

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 lentiginos.

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]

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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

Department of the Interior at 202-219-1285. Space is limited; if you plan to attend, please respond by November 14 to Angela Mathews at 202-208-5606. Please let us know if you have special needs.

Other Details

The AIA building is directly behind the Octagon House. The closest Metro stops are Farragut West (Blue and Orange Line) and Farragut North (Red Line). Exit the Metro on the 18th Street side and walk approximately 4 blocks south. Street parking is available, but parking in this area is limited. There is parking available for a fee at the Colonial parking garage at G and 18th St. There are also numerous coffee shops and restaurants in the area.

Dated: November 7, 2002.

Scott Cameron,

Deputy Assistant Secretary, Performance and Management.

[FR Doc. 02-28916 Filed 11-13-02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

National Wildlife Refuge System; Big Game Guide Permits; Solicitations and Extensions

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of solicitation of applications for refuge big game guide permits and extension of existing refuge permits.

SUMMARY: The Fish and Wildlife Service is soliciting proposals to conduct commercial big game guide services on National Wildlife Refuges in Alaska for a 5-year period beginning in 2004. We are also providing a 6-month extension of existing big game guide permits.

DATES: The application period opens November 14, 2002. Applications must be received at the address indicated below by 4 p.m., Friday, February 28, 2003.

FOR MORE INFORMATION CONTACT: Tony Booth, U.S. Fish and Wildlife Service, Division of Visitor Services and Communications, 1011 East Tudor Road MS 235, Anchorage, Alaska, 99503; telephone (907) 786-3357; e-mail tony_booth@fws.gov.

SUPPLEMENTARY INFORMATION: The Fish and Wildlife Service is requesting proposals to conduct commercial big game guide services within designated guide use areas in each of the National Wildlife Refuges in Alaska. The Service

will award special use permits to successful applicants authorizing them to provide commercial guide services to the public in specific refuge guide use areas for the period of January 1, 2004, through December 31, 2008. We will award the permits through a competitive selection process in which qualified big game guides may apply for specific refuge areas offered by the Service. Each application or proposal will be evaluated and scored/ranked according to evaluation criteria and selection factors developed by the Service.

The application period will begin on the date specified in the DATES section near the beginning of this notice. We will send a letter to all registered big game guides in the State of Alaska providing information on the guide areas being offered and application instructions. We are also publishing notices in Anchorage and Fairbanks newspapers that provide general circulation in Alaska. Applications are available to any interested party by calling or writing to the above address. Applicants must postmark their proposals or hand deliver them to the above address by Friday, February 28, 2003.

The Service is also providing notice that we are extending the expiration date of existing Alaska National Wildlife Refuge big game guide permits and the competitive guide selection process for 6 months. This 6-month extension will put all permits on a calendar year cycle. The big game guide permits currently in effect for the refuge use areas being offered will expire on June 30, 2003. We are extending the expiration date of these permits to December 31, 2003. We are moving the effective date for new guide permits from July 1, 2003, to January 1, 2004.

The Service issued 12 big game guide permits under the competitive selection process in 1999 to fill vacant guide use areas where we did not renew permits. These permits are slated to expire on June 30, 2004. This notice extends the terms of these permits to December 31, 2004, to make them consistent with the calendar year cycle as well. The new permit cycle will be consistent with most other State and Federal licensing and permitting requirements for Alaska big game guides. The State of Alaska Division of Occupational Licensing administers hunting guide and transporter licenses on a calendar year basis.

The extension in the selection process was also necessary to allow the Service to extend the public review period for the proposed revisions of the evaluation factors and guidance that we will use to

score and rank guide applications. This was done in response to public requests, and to provide a longer and more reasonable application period for big game guide permits. The extension of the permitting process will accommodate flexibility to extend the permit application deadline further into the winter, well after the fall hunting season, and thereby allow guides more reasonable time to prepare their applications during the slower time of year for the guiding industry.

Alaska refuge permit regulations (50 CFR part 36.41(e)(10)) require the Service to issue competitively awarded permits for 5-year terms (except where permits are issued to fill vacancies occurring during a scheduled award cycle). The regulations require the refuge manager to renew the permits noncompetitively for 5 additional years, if the permittee applies for the renewal, and has maintained a satisfactory record of performance and complied with all applicable permit terms and conditions. The regulations state that after one renewal the Service will not extend or noncompetitively renew another permit. We are providing 6-month extensions to all existing guide permits, in addition to the 5-year renewals cited above. Therefore, the 6-month extensions require a one time waiver of the Alaska refuge permit regulations.

Dated: August 29, 2002.

David B. Allen,

Regional Director.

[FR Doc. 02-28871 Filed 11-13-02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-090-1610-PG; DBG-0200001]

Notice of Public Meeting: Resource Advisory Council to the Lower Snake River District, Bureau of Land Management, Department of the Interior

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Lower Snake River District Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held December 4, 2002, at the Lower Snake