2. Improve the existing home and community based care system to better respond to the needs of persons with dementia and their families.

Eligibility for Grant Awards and Other Requirements

Eligibility for grant awards is limited to state agencies. The twenty-five states currently funded under the Alzheimer's Demonstration Program are not eligible. Only one application per state will be accepted. Applicants must provide a letter from their state's Governor designating the applicant agency as the sole applicant for the state.

Grantees are required to provide a 25% non-federal match during the first year, 35% during the second year, and 45% during the third year of the grant.

DATES: The deadline date for the submission of applications is April 24, 2002.

ADDRESSES: Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Center for Policy and Planning Development, 330 Independence Ave., SW, Room 4270, Washington, DC 20201, by calling 202/401–4547, or online at *http://www.aoa.gov/egrants.*

Applications may be mailed or hand-delivered to the AoA Office of Grants Management at the same address. Instructions for electronic submission of grant applications are available at *http://www.aoa.gov/egrants.*

Dated: February 25, 2002.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 02–4917 Filed 2–28–02; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1233]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HECTOROL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (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: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner 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 HECTOROL (doxercalciferol). HECTOROL is indicated for the reduction of elevated iPTH levels in the management of secondary hyperparathyroidism in patients undergoing chronic renal dialysis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HECTOROL (U.S. Patent No. 4,555,364) from The Wisconsin Alumni Research Foundation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of HECTOROL 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 HECTOROL is 4,072 days. Of this time, 3,614 days occurred during the testing phase of the regulatory review period, while 458 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* April 17, 1988. The applicant claims April 16, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 17, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* March 9, 1998. The applicant claims March 7, 1998, as the date the new drug application (NDA) for HECTOROL (NDA 20–862) was initially submitted. However, FDA records indicate that NDA 20–862 was submitted on March 9, 1998.

3. *The date the application was approved:* June 9, 1999. FDA has verified the applicant's claim that NDA 20–862 was approved on June 9, 1999.

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 1,824 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 30, 2002. 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

August 28, 2002. 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 Dockets Management Branch. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 23, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–4889 Filed 2–28–02; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 23, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail at *PerezT@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting. Background materials for this meeting when available will be posted on the Internet one business day before the meeting at *www.fda.gov/ohrms/dockets/ac/acmenu.htm.*

Agenda: The committee will discuss risk management for new drug application (NDA) 21–107, LOTRONEX (alosetron), GlaxoSmithKline.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 15, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–4890 Filed 2–28–02; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 7, 2002, from 10:30 a.m. to 3:30 p.m., and on March 8, 2002, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, ext. 111, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 7, 2002, the committee will discuss and make recommendations on the classification of preamendments in vitro diagnostic products to identify *Bacillus anthracis* and *Yersinia pestis.* No applications will be reviewed at this meeting. On March 8, 2002, the committee will discuss, make recommendations, and vote on a supplement to a premarket approval application for a nucleic acid hybridization in vitro diagnostic device for the detection of 13 high-risk types of human papilloma virus DNA in cervical specimens. The test is indicated for use as a general population screening test in conjunction with the *Papanicolaou* smear for women 30 years of age and older, as an aid to determine the absence of high-grade cervical disease or cancer. The test is not intended for use as a screening test in the general population for women under 30 years of age.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.* Material for the March 7 session will be posted on March 6, 2002; material for the March 8 session will be posted on March 7, 2002.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 4, 2002. On March 7, 2002, formal oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:15 p.m., and between approximately 2:30 p.m. and 2:45 p.m. On March 8, 2002, formal oral presentations from the public will be scheduled between approximately 11 a.m. and 11:45 a.m., and between approximately 3 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 4, 2002, and submit a brief statement of the