Dated: October 4, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–16746 Filed 10–10–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHACHSPT)

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) and the Health Resources and Services Administration (HRSA) announce the following committee meeting.

Name: CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment.

Times and Dates: 8 a.m.–5 p.m., November 13, 2006. 8 a.m.–12:15 p.m., November 14, 2006.

Place: Hotel Washington, 15th Street and Pennsylvania Avenue, NW., Washington, DC 20004, Telephone: 202–638–5900 or Fax 202–638–1594.

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

Purpose: This Committee is charged with advising the Secretary, the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS and other STDs.

Matters To Be Discussed: Agenda items include issues pertaining to (1) HIV issues related to stigma, racism and discrimination and (2) Comprehensive adolescent sexual health and other HIV related issues. Agenda items are subject to change as priorities dictate.

For Further Information Contact: Margie Scott-Cseh, Committee Management Specialist, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, Georgia 30333. Telephone: 404–639–8317, or Fax 404–639–3125, e-mail *zkr7@cdc.gov.*

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: October 4, 2006.

Alvin Hall,

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

[FR Doc. E6–16739 Filed 10–10–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH); Advisory Board on Radiation and Worker Health

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

Name: Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health.

Time and Date: 10 a.m.–4 p.m., October 18, 2006.

Place: Via Teleconference. For toll-free access, please dial 866–643–6504. Participant Pass Code 9448550.

Status: Open to the public, but without a public comment period.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort.

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2007.

Purpose: The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: The agenda for the Advisory Board meeting includes Updates on Conflict of Interest Issues; Working Group Updates; Selection of Board Members for Individual Dose Reconstruction Reviews; Planning for Board Future Meetings and Activities; and Discussion of Past Public Comments and Possible Board Actions.

The agenda is subject to change as priorities dictate. In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Due to programmatic matters, this **Federal Register** Notice is being published on less than 15 calendar days notice to the public (41 CFR 102–3.150(b)).

Contact Person for More Information: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513–533–6825, fax 513–533–6826.

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: October 4, 2006.

Alvin Hall,

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

[FR Doc. E6–16747 Filed 10–10–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted

for current vacancies and those that will or may occur through August 31, 2007.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons in table 1 of this document:

TABLE 1.

Contact Person	Committee/Panel
Geretta P. Wood, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022, e-mail: *geretta.wood@fda.hhs.gov*	Certain Device Panels of the Medical Devices Advisory Committee
Nancy M. Wynne, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *nancy.wynne@fda.hhs.gov*	National Mammography Quality Assurance Advisory Committee
Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, e-mail: *collin.figueroa@fda.hhs.gov*	Device Good Manufacturing Practice Advisory Committee
Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *richard.kaczmarek@fda.hhs.gov*	Technical Electronic Product Radiation Safety Standards Committee

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–7293, e-mail: *kathleen.walker@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations of voting members for vacancies listed as follows:

TABLE 2.

Committee/Panel Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee—anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia	2 2	Immediately December 1, 2006
Circulatory System Devices Panel of the Medical Devices Advisory Committee—interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure	4	July 1, 2007
Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee—doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology	2	March 1, 2007
Dental Products Panel of the Medical Devices Advisory Committee—dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy	2	November 1, 2006
Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee—otologists, neurotologists, and audiologists	1	November 1, 2006
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee—gastroenterologists, urologists, and nephrologists	2	January 1, 2007
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians	2 2	Immediately September 1, 2007

TABLE 2.—Continued

Committee/Panel Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed
Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee—hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and homeostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers	3	Immediately
Immunology Devices Panel of the Medical Devices Advisory Committee—persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine	2	March 1, 2007
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—experts with broad, cross-cutting scientific, clinical, analytical, or mediation skills	1	Immediately
Microbiology Devices Panel of the Medical Devices Advisory Committee—infectious disease clinicians (e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, and mycologists); clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays (e.g., hepatologists and molecular biologists)	3 2	Immediately March 1, 2007
Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee—experts in human genetics and in the clinical management of patients with genetic disorders (e.g., pediatricians, obstetricians, and neonatologists); individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology, and related statistical training; individuals with experience in genetic counseling or medical ethics; ancillary fields of study will be considered as well	1 3	Immediately June 1, 2007
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee—experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing	2	February 1, 2007
Radiological Devices Panel of the Medical Devices Advisory Committee—physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties, and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging, and image analysis	1	February 1, 2007
National Mammography Quality Assurance Advisory Committee—physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography	1	February 1, 2007
Device Good Manufacturing Practice Advisory Committee—Nine vacancies occurring immediately; three government representatives, two industry representatives, two public representatives, and two health professionals	9	Immediately
Technical Electronic Product Radiation Safety Standards Committee—10 vacancies occurring immediately, 4 government representatives, 2 industry representatives, and 4 general public representatives; 5 vacancies occurring January 1, 2007, 3 industry representatives, 1 government representative, and 1 general public representative	10 5	Immediately January 1, 2007

II. Functions

A. Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, performs the following duties: (1) Advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4)

reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the act, (7) advises on the necessity to ban a device, and (8) responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or agency decisions or actions.

B. National Mammography Quality Assurance Advisory Committee

The functions of the committee are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities, (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program, (3) developing regulations with respect to sanctions, (4) developing procedures for monitoring compliance with standards, (5) establishing a mechanism to investigate consumer complaints, (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities, (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas, (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999, and (9) determining the costs and benefits of compliance with these requirements.

C. Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the act (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) two shall be representatives of the interests of the general public.

D. Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the act (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990, provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental agencies, including State or Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor.

III. Qualifications

A. Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated should be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations will include complete curriculum vitae of each nominee, current business address and telephone number. Nominations will specify the advisory panel(s) or advisory committee(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee if selected, and appears to have no conflict of interest that would preclude membership. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: October 3, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–16679 Filed 10–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0444]

Redetermination of Regulatory Review Period for Purposes of Patent Extension; BONIVA; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 22, 2006 (71 FR 35918). The document announced that FDA had determined the regulatory review period for BONIVA. The notice provided that on or before August 21, 2006, anyone with knowledge that any of the dates as published are incorrect may submit a request for a redetermination of the regulatory review period. A request for revision of the regulatory review period was filed for the product on July 25, 2006. FDA reviewed its records and found that the effective date of the investigational new drug application (IND) was incorrect because of a clerical error. Therefore, FDA is republishing a determination of the regulatory review period to reflect the corrected effective date for the IND. FDA has made a determination of the regulatory review period because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product BONIVA (ibandronate sodium). BONIVA is indicated for treatment and prevention of osteoporosis in postmenopausal women. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BONIVA (U.S. Patent No. 4,927,814) from Hoffmann-La Roche, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BONIVA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable adjusted regulatory review period for BONIVA is 3,122 days. Of this time, 2,817 days occurred during the testing phase of the regulatory review period, while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective: October 30, 1994. FDA has verified the applicant's claim that the date the IND became effective was on October 30, 1994.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: July 16, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for BONIVA (NDA 21–455) was initially submitted on July 16, 2002.

3. The date the application was approved: May 16, 2003. FDA has verified the applicant's claim that NDA 21–455 was approved on May 16, 2003.

This redetermination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations