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

of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,713 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by December 11, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 9, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 22, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–16816 Filed 10–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: October 16, 2006.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate the Rehabilitation Medicine Program.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room 6–1480, Bethesda, MD 20892, 301/402–0244.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: October 4, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8602 Filed 10–10–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Interagency Autism Coordinating Committee

The National Institutes of Health (NIH) hereby announces a meeting of the Interagency Autism Coordinating Committee (IACC) to be held on November 17, 2006, on the NIH campus in Bethesda, Maryland.

The Children's Health Act of 2000 (Pub.L. 106–310), Title I, Section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services (DHHS). In April 2001, the HHS Secretary delegated the authority to establish the IACC to the National Institutes of Health (NIH). The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The IACC meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee.

Date: November 17, 2006.

Time: 9 a.m.–4 p.m.

Agenda: Discussion of autism activities across Federal agencies.

Place: National Institutes of Health, Building 31, Conference Room 10 (6th floor), 31 Center Drive, Bethesda, Maryland 20892.

Contact Person: Ann Wagner, Ph.D., Division of Pediatric Translational Research and Treatment Development, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6184, MSC 9617, Bethesda, Maryland 20892. E-mail: *awagner@mail.nih.gov.* Phone: 301–443–5944.

Any member of the public interested in presenting oral comments to the Committee may notify the contact person listed on this notice at least 5 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Presentations may be limited to 5 minutes; both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding his/her statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and, when applicable, the business or professional affiliation of the interested person.

Information about the meeting and online registration forms are also available on-line on the NIMH homepage at *http://www.nimh.nih.gov/autismiacc/index.cfm.*

Dated: September 29, 2006.

Raynard S. Kington, M.D., Ph.D.,

Deputy Director, National Institutes of Health.

[FR Doc. E6–16721 Filed 10–10–06; 8:45 am]

BILLING CODE 4167–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 522b(c)(6), Title 5 U.S.C.,