nominee, including current business address, telephone number, and e-mail address if available. Nominations must also acknowledge that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning matters related to financial holdings, employment, and research grants and/or contracts.

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: May 28, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–10737 Filed 6–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Risk Communication Advisory Committee; Establishment

AGENCY: Food and Drug Administration

ACTION: Notice of establishment.

Under the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Commissioner of Food and Drugs (the Commissioner), announces the establishment of the Risk Communication Advisory Committee. The Commissioner has determined that it is in the public interest to establish such a committee.

The Risk Communication Advisory Committee shall provide advice to the Commissioner or designee on strategies and programs designed to communicate with the public about both the risks and benefits of Food and Drug Administration (FDA)-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products. Duration of this committee is 2 years from the date the Charter is filed, unless the Commissioner formally determines that renewal is in the public interest.

The Risk Communication Advisory Committee will be composed of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of risk communication, social marketing, health literacy, cultural competency, journalism, bioethics, and other relevant behavioral and social sciences. Some members will be selected to provide experience-based insights on the communications needs of the various groups who use FDA-regulated products. The latter may include patients and patients' family members, health professional, communicators in health, medicine and science, persons affiliated with consumer, specific disease, or patient safety advocacy groups. Depending on the meeting topic(s), at least one nonvoting member identified with relevant industry interests may be invited from existing members of other FDA Advisory Committees.

FOR FURTHER INFORMATION CONTACT: Lee Zwanziger, Office of Planning, Office of the Commissioner (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2895, FAX: 301–827–5260, or *rcac@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, FDA is publishing a request for nominations for advisory committee members and notice of a change to the advisory committee telephone information line adding the establishment of the Risk Communication Advisory Committee. FDA plans to publish in the near future a final rule adding the Risk Communication Advisory Committee to the list of FDA standing advisory committees in 21 CFR 14.100.

Dated: May 28, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–10740 Filed 6–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006E–0332 and 2006E–0333]

Determination of Regulatory Review Period for Purposes of Patent Extension; NAMENDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NAMENDA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim 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 human drug product 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 drug 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, NAMENDA

(memantine hydrochloride). NAMENDA is indicated for the treatment of moderate to severe dementia of the Alzheimer's type. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for NAMENDA (U.S. Patent Nos. 5,061,703 and 5,614,560) from Forest Laboratories, Inc., acting as agent for Merz Pharma GmbH & Co. KGaA, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated January 26, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NAMENDA 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 regulatory review period for NAMENDA is 5,001 days. Of this time, 4,699 days occurred during the testing phase of the regulatory review period, while 302 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*: February 7, 1990. The applicant claims October 9, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the original IND effective date was February 7, 1990, which was the date the original IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 19, 2002. FDA has verified the applicant's claim that the new drug application (NDA) (NDA 21–487) was initially submitted on December 19, 2002.

3. *The date the application was approved*: October 16, 2003. FDA has verified the applicant's claim that NDA 21–487 was approved on October 16, 2003.

This determination 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 1,250 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 August 6, 2007. 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 December 3, 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: May 2, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10730 Filed 6–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Information Hotline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that we have revised the Advisory Committee Information Hotline (the hotline). The hotline provides the public with access to the most current information available on FDA advisory committee meetings. This notice supersedes all previously published announcements of the hotline.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Committee Management Officer (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: The hotline can be accessed by dialing 1–800–741–8138 or 301–443–0572. The advisory committee meeting information and information updates can also be accessed via FDA's advisory committee calendar at *http://www.fda.gov/oc/advisory/accalendar/2007/default.htm*.

Each advisory committee is assigned a 10–digit number. This 10–digit number will appear in each individual notice of meeting. The public can obtain information about a particular advisory committee meeting by using the committee's 10–digit number. Information on the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made. The following is a list of each advisory committee's 10–digit number to be used when accessing the hotline.

Advisory Committee	10–Digit Access Number
Office of the Commissioner	
Pediatric Advisory Committee	8732310001
Risk Communication Advisory Committee	8732112560
Science Board to the FDA	3014512603
Center for Biologics Evaluation and Research	
Allergenic Products Advisory Committee	3014512388
Blood Products Advisory Committee	3014519516