such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to receive an update from the Inter-tribal Council on Hanford Health Projects; to review and approve the Minutes of the previous meeting; to receive updates from ATSDR/NCEH and NIOSH: to receive reports from the Outreach, Public Health Assessment, Public Health Activities, and the Studies Workgroups; and to address other issues and topics, as necessary.

Matters to be Discussed: Agenda items include a presentation and discussion on the health effects subcommittee evaluations, Federal Task Order and request for proposal process, the National Academy of Science June 19th meeting, and agency updates. Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Leslie C. Campbell, Executive Secretary HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation ATSDR, 1600 Clifton Road, NE M/S E–56, Atlanta, Georgia 30333, telephone 1–888/42–ATSDR (28737), fax 404/639–6075.

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: June 29, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–16986 Filed 7–2–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2080]

Engelhard Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Engelhard Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a solution of 1-naphthalenesulfonic acid, 2-[(2-hydroxy-6-sulfo-1-naphthalenyl)azo]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy-, strontium salt (1:1) (C.I. Pigment Red 277) as a colorant for polymers intended for use in contact with food.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4667) has been filed by Engelhard Corp., 3400 Bank St., Louisville, KY 40212. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of a solution of 1-naphthalenesulfonic acid, 2-[(2-hydroxy-6-sulfo-1-naphthalenyl)azo]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy-, strontium salt (1:1) (C.I. Pigment Red 277) as a colorant for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 11, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–16944 Filed 7–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

The Food and Drug Administration (FDA) is being restructured to create a more streamlined and efficient Office of the Commissioner that will provide leadership without compromising programmatic effectiveness. More specifically, the goals of this reorganization are to: Create an Office of the Commissioner (OC) for which the principal focus is to provide leadership in building effective, two-way communication between the agency and all of our stakeholders, including patients, consumers, Congress, the Administration, the regulated industry, health care professionals, and other scientific advisors and between agency management and employees; enable FDA to implement agency priorities and to develop agency policy with primary input from the Center Directors and the Associate Commissioner for Regulatory Affairs, and with legal advice from the Chief Counsel; streamline the OC to make the overall agency more effective and efficient with roles and responsibilities clearly delineated; and retain in OC only those staff functions which cannot be reasonably and more effectively performed in the Centers or the Office of Regulatory Affairs (ORA).

The new agency structure will consist of one Deputy Commissioner rather than the current four deputy structure. The Deputy Commissioner position will be established within the immediate OC. The Office of Operations will be abolished and the Center Directors and Associate Commissioner for Regulatory Affairs will report directly to the Commissioner. In addition, the Office of the Chief Counsel, Office of the Administrative Law Judge, and the Office of Equal Opportunity (OEO) (formerly titled the Office of Equal Employment and Civil Rights) will remain in OC. The OEO will assume the agency wide diversity program functions.

A new position will be established in the OC titled the Senior Associate Commissioner. The incumbent will head a new Office of the Senior

Associate Commissioner (OSAC). This Office will be responsible for coordinating all activities within the OC as well as providing advisory committee oversight. This Office will include the Office of the Ombudsman, the Office of Executive Secretariat, the Office of Public Affairs (formerly in the Office of External Affairs (OEA)), the Office of Orphan Products Development (formerly in the Office of Operations (OO)), the Office of Internal Affairs, and the Office of Tobacco Programs (formerly in the Office of Policy (OP)).

The former Office of Policy will be abolished. A new position will be established in the OC titled the Senior Associate Commissioner for Policy, Planning and Legislation. The new Office of Policy, Planning, and Legislation will be comprised of a new Policy office, the Office of Legislation (formerly titled the Office of Legislative Affairs in the OEA), and the Office of Planning (formerly titled the Office of Planning and Evaluation from the Office of Management and Systems), which will include the Management Initiatives Staff.

The Office of External Affairs will be abolished. As a result of the growing importance of international policy and activities, a new Office of International and Constituent Relations will be established. The new Office of International and Constituent Relations will consist of a new Office of International Programs, the Office of Consumer Affairs, the Office of Women's Health and the Office of Special Health Issues, all formerly in the OEA.

The current incumbent's position will be retitled Deputy Commissioner for International and Constituent Relations. This position will be converted to Senior Associate Commissioner when vacated.

The Industry and Small Business Liaison Staff (formerly in the OEA) will be abolished and its staff reassigned; some of its meeting scheduling functions will be realigned to the Office of Public Affairs, OSAC. The Office of Health Affairs (formerly in the OEA) will be abolished. Some of its functions (health assessments, patent term restorations, and scheduling of controlled substances) will be realigned to the Center for Devices and Radiological Health. Responsibility for 21 CFR parts 16 and 12 hearings will be realigned to the Office of the Ombudsman, OSAC.

The Office of Management and Systems will remain relatively unchanged in function except that many of the transactional functions of management will be decentralized to the Centers. The Divisions of Personnel Operations I, II, and III will be decentralized. The Centers and ORA will be functionally responsible for processing their personnel actions. The Office of Human Resources and Management Services will continue to process OC personnel actions. As noted earlier, the Office of Planning and Evaluation will be realigned to the Office of Policy, Planning, and Legislation.

The position title Deputy Commissioner for Management and Systems will be retained until this position is vacated. At such time the position will be converted to Senior Associate Commissioner for Management and Systems.

Part D, Chapter DA, Office of the Commissioner, FDA, 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 56605, November 9, 1995, and in pertinent part at (56 FR 29484, June 27, 1991)) is amended to reflect the restructuring of FDA as follows:

Office of the Commissioner (DA): The Commissioner and Deputy Commissioner are responsible for the efficient and effective implementation of the FDA mission.

Office of the Chief Counsel (DAA): Subject to the professional supervision and control of the General Counsel, represents FDA in court proceedings and administrative hearings with respect to programs administered by FDA.

Provides legal advice and policy guidance for programs administered by FDA.

Acts as liaison to the Department of Justice and other Federal departments for programs administered by FDA.

Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by FDA.

Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.

Reviews proposed legislation affecting FDA that originates in the Department or on which Congress requests the views of the Department.

Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel.

Office of Equal Opportunity (DAC): Advises and assists the Commissioner and other key agency officials on Equal Employment Opportunity (EEO) and Civil Rights activities which impact on policy development and execution of program goals.

Serves as the agency focal point and liaison with the Department, and other Federal agencies, State, and local governments, and other organizations regarding EEO and Civil Rights matters.

Develops and recommends policies and priorities designed to implement the intent of the Office of Personnel Management, Equal Employment Opportunity Commission, Office of Civil Rights, Department of Health and Human Services requirements under Executive Orders, regulations, EEO and Civil Rights legislation.

Provides leadership, direction, and technical guidance to the agency on EEO and Civil Rights matters.

Develops plans, programs, and procedures designed to ensure the prompt adjudication of complaints of alleged discrimination based on race, color, sex, age, religion, national origin, handicap, and sexual orientation.

Develops and oversees agency diversity initiatives and the diversity databank.

Provides alternative dispute resolution and mediation services as needed.

Develops and maintains training and technical assistance programs for agency EEO managers, counselors, special emphasis/program representatives, employees, supervisory personnel, and other key agency officials.

Examines the use and impact of administrative mechanisms on work assignments, pay systems, award systems, performance appraisal systems, promotion patterns, reorganization impacts, delegations of authority, management controls, information and documentation systems, and similar functions of management as they impact upon equal employment opportunities for all employees within the agency's representatives, and such other assistance as may be needed for EEO activities.

Develops, implements, and monitors the agency's Affirmative Action Plan and directs the agency's Affirmative Employment Program to achieve specific objectives.

Issues policies, publications and information dissemination services to agency employees including Commissioner Policy Statements, brochures, the EEO Counselors Manual, etc.

Develops labor-management partnerships on EEO matters.

Provides sign language interpreting services and manages the interpreting services contracts.

Office of the Administrative Law Judge (DAD): Schedules and conducts formal evidentiary public hearings under 21 CFR part 12, under the Federal

Food, Drug, and Cosmetic Act, as amended, as well as other related laws and the Administrative Procedure Act (5 U.S.C. 511 *et seq.*).

Issues Initial Decisions containing findings of fact and conclusions of law based on the independent review and evaluation of all evidence of record in formal hearings.

Office of the Senior Associate Commissioner (DAF): Advises the Commissioner and other key agency officials on agency-level activities and issues that affect agency wide programs, projects, strategies, and initiatives.

Coordinates activities involving emergency or crises situations and resolves complex problems and issues related to agency programs that are sensitive and controversial that impact upon agency relations with other Federal agencies and foreign governments.

Oversees and directs the agency's ombudsman, public affairs, tobacco program, orphan products, executive secretariat, and advisory committee functions to ensure coherence in decisionmaking and the efficient operation of these functions internally and across agency jurisdictions.

Provides leadership and direction to assure the efficient and effective planning, performance, and evaluation of oversight activities.

Office of Executive Secretariat (DAFA): Coordinates identification of and expedites development and implementation of the agency's highest program priorities and initiatives for the Commissioner.

Develops and maintains management information necessary for monitoring the Commissioner's and agency's goals and priorities.

Advises the Commissioner and other key agency officials on all activities that affect agency wide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner and other key agency officials.

Ensures that materials in support of recommendations presented for the Commissioner's consideration are comprehensive, accurate, fully discussed, and encompass the issues involved.

Provides correspondence control for the Commissioner and controls and processes all agency public correspondence directed to the Commissioner. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

Provides direct support to the Commissioner and other key agency officials, including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.

Performs agency wide assignments involving complex problems and issues related to agency programs, strategies and activities, including preparation of special reports for the Department.

Coordinates the agency's communications with the Public Health Service (PHS), DHHS, and the White House including correspondence for the Assistant Secretary for Health and Secretarial signatures.

Office of Public Affairs (DAFB): Advises and assists the Commissioner and other key agency officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with PHS and the Department on public information programs.

Plans, develops, implements, and monitors policy and programs on agency media relations and consumer information and education programs conducted through the media, FDA's consumer affairs officers, and other communications sources.

Plans, develops, produces, and publishes agency publications and graphic arts materials.

Coordinates agency implementation of the Freedom of Information (FOI) Act and the Privacy Act.

Processes requests for information under FOI.

Executes FOI denial authority for the agency.

Press Relations Staff (DAFB–1): Advises and assists top level agency officials on print press matters involving mass media communications.

Plans, develops, and implements agency wide print media strategies for disseminating regulatory and educational material to the public through the mass media.

Serves as the agency focal point for preparing, clearing, and disseminating press releases and other print media statements representing agency policy and responding to media inquiries; maintains liaison with news media and pertinent publications.

Establishes policy for and coordinates all print media information activities, including news interviews and responses to inquiries; prepares position and policy statements for use by agency employees in responding to print media questions; tracks issues of potential interest to the media.

Coordinates the research and drafting of major public statements by the Commissioner including transmittal documents and supportive statements for use in transactions with the Department, other agencies, and the White House; provides editorial consultation and review for manuscripts, articles, and speeches written by the staff offices serving the Commissioner to ensure consistency of information and policy interpretation and maintains mailing lists for these documents.

Compiles, publishes, and distributes the weekly FDA Enforcement Report and the FDA Public Calendar; maintains the FDA Daily Clipping Service and FDA's electronic bulletin board; and coordinates the Daily Media Report.

Communications Staff (DAFB–2): Identifies consumer communication and educational requirements for the agency and creates, implements, and coordinates appropriate programs conducted through the media, agency consumer affairs officers, and other communication sources.

Plans, designs, produces, publishes, and disseminates audiovisual materials, exhibits, posters, publications, and periodicals, including *FDA Consumer*, *FDA Today*, and the *FDA Drug Bulletin*; participates in the planning and development of all publications and audiovisual aspects of communications programs directed at mass audiences.

Provides centralized agency graphic arts and editorial services for public information materials.

Acts as the public information liaison with the Department for all publications and audiovisual needs; provides prepublication clearance of publications, exhibits, and audiovisual materials in accordance with procedures established by the agency, PHS, the Department, Office of Management and Budget (OMB), and the White House.

Provides agency wide advice and consultation in the production of audiovisual materials; maintains centralized files of photographs and audiovisual materials for use by all agency components.

Freedom of Information Staff (DAFB–3): Establishes agency wide policy and provides overall direction and leadership for the Freedom of Information (FOI) program and Privacy Act program.

Serves as the agency expert and focal point for Headquarters and field personnel in the development and implementation of effective policies and procedures in accordance with the Freedom of Information Act, the Privacy Act, FDA regulations, and other relevant statutes.

Receives, reviews, controls, coordinates, and routes all FOI requests to the proper action office; designs and implements control mechanisms to

ensure that FOI and Privacy Act inquiries are processed and responded to within established timeframes.

Reviews all recommendations for denials submitted by Headquarters and field FOI Officers. Determines the need for supplemental information and/or changes in the denial recommendation and coordinates required action with the submitting office.

Analyzes, compiles, and prepares reports on privacy and FOI activities in the agency for the annual reports to the Department and for other reporting requirements.

Maintains copies of agency manuals, indexes, and other records required to be on public display.

Operations Staff (DAFB–4): Directs the effective utilization of all management resources by coordinating the management, facilities, budget, and equipment resources for the Office of Public Affairs.

Reviews organizational, management, and administrative policies of the Office to appraise the efficiency and effectiveness of operations.

Identifies potential management problems and/or needs and plans, develops, and conducts management studies.

Broadcast Media Staff (DAFB–5): Advises and assists top level agency officials on electronic media matters involving mass media communications.

Plans, develops, and implements agency wide broadcast media strategies for disseminating regulatory and educational materials to the public through the mass media.

Serves as the agency focal point for preparing, clearing, and disseminating electronic media requests representing agency policy and responding to electronic media inquiries; maintains liaison with broadcast media contacts.

Establishes policy for and coordinates all broadcast media information activities, including on-camera interviews and response to media inquiries; prepares position and policy statements for use by agency employees in responding to broadcast media questions; tracks issues of potential interest to the media.

Plans and coordinates all broadcast media training for the agency.

Office of the Ombudsman (DAFC): Serves as the agency lead on issues involving the administrative processing of product applications for FDA regulated products.

Provides advice and guidance to the Commissioner and other key agency officials regarding premarket approval processes for all FDA regulated products including requirements pertaining to applications, petitions, amendments, and supplements; and product, processing, packaging, and emerging product technologies.

Investigates and resolves internally and externally generated complaints and disagreements regarding the administrative processing of various applications for products regulated by the agency as well as regarding the fair and even handed application of agency policy and procedures in this process.

Represents the Commissioner or other key agency officials and serves as the agency's principal authority and spokesperson to top level agency and departmental officials, regulated industry representatives, scientific and professional organizations and groups, and other professional, and consumer associations concerning critical and significant issues and activities related to FDA regulated products.

Office of Orphan Products Development (DAFD): Manages the implementation of the provisions of the Orphan Drug Act and its amendments and manages a program to encourage the development of drugs of limited commercial value for use in rare or common diseases and conditions.

Develops and communicates agency policy and makes decisions on approval of sponsor requests and incentives, under the Federal Food, Drug, and Cosmetic Act (the act), including orphan drug protocol assistance under section 525 of the act (21 U.S.C. 360aa), orphan drug designation under section 526 (21 U.S.C.360bb), orphan drug exclusivity under section 527 (21 U.S.C.360cc), and orphan drug grants and contracts to support clinical research and other areas of agency policy related to the development of products for rare disorders.

Represents the Commissioner or serves as the agency's principal authority and spokesperson to the PHS Orphan Products Board, other governmental committees, industry, professional and consumer associations, requesting agency participation in orphan product development activities.

Reviews investigational new drug and biologics applications and investigational device exemptions to locate the existence of products under investigational study that show evidence of effectiveness for rare or common diseases but lack commercial sponsorship. Assists sponsors, researchers, and investigators in communicating with agency regulatory officials and expediting solutions to problems in obtaining investigational or market approval status.

Manages an extramural program of clinical research to evaluate safety and effectiveness of orphan products by funding grants and contracts, requesting applications for funding, organizing peer review of applications, monitoring and guiding investigators, and evaluating study results.

Office of Tobacco Programs (DAFE): Serves as the FDA focal point to provide programmatic direction to agency personnel on tobacco matters related to compliance, outreach activities, and product review under the Federal Food, Drug, and Cosmetic Act as amended.

Provides advice, guidance, oversight, and coordination to a variety of substantive activities in response to the FDA's rule to regulate the sale and distribution of cigarettes and smokeless tobacco products.

Establishes and maintains partnerships with Congress, other Federal agencies (e.g., Center for Disease Control and Prevention, Substance Abuse and Mental Health Services Agency, and the National Institutes of Health, etc.), State and local authorities, consumer groups, industry, and other key stakeholders on matters related to cigarettes and smokeless tobacco products.

Designs and implements a regulatory program that specifically addresses cigarettes and smokeless tobacco products.

Provides oversight and coordination for compliance, surveillance, and education programs and develops and disseminates pertinent information related to the FDA's rule to regulate the sale and distribution of cigarettes and smokeless tobacco products.

Provides agency guidance and coordinates technical evaluation of complex, precedent setting regulatory and scientific issues for existing, new, and/or novel tobacco products.

Identifies, plans, and develops policies, strategies, guidelines, programs, research protocols, standards, and educational materials, in cooperation with appropriate agency personnel.

Develops and utilizes methods to evaluate the effectiveness of program operations.

Develops and implements guidelines to ensure advertising, marketing, and youth access restrictions.

Office of Internal Affairs (DAFF): Provides a centralized agency wide investigative resource for the Commissioner and top agency management.

Provides a centralized investigative liaison between FDA and the Office of the Inspector General (OIG).

Serves as a FDA investigative resource to conduct internal FDA investigations and to support OIG investigations.

Conducts special assignments relative to the functions of this Office as requested.

Office of International and Constituent Relations (DAG): Serves as the agency focal point for developing and maintaining international communications and programs.

Advises and assists the Commissioner on health issues that have an impact on policy, direction, and long-range program goals.

Advises and assists the Commissioner on consumer affairs issues. Serves as the agency focal point for coordinating information from the appropriate agency components about significant consumer affairs issues.

Office of International Programs (DAGA): Serves as the agency focal point for international matters.

Advises the Commissioner and other key agency officials on agency formulation and execution and cross cutting and precedent setting issues involving international matters.

Serves as the agency liaison with other U.S. Government components, international and foreign governments (including Washington, DC embassies) for policy formulation and execution impacting FDA and FDA regulated products.

Directs and monitors agency strategic planning, priority-setting, and resource allocation processes for agency international matters.

Provides support to agency program areas for international activities.

Serves as the focal point for the agency international visitor program.

Provides support and issues guidelines for the visiting scientist program.

Serves as the focal point for the agency international travel program.

Serves as the focal point for international-related training (external and internal).

Serves as the focal point for agency technical cooperation and assistance activities.

Serves as the agency focal point for information exchange on international matters to ensure consistency internally and externally.

Provides a focal point for contacts with foreign governments and international organizations (including Washington, DC embassies).

Serves as the agency focal point for planning and coordinating meetings involving international matters.

Office of Consumer Affairs (DAGB): Serves as the agency focal point for coordinating information from the Centers, the Office of Regulatory Affairs, and other agency components about significant or public interest issues; develops mechanisms to gather consumer views for use in developing agency policy on these issues; monitors the development of agency policy on these issues; apprises the Commissioner and other key agency officials on the impact of consumer involvement in resolving these issues.

Serves as the agency focal point for contacting and involving national consumer groups on agency public participation programs; analyzes consumer feedback at the national level to assess potential major health issues, to determine national trends in consumer concerns, and to compile a consumer perspective of agency regulatory policies and activities; informs other agency components of consumer trends.

Serves as the agency focal point for coordinating information from Centers, the Office of Regulatory Affairs, and other agency components about potential public participation opportunities and informs the consumer of these activities.

Designs and administers special community outreach projects to broaden agency interaction with special target audiences, including the economically and educationally disadvantaged and the minorities.

Administers consumer awareness and advocacy skills training programs designed to educate lay consumers and current/potential consumer representatives for advisory committees to enhance their participation in agency regulatory and decisionmaking processes.

Administers the agency selection process for consumer representatives on advisory committees and panels.

Office of Women's Health (DAGC): Serves as the principal advisor to the Commissioner and other key agency officials on scientific, ethical, and policy issues relating to women's health.

Provides leadership and policy direction for the agency regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the agency.

Monitors the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of gender analysis.

Identifies and monitors the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission.

Serves as the agency's liaison with other agencies, industry, and professional associations with regard to the health of women.

Office of Special Health Issues (DAGD): Serves as an information resource to FDA and provides advice to the Commissioner and other key agency officials on matters related to the acquired immune deficiency syndrome (AIDS), cancer, Alzheimer's Disease, and other special health issues.

Coordinates interactions between FDA and consumer and professional groups dealing with AIDS, cancer, Alzheimer's Disease, and other special health issues.

Serves as a liaison point to coordinate contacts between FDA and other Federal agencies to ensure effective coordination and communication on AIDS, cancer, Alzheimer's Disease, and other special health issues.

Provides internal coordination on FDA activities related to AIDS, cancer, Alzheimer's Disease, and other special health issues.

Assists in the planning, administration, development, and evaluation of FDA policies related to AIDS, cancer, Alzheimer's Disease, and other special health issues.

Office of Policy, Planning, and Legislation (DAH): Advises the Commissioner and other key agency officials on matters relating to agency policy, regulations development, legislative issues, and planning and evaluation activities.

Participates with the Commissioner in the formulation of the basic policies and operational philosophy, which guide the Agency in effectively implementing its responsibilities.

Oversees and directs the agency's legislative activities, including legislative needs, pending legislation, and oversight activities.

Oversees and directs the agency's rulemaking activities and regulations development system.

Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

Oversees and directs FDA's planning and evaluation activities, including the development of programs and planning strategies through analysis and evaluation of issues affecting policies and program performance.

Office of Policy (DAHA): Advises and assists the Commissioner, the Senior Associate Commissioner for Policy, Planning and Legislation and other key agency officials on matters relating to agency policy and regulations development.

Serves as the agency focal point for developing broad agency policy.

Oversees, directs, and coordinates the agency's rulemaking activities and regulations development system.

Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

Initiates new and more efficient systems and procedures to accomplish agency goals in the rulemaking process.

Regulations Policy and Management Staff (DAHA–1): Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development. Directs, manages, and coordinates the agency's rulemaking activities and regulations development system. Initiates new and more efficient systems or procedures to accomplish agency goals in the rulemaking process.

Serves as the agency's focal point with the Department of Health and Human Services, Office of Managament and Budget, and other Federal agencies for policies and programs concerning regulations development.

Reviews proposed regulations, final regulations, and other agency documents to be published in the **Federal Register**. Ensures regulations are necessary; consistent with established agency policy; clearly written; enforceable; coordinated with other agency components, the Office of the General Counsel, and Federal, State, and local government agencies; appropriately responsive to public participation requirements and applicable executive orders; and responsive to any applicable requirements for assessment of economic and environmental effects.

Ensures that all regulations required by statute are issued.

Coordinates, with other agency components, the evaluation of existing regulations to determine whether they are efficiently and/or effectively accomplishing their intended purpose. Identifies regulations that require revision to correspond with current standards and those that should be revoked due to obsolescence. Makes recommendations for disposition of these regulations.

Arbitrates regulatory policy disagreements between agency components during the preparation of **Federal Register** documents.

Regulations Editorial Section (DAHA–11): FDA's official liaison with the Office of the Federal Register. Edits, processes, and prepares finished manuscript material for the issuance of agency proposed and final regulations and other documents published in the **Federal Register**.

Provides all **Federal Register** document development support functions (including cross-referencing, record retention, incorporation by reference, document tracking, and agency master print books of current CFR materials). Controls numbering and organization of agency codified material to insure proper structure of regulations being issued.

Policy Development and Coordination Staff (DAHA–2): Advises and assists the Senior Associate Commissioner for Policy, Planning, and Legislation concerning information that may affect current or proposed FDA policies.

Advises the Senior Associate Commissioner for Policy, Planning, and Legislation and other key agency officials on the formulation of broad agency regulatory policy.

Establishes procedures for agency policy formulation and monitors policy formulation activities throughout the agency.

Negotiates the resolution of policy issues involving more than one component of the agency.

Develops and coordinates the review and analysis of policy.

Initiates and participates in interagency discussions on agency regulations, plans, and policies to improve coordination of Federal regulations. When appropriate, assumes the lead in working with other Federal, State, or local agencies on a specific regulation or in developing an effective alternative regulatory approach.

Serves on agency task forces that are critical elements in the initiation, study, and resolution of priority policy issues.

Serves as the agency liaison for intergovernmental policy development.

Office of Planning (DAHB): Advises and assists the Commissioner and other key agency officials concerning the performance of the FDA planning and evaluation activities.

Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.

Develops, installs, and monitors the agency wide planning system including the 5-year plan, strategic plan, and functional plans.

Conducts operations research, economic, and special studies as a basis for forecasting trends, needs, and major problems requiring solutions, and provides assistance and consultation in these areas to operating units.

Evaluates impact of external factors on FDA programs, including industry economics, consumer expectations, and prospective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

Develops FDA evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

Evaluates impact of FDA programs on consumer protection.

Manages the operation of the agency wide Evaluation Review Board.

Coordinates the evaluation reviews of FDA by external groups.

Planning Staff (DAHB–1): Directs the agency long-range planning processes, including strategic and program planning, and coordinates with the Department of Health and Human Services (DHHS) long-range planning process.

Prepares the FDA Forward Plan and Annual Report.

Assists and consults with agency components in their planning.

Analyzes base line data and determines importance of external factors, including consumer safety and regulatory expectations, which affect the agency.

Consults with and supports the Office of Management and Systems in preparation of the agency budget; consults with and supports the Office of Legislation in the preparation of legislative proposals.

Conducts special planning-related studies and critiques as requested.

Coordinates the agency functional (regulatory, research, etc.) planning processes and supports agency staff units in planning, design, preparation, coordination, and execution.

Represents the agency in departmental planning activities.

Conducts analysis of resource requests submitted by agency components in order to develop resource recommendations for the Commissioner, to support the planning process, and to fulfill DHHS requirements.

Designs and operates management communications systems.

Coordinates and presents an annual regulatory development plan.

Conducts the agency manpower management system.

Evaluation Staff (DAHB–2): Performs agency program and policy evaluations and analytical studies. Recommends alternative courses of action to increase effectiveness of agency allocation of resources and to improve program and project performance.

Performs analyses of significantly broad agency issues identified in the planning process. Recommends and/or

implements steps to resolve these issues.

Ensures that appropriate program evaluation activities are taken in agency components. Monitors and coordinates these efforts to assure uniqueness and a contribution to agency program goals.

Develops the annual evaluation plan for the agency and coordinates with DHHS.

Conducts special evaluation, analytical, and economic-related studies in support of agency policy development and in resolution of broad agency problems.

Evaluates impact of external factors on agency programs, including consumer expectations and prospective legislation.

Evaluates the impact of agency operations and policies on regulated industries and other agency constituents.

Evaluates Program Management System (PMS) projects to provide a basis for agency decisionmaking. Recommends PMS project selections for evaluation, conducts the evaluations, and provides written and/or oral reports to the Commissioner and/or program managers.

Approves survey methodology, design, and questionnaires within the agency prior to Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act; reviews Memoranda of Need, which require the collection of health research data and advises agency components on the planning and design of health research studies.

Advises international health organizations (e.g., World Health Organization) on the use of program evaluation to strengthen program operations in member countries.

Economics Staff (DAHB–3): Provides economic analyses as input to and support for decisions regarding agency policy issues.

Serves as the agency focal point for economic analysis assistance and consultation; provides economic analysis assistance to agency components for regulatory and other program functions.

Advises and assists the Commissioner and other key agency officials on a day-to-day basis concerning economic factors relating to current and proposed agency activities.

Provides a resource of economic research material for use by agency officials in preparing testimony before congressional committees and in developing replies to inquiries directed to the agency.

Conducts economic studies of FDA-related industries as a basis for forecasting trends, needs, and major problems affecting the agency.

Provides agency representation to Congress, OMB, DHHS, and others, as appropriate, on economic issues relating to agency regulations and other current and proposed actions.

Management Initiatives Staff (DAHB–4): Provides process expertise to agency components in designing consensus sessions with internal and external stakeholders.

Assists and consults with agency components on the design and execution of key program and process reinventions.

Assists and consults with agency scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.

Facilitates cross organizational sharing of key program and process improvements.

Serves as agency focal point on project management.

Maintains an agency team of interactive management practitioners.

Maintains and manages a facility for interactive management sessions for group problem-solving, action planning, consensus building, and redesign.

Office of Legislation (DAHC): Advises and assists the Commissioner and other key agency officials concerning legislative needs, pending legislation, and oversight activities that affect FDA.

Serves as the focal point for overall legislative liaison activities within FDA and between FDA, the Department, PHS, and other agencies; and analyzes the legislative needs of FDA and drafts or develops legislative proposals, position papers, and departmental reports on proposed legislation for approval by the Commissioner.

Advises and assists members of Congress and congressional committees and staffs in consultation with the Office of the Secretary, on agency actions, policies, and issues related to legislation which may affect FDA.

Congressional Affairs Staff I (DAHC–1): Serves as the agency focal point with Congress, the Department, PHS, and other agencies on all congressional and legislative issues and activities as they pertain to the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the National Center for Toxicological Research, and cross cutting agency organizational components and issues.

Coordinates and prepares agency responses to congressional and legislative inquiries and other sensitive correspondence on various issues that affect the agency including proposed legislation, oversight, investigative, and constituent matters.

Initiates, coordinates, and provides indepth analyses of agency legislative needs and proposed and pending legislation by preparing supporting documents, legislative proposals, and position papers for the Commissioner, other agency officials, Congress, and OMB.

Develops and coordinates testimony for the agency and the Department for presentation to congressional committees; monitors hearings; and edits transcripts of agency testimony.

Provides information on the agency's legislative programs and proposals to consumers and regulated industry.

In collaboration with other FDA and Department offices, initiates and conducts appraisals of regulatory and scientific policies to resolve problems pertaining to FDA programs and policies under existing statutes.

Congressional Affairs Staff II (DAHC–2): Serves as the agency focal point with Congress, the Department, PHS, and other agencies on all congressional and legislative issues and activities as they pertain to the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health.

Coordinates and prepares agency responses to congressional and legislative inquiries and other sensitive correspondence on various issues that affect the agency including proposed legislation, oversight, investigative, and constituent matters.

Initiates, coordinates, and provides indepth analyses of agency legislative needs and proposed and pending legislation by preparing supporting documents, legislative proposals, and position papers for the Commissioner, other agency officials, Congress, and OMB.

Develops and coordinates testimony for the agency and the Department for presentation to congressional committees; monitors hearings; and edits transcripts of agency testimony.

Provides information on the agency's legislative programs and proposals to consumers and regulated industry.

In collaboration with other FDA and Department offices, initiates and conducts appraisals of regulatory and scientific policies to resolve problems pertaining to FDA programs and policies under existing statutes.

Congressional Affairs Support Staff (DAHC–3): Receives, assigns, and tracks all congressional correspondence, reviews written responses for grammar, accuracy, completeness, and general

quality and maintains congressional correspondence files.

Prepares briefing books for congressional hearings, assists in the preparation and finalization of testimony, researches information in response to congressional, department and interagency requests (verbal or written), responds to incoming calls from Congress (subject to knowledge of program area), and provides office automation support.

Office of Management and Systems (DAJ): Advises and assists the Commissioner and other key agency officials on various management and systems activities.

Ensures that the conduct of agency administrative and financial management activities, including budget, finance, personnel, organization, methods, grants and contracts, procurement and property, records, and similar support activities, effectively support program operations.

Coordinates the integration and development of management information systems.

Advises the Commissioner on management information systems policies.

Executive Management Staff (DAJ–1): Advises the Commissioner and other key agency officials in regard to administrative management matters for their components.

Provides a focal point for administrative activities for the Office of the Commissioner.

Develops, coordinates, and facilitates various administrative processes such as personnel, procurement, training, travel, and other pertinent areas as necessary.

Establishes and maintains liaison with administrative officers throughout the serviced components to keep abreast with current issues.

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

Dated: June 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry that has been developed by the Office of Inspector General in cooperation with, and with input from, the Health Care Financing Administration (HCFA), the Department of Justice (DOJ) and representatives of various trade associations and health care practice groups. The OIG has previously developed and published compliance program guidance focusing on hospitals, clinical laboratories, home health agencies, and third-party medical billing companies. We believe that the development and issuance of this compliance guidance will serve as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care industry.

FOR FURTHER INFORMATION CONTACT: Christine Pullifrone, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

The creation of compliance program guidances has been an important undertaking by the OIG in its effort to engage the health care community in combating fraud and abuse. In formulating this compliance guidance, the OIG has worked closely with HCFA, and has received input from interested parties and industry trade associations. The 4 previously-issued compliance program guidances focused on the hospital industry, home health agencies, clinical laboratories and third-party medical billing companies. The development of these types of compliance program guidances are based on our belief that a health care provider can efficiently use internal controls to monitor adherence to applicable statutes, regulations and program requirements.

Guidance for the DMEPOS Industry

On August 7, 1998, the OIG published a solicitation notice (63 FR 42409) seeking information and recommendations for developing guidance for the durable medical equipment, prosthetics, orthotics and supply (DMEPOS) industry. In response to that solicitation notice, the OIG received numerous comments from various parts of the industry and from their representatives. We carefully considered those comments, as well as consulted with DOJ, HCFA and the durable medical equipment regional carriers in developing a draft compliance program guidance for the DMEPOS industry. In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, the draft guidance for the DMEPOS industry was published in the **Federal Register** on January 28, 1999 (64 FR 4436) for further comment and recommendations.

Elements for an Effective Compliance Program

Through experience, the OIG has identified 7 fundamental elements applicable to an effective compliance program. They are:

- Implementing written policies, procedures and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

Using these 7 elements, the OIG has identified specific areas of DMEPOS industry operations that may prove to be vulnerable to fraud and abuse. Like previously-issued OIG compliance guidance, adoption of the Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry set forth below will be strictly voluntary.

A reprint of the newly-issued compliance program guidance follows:

Office of Inspector General's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry (June 1999)

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human