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]

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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