and issues related to dietary supplement safety and nutrition.

III. Delegations of Authority. Pending further delegation, directives, or orders by the Commissioner of the Food and Drugs, all delegations or re-delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: December 20, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–6257 Filed 12–31–07; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0492]

Guidance for Industry and Food and Drug Administration; Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements.'' The purpose of this guidance document is to recommend an