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 ACOVA (argatroban). ACOVA is an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ACOVA (U.S. Patent No. 5,214,052) from Texas Biotechnology 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 May 3, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ACOVA 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 ACOVA is 4,022 days. Of this time, 2,971 days occurred during the testing phase of the regulatory review period, while 1,051 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 (the act) (21 U.S.C. 355(i)) became effective*: June 28, 1989. The applicant claims January 12, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 1989, 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(b) of the act*: August 15, 1997. The applicant claims August 20, 1997, as the date the new drug application (NDA) for ACOVA (NDA 20–883) was initially submitted. However, FDA records indicate that NDA 20–883 was submitted on August 15, 1997.

3. *The date the application was approved*: June 30, 2000. FDA has verified the applicant's claim that NDA 20–883 was approved on June 30, 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 839 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by January 13, 2003. 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 May 13, 2003. 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 is 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: September 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–28884 Filed 11–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0022]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SOLAGE 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 which 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, Regulatory Policy Staff (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 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 SOLAGE (mequinol). SOLAGE is indicated for the treatment of solar lentigines. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SOLAGE (U.S. Patent No. 5,194,247) from Bristol-Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SOLAGE 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 SOLAGE is 2,689 days. Of this time, 1,978 days occurred during the testing phase of the regulatory review period, while 711 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*: August 1, 1992. The applicant claims August 3, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 1992, 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*: December 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for SOLAGE (NDA 20–922) was initially submitted on December 30, 1997.

3. *The date the application was approved*: December 10, 1999. FDA has verified the applicant's claim that NDA 20–922 was approved on December 10, 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 1,365 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by January 13, 2003. 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 May 13, 2003. 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 is 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: September 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–28885 Filed 11–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Meeting To Update Stakeholders on the Progress of the Recreation One-Stop Initiative

Date: Thursday, November 21, 2002.
Registration: 12:30 p.m.–1 p.m.
Meeting: 1 p.m.–4 p.m.
Location: American Institute of Architects (AIA), 1735 New York Avenue NW., Washington, DC 20006.

Background

Recreation.gov (*www.recreation.gov*) is an Internet portal providing one-stop access to federal recreation information. The service, which is hosted by the Interior Department, is a partnership among Federal natural resources agencies, with participation from State and local agencies. Recreation.gov is being expanded to a broader service called Recreation One-Stop. The Administration's E-Government task force selected Recreation One-Stop as one of 24 government-wide Internet projects intended to expand and improve on-line access to government information and services. The goals of the Recreation One-Stop initiative are to improve the quality and availability of recreation information through partnerships, data sharing, and innovative uses of technology.

The Recreation One-Stop Team held a public meeting on March 7, 2002, in Washington, DC to discuss the goals and objectives of the project, and to obtain feedback from stakeholders and interested parties. A summary of the meeting is available on the web at *http://recreation.gov/summary.cfm.*

The project team has taken action on many of the recommendations made at the March 7 meeting. Additional features have been added to the Recreation.gov site, and the project team commissioned an independent report by the Industry Advisory Council (IAC) to identify best practices related to development of data standards and governance of intergovernmental portal projects.

Purpose of Meeting

The purpose of this meeting is to provide the public and our stakeholders with an update on actions taken since the March meeting, and to solicit feedback and suggestions on the next phases of the project.

Topics

Areas to be covered at the meeting include the following:

Update: The Recreation One-Stop Team will provide an overview of actions taken since the last stakeholder meeting, and provide an overview of the IAC best practices study.

Technology: One of the common themes from the March stakeholder meeting was the importance of developing data standards and the importance of data quality and availability. The status of intergovernmental data standards for recreation will be discussed.

Governance: Recreation One-Stop is evolving toward a Federal-State/Public-Private partnership to promote data sharing related to recreational resources. One of the issues to be discussed is the development of an appropriate governance structure for this initiative.

Attendance

This is a public meeting open to anyone interested in learning more about Recreation One-Stop and providing input on the development of the project. For more information, please contact Charlie Grymes at the