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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological 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 biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product CAMPATH (alemtuzumab). CAMPATH is indicated for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CAMPATH (U.S. Patent No. 5,545,403) from Millenium and Ilex Partners, L.P., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of CAMPATH represented the first permitted commercial marketing or use of the product. 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 CAMPATH is 3,423 days. Of this time, 2,921 days occurred during the testing phase of the regulatory review period, while 502 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 (21 U.S.C. 355(i)) became effective: December 25, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 25, 1991.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 23, 1999. The applicant claims December 22, 1999, as the date the product license application (BLA) for CAMPATH (BLA 103948/0) was initially submitted. However, FDA records indicate that BLA 103948/0 was submitted on December 23, 1999.

3. The date the application was approved: May 7, 2001. FDA has verified the applicant's claim that BLA 103948/0 was approved on May 7, 2001.

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 632 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 September 13, 2004. 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 January 10, 2005. 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 (see **ADDRESSES**). 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: June 21, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–15802 Filed 7–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0279]

Developing Drug Information Association/Food and Drug Administration Workshop: Pharmacogenomic Combination Product Co-Development; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Drug Information Association (DIA), is announcing a public meeting to solicit views and to provide an interactive forum for discussion of industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. The input received at the meeting, comments received during the meeting, and comments made to the docket after the meeting, may be considered in developing a draft guidance on this topic.

DATES: The public meeting will be held on July 29, 2004, from 8 a.m. to 5:30 p.m. Attendees must register to attend. Submit written or electronic requests to speak at the public meeting by July 26, 2004. Submit written or electronic comments before or after the meeting by August 30, 2004.

ADDRESSES: The public meeting will be held at the Marriott Crystal Gateway Hotel, 1700 Jefferson Davis Hwy., Arlington, VA. A copy of the meeting's program is available on the Internet at *http://www.diahome.org/Content/Events/04040.pdf.*

Submit written comments 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:

Those wishing to speak should contact: Allen Rudman, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7691, e-mail: *RUDMANA@CDER.FDA.GOV*.

Those wishing to register for the meeting should contact: Drug Information Association, P.O. Box 827192, Philadelphia, PA 19182–7192, e-mail: *DIA@DIAHOME.ORG*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is embarking on a new initiative to develop guidance for the codevelopment of pharmacogenomic-based therapeutic drug and biological products and the diagnostic tests that are necessary for therapeutic decision making. A number of diagnostic tests could be developed for use with drug or biological products including, for example, tests related to treatment decisions, such as whether patients should be treated, the dose used for treatment, or to identify the risks associated with treatment. FDA expects to develop guidance for the codevelopment of therapeutic and diagnostic products where both will be necessary in the clinical management of patients.

In preparation for drafting the guidance, FDA and DIA have planned a 1-day mini-meeting, in collaboration with Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Advanced Medical Technology Association, Medical Device Manufacturers Association, the DIA Biotechnology Special Interest Action Committee, and the Pharmacogenomics Working Group, to identify important issues related to the codevelopment of pharmacogenomic combination products. FDA believes it is important to receive input from industry and other interested parties through a public meeting before drafting the guidance.

Previously, FDA and industry have cosponsored two multi-day meetings on pharmacogenomics in May 2002 and November 2003, respectively. This collaboration between industry, FDA, and other interested parties has also facilitated the writing and issuance of the draft guidance for industry entitled ''Pharmacogenomic Data Submissions,'' which was issued in November 2003 and is currently being finalized.

II. Goals of the Meeting

The primary intent of this mini-meeting is to provide an interactive forum for discussing industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. This meeting is intended to be highly interactive, identify issues, and address questions that will provide FDA with valuable information to consider during development of guidance for industry on the codevelopment of pharmacogenomic combination products for therapeutic and diagnostic use.

Key areas identified for particular focus include the following:

- Industry vision of an ideal codevelopment process and regulatory framework,
- Clinical trial design and statistical challenges for the codevelopment of therapeutic and diagnostic pharmacogenomic products,
- Case studies to explore detailed considerations for the analytical validation of pharmacogenomic diagnostic products, and
- Clinical utility of pharmacogenomic diagnostic products.

Specific goals of the meeting include the following:

1. Provide greater awareness and understanding of the regulatory and scientific challenges of codeveloping pharmacogenomic combination products.

2. Obtain greater clarity on the clinical and statistical design issues that affect the codevelopment of drug and pharmacogenomic combination products.

3. Provide an opportunity to help define the elements that are needed in guidance for industry to enhance the codevelopment of pharmaogenomic combination products.

4. Provide pharmaceutical, biological product, device industries, and other public stakeholders with an opportunity to identify issues and propose recommendations for FDA consideration as it develops formal guidance on the codevelopment of pharmaogenomic combination products.

III. Intended Audience

This meeting is intended for developers and potential developers of therapeutic drug and biological products and pharmacogenomic-based diagnostic products to be developed and approved with them as combination products. Other interested persons may include regulatory/clinical decision-makers, designers of clinical and laboratory validation protocols, clinical pharmacologists, physicians, biostatisticians, and geneticists working in industry or academia.

IV. Request for Comments

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics presented in this document. The agency welcomes comments before and after the meeting. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15935 Filed 7–9–04; 2:24 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93.145, HRSA 04–076]

Cooperative Agreement for a Twinning Center (CATC)

AGENCIES: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: This notice announces the availability of funds for a Cooperative Agreement for the establishment of a Twinning Center (TC) to support twinning and volunteer activities as part of the implementation of the President's Emergency Plan for AIDS Relief (the President's Emergency Plan). The Cooperative Agreement will be awarded for a 5-year project period.

Program Purpose: The purpose of this funding is to support the President's Emergency Plan by strengthening human and organizational capacity through twinning and use of health care volunteers to rapidly expand the pool of trained providers, managers, and allied health staff delivering quality HIV/AIDS services to people with HIV/AIDS. Fourteen countries including 12 in African and two in the Caribbean (Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia), are the focus of the initiative, based on high HIV burden and limited country resources. A fifteenth country, outside of Africa and the Caribbean, will soon