Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 9, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–18017 Filed 7–13–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health; Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: Public Meeting of the Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 5:30 p.m.–7:30 p.m., July 27, 1999.

Place: Santa Fe Community College, Lecture Hall Room 216, 6401 Richards Avenue, Santa Fe, New Mexico 87505, telephone 505/428–1675.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) is 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 use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This Study Team is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purposes of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns to CDC.

Matters to be discussed: Agenda items include presentations from NCEH and/or its contractor regarding the information gathering project that recently began, and presentations from the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR) regarding the progress of current studies. There will be time for public input, questions, and comments. All agenda items are subject to change as priorities dictate.

Contact persons for additional information: Paul G. Renard, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (M/S F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, fax 770/488–7044.

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 ATSDR.

Dated: July 6, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–17899 Filed 7–13–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2244]

Bayer Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Bayer Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a terpolymer of styrene, divinyl benzene and ethylvinyl benzene, aminomethylated, then quaternized with methyl chloride as an ion exchange resin for use in treating aqueous solutions of sugar and hydrolyzed starch.

FOR FURTHER INFORMATION CONTACT: Parvin M. Yasaei, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3023.

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 9A4677) has been filed by Bayer Corp., 100 Bayer Rd., Pittsburgh, PA 15205, c/o ENVIRON International Corp., 4350 North Fairfax Dr., suite 300, Arlington, VA 22203. The petition proposes to amend the food additive regulations in § 173.25 *Ion-exchange resins* (21 CFR 173.25) to provide for the safe use of a terpolymer of styrene, divinyl benzene and ethylvinylbenzene, aminomethylated, then quaternized with methyl chloride (chemical abstracts name: Benzene, diethenyl-, polymer with ethenylbenzene and ethenylethylbenzene, aminomethylated, chloromethane-quaternized, chloride (CAS Reg. No. 113114–5–9)) as an ion-exchange resin for use in treating aqueous solutions of sugar and hydrolyzed starch.

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

Dated: June 25, 1999.

Alan M. Rulis,

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

[FR Doc. 99–17821 Filed 7–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2245]

BP Amoco Chemicals, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BP Amoco Chemicals, Inc. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene) prepared by the reaction of biphenol and 4,4'-dichlorodiphenylsulfone as articles or components of articles intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration,

200 C St. SW., Washington, DC 20204, 202–418–3086.

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 9B4672) has been filed by BP Amoco Chemicals, Inc., 28100 Torch Pkwy., Warrenville, IL 60555–4015. The petition proposes to amend the food additive regulations in part 177(21 CFR part 177) by adding a section to provide for the safe use of poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene) prepared by the reaction of biphenol and 4,4'-dichlorodiphenylsulfone as articles or components of articles intended for contact with food.

The agency has determined under 21 CFR 25.32(j)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 25, 1999.

Alan M. Rulis,

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

[FR Doc. 99–17915 Filed 7–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

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

ACTION: Notice.

SUMMARY: In its role of identifying and eliminating fraud, waste and abuse in the Department's health care programs, the OIG periodically develops and issues guidance, including Special Fraud Alerts and Advisory Bulletins, to alert and inform health care providers and program beneficiaries about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently-issued OIG Special Advisory Bulletin addressing the civil money penalty (CMP) for hospital payments to physicians as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries, and its application to ''gainsharing'' arrangements involving hospitals and physicians.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Counsel to the Inspector General, (202) 619–1306.

SUPPLEMENTARY INFORMATION:

I. Background

This Special Advisory Bulletin addresses the CMP for hospital payments to physicians to induce reductions or limitations in services to Medicare or Medicaid beneficiaries (section 1128A(b)(1) and (2) of the Social Security Act (the Act)), and its application to ''gainsharing'' arrangements and potentially to certain other hospital-physician clinical ventures. The OIG has concluded that section 1128A(b)(1) of the Act specifically prohibits any gainsharing arrangements that involve payments by or on behalf of a hospital, directly or indirectly, to induce physicians with clinical care responsibilities to reduce or limit services to Medicare or Medicaid patients.

II. Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

A. Introduction

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse and waste in the Department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996, authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

This Special Advisory Bulletin addresses the application of sections 1128A(b)(1) and (2) of the Social Security Act (the Act) to gainsharing arrangements.[1] The civil money penalty (CMP) set forth in section 1128A(b)(1) of the Act prohibits any hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care.

While the OIG recognizes that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, section 1128A(b)(1) of the Act clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization.

Some hospitals and physicians may have already implemented programs that involve Medicare or Medicaid beneficiaries. In exercising its enforcement discretion, and in the absence of any evidence that a gainsharing arrangement has violated any other statutes or adversely affected patient care, the OIG will take into consideration whether a gainsharing arrangement was terminated expeditiously following publication of this Bulletin.

B. Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services

Under section 1128A(b)(1) of the Act, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (section 1128A(b)(2) of the Act).

The statutory proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute.

The breadth of the prohibition was intentional. As initially enacted by Congress, section 1128A(b)(1) of the Act prohibited payments by both hospitals and Medicare managed care plans to induce physicians to reduce clinical services.[2] Section 1128A(b)(1) of the Act was subsequently amended to delete the reference to Medicare managed care plans, and to add a new subsection to section 1876 of the Act that permitted

[1] Gainsharing arrangements may also implicate the anti-kickback statute (section 1128B(b) of the Act) and the physician self-referral prohibitions of the Act (section 1876 of the Act).

[2] Section 9313(c) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (P.L. 99–509).