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Dated: March 8, 2006.

Robert Sargis,

Reports Clearance Officer.

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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: éalston@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.

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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