document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recomendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: March 8, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–2453 Filed 3–14–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities: Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), Administration for Children and Families, HHS.

ACTION: Notice of meeting.

DATES: The meeting will be held on Friday, March 24, 2006, from 3 p.m. to 5 p.m. Eastern Daylight Savings Time. The full committee meeting of PCPID will be conducted by telephone conference call and will be open to the public. Anyone interested in participating in the conference call should advise Ericka Alston at 202–619–0634, no later than March 17, 2006.

ADDRESSES: The conference call may be accessed by dialing, U.S. toll-free 1–888–395–6878, and the passcode ''March 2006'' on the date and time indicated.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2) notice is hereby given that the President's Committee for People with Intellectual Disabilities will hold its first quarterly meeting of 2006 by telephone conference call. The conference call will be open to the public to listen, with call-ins limited to the number of telephone lines available. Individuals who plan to call in and need special assistance, such as TTY, assistive listening devices, or materials in alternative format, should inform Ericka Alston, Executive Assistant, PCPID, Telephone—202–619–0634, Fax—202–205–9519, E-mail: *ealston@acf.hhs.gov*, no later than March 10, 2006. Efforts will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed.

AGENDA: Committee members will be briefed on the outcome of the March 22, 2006 Roundtable on Personal and Economic Freedom for People with Intellectual Disabilities: An Exploration of Asset Development for People with Intellectual Disabilities that will be jointly sponsored by PCPID, the Administration for Children and Families' Office of Community Services, and the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE).

FOR FURTHER INFORMATION CONTACT: Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, Aerospace Center Office Building, Suite 701, 901 D Street, SW., Washington, DC 20447, Telephone—202–619–0634, Fax—202–205–9519, E-mail: *satwater@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: March 1, 2006.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. E6–3642 Filed 3–14–06; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0256]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OVIDREL 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 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

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 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 OVIDREL (choriogonadotropin alfa for injection). OVIDREL is indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been

appropriately treated with follicle stimulating hormones as part of an assisted reproductive technology program such as *in vitro* fertilization and embryo transfer. Ovidrel is also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OVIDREL (U.S. Patent No. 4,840,896) from Genzyme Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OVIDREL 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 OVIDREL is 1,787 days. Of this time, 1,485 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 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: November 1, 1995. The applicant claims October 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 1, 1995, 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*: November 24, 1999. The applicant claims November 23, 1999, as the date the new drug application (NDA) for OVIDREL (NDA 21–149) was initially submitted. However, FDA records indicate that NDA 21–149 was submitted on November 24, 1999.

3. *The date the application was approved*: September 20, 2000. FDA has verified the applicant's claim that NDA 21–149 was approved on September 20, 2000.

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 1,054 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 15, 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 September 11, 2006. 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 are to 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: February 13, 2006.

Jane Axelrad,

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

[FR Doc. E6–3640 Filed 3–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0039]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CRESTOR 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 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

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 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 CRESTOR (rosuvastatin calcium). CRESTOR is indicated in the following ways: (1) As an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Type IIa and IIb); (2) as an adjunct to diet for the treatment of patients with elevated serum TG levels (Frederickson Type IV); and (3) to reduce LDL-C, total-C, and ApoB in patients with homozygous