

comments submitted to the agency by e-mail. We encourage you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Chasey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301-796-2090.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Eligibility of SSOS**

In November 2007, we received a TEA (Ref. 1) requesting that SSOS be eligible for review under our OTC dandruff, seborrheic dermatitis, and psoriasis monograph (21 CFR part 358 subpart H). In February 2008, we received a supplement to the TEA, which included data and information clarifying some points in the TEA (Ref. 2). After reviewing the TEA and its supplement, we believe that it includes adequate data demonstrating that SSOS has been marketed for a material time and to a material extent as required by § 330.14 (21 CFR 330.14) (Ref. 3). SSOS-containing products have been marketed directly to consumers for over 5 continuous years in 26 countries, with an estimated 21 million dosage units marketed in 34 countries.

The applicant requested that SSOS be indicated for use to treat dandruff and psoriasis, in rinse-off and leave-on formulations. However, nearly all of the submitted marketing data concerns SSOS in rinse-off formulations for dandruff treatment. More marketing experience of SSOS in leave-on formulations for dandruff treatment would be necessary to find SSOS

eligible in leave-on formulations. SSOS in leave-on formulations does not meet the "material extent" requirement of § 330.14(b)(2) and section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). Only 2 to 4 million dosage units of SSOS in leave-on formulations have been sold, which is inadequate compared to the number of dosage units sold for other conditions found eligible for inclusion in the OTC drug monograph system via the TEA process (tens of millions). Therefore, we conclude that SSOS, 0.5 to 2.0 percent in rinse-off formulations for dandruff treatment, is eligible for inclusion in the OTC dandruff, seborrheic dermatitis, and psoriasis monograph.

##### **II. Request for Data and Information**

We invite all interested persons to submit data and information on the safety and effectiveness of SSOS in order for us to determine whether it is GRASE and not misbranded under recommended conditions of OTC use (see § 330.14(f)). The data submitted should include animal and human studies that meet current scientific standards. The TEA does not include an official or proposed United States Pharmacopeia-National Formulary (USP-NF) drug monograph. According to § 330.14(i), an official or proposed USP-NF monograph for each ingredient must also be included as part of the safety and effectiveness data for this ingredient.

##### **III. Marketing Policy**

Under § 330.14(h), any product containing SSOS may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

##### **IV. References**

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for Sodium Shale Oil Sulfonate (SSOS) Submitted by DOW Pharmaceutical Sciences, Inc., dated November 30, 2007.
2. Supplement to the SSOS TEA Submitted by DOW Pharmaceutical Sciences, Inc., dated February 1, 2008.
3. FDA's evaluation of the TEA for SSOS.

Dated: March 24, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-7766 Filed 4ndash;6-09; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF INTERIOR**

### **National Park Service**

#### **60-Day Notice of Intention To Request Clearance of Collection of Information; Opportunity for Public Comment**

**AGENCY:** Department of Interior, National Park Service.

**ACTION:** Notice and request for comments.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on an extension of a currently approved collection of information (OMB #1024-0226).

**DATES:** Public comments on this Information Collection Request (ICR) will be accepted on or before June 8, 2009.

**ADDRESSES:** Send comments to: Charlie Stockman, Outdoor Recreation Planner, Rivers, Trails and Conservation Assistance Program, NPS, 1849 C St., NW., (2220), Washington, DC 20240; or via fax at 202/371-5179; or via e-mail at [Charlie\\_Stockman@nps.gov](mailto:Charlie_Stockman@nps.gov). All responses to the Notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

*To Request a Draft of Proposed Collection of Information Contact:* Charlie Stockman, NPS, 1849 C St., NW., (2220), Washington, DC 20005; or via phone at 202/354-6900; or via fax at 202/371-5179; or via e-mail at [Charlie\\_Stockman@nps.gov](mailto:Charlie_Stockman@nps.gov). You are entitled to a copy of the entire ICR package free of charge once the package is submitted to OMB for review. You can access this ICR at <http://www.reginfo.gov/public/>.

#### **SUPPLEMENTARY INFORMATION:**

*Title:* National Park Service Partnership Assistance Programs GPRA Information Collection.

*Form(s):* None.

*OMB Control Number:* 1024-0226.

*Expiration Date:* 8/31/2009.

*Type of Request:* Extension of a currently approved collection of information.

*Description of Need:* The Government Performance and Results Act (GPRA) of 1995 (Pub. L. 103–62) and the National Park Service (NPS) Strategic Plan require that the NPS develop goals to improve program effectiveness and public accountability. GPRA also requires Federal agencies to prepare annual performance reports documenting the progress made toward achieving long-term goals. Surveys for the Rivers, Trails, and Conservation Assistance Program (RTCA) and the Federal Lands to Parks Program (FLP) will measure performance and suggest improvements towards these goals. Data from these studies are needed to meet the requirement of GPRA and the NPS Strategic Plan. The two programs are to meet Long-term Goal IIIb2. This goal states: 95% of communities served are satisfied with NPS partnership assistance in providing recreational conservation benefits on lands and waters. The NPS needs the information in these collections to assess the annual progress being made toward meeting Long-term Goal IIIb2 of the NPS Strategic Plan.

The proposed surveys will provide the NPS with data from its partners. Partners are those individuals or organizations that seek NPS assistance through these two programs. NPS will obtain critical information to determine if it's meeting the diverse needs of its constituency and how to respond to future changes. The information sought is not collected elsewhere by the Federal Government. The NPS needs this information to help evaluate and improve its partnership assistance programs. NPS' RTCA Program and FLP Program will conduct surveys to assess client satisfaction with the services received and to identify needed program improvements. The NPS goal in conducting these surveys is to use the information to identify areas of strength and weakness in its recreation and conservation assistance programs, to provide an information base for improving those programs, and to provide a required performance measurement (Goal IIIb2 of the National Park Service Strategic Plan) under GPRA. The obligation to respond is voluntary.

*Automated Data Collection:* The information will be collected primarily through the use of an electronic survey.

*Description of respondents:* This is a census survey of all principal cooperating organizations and agencies which have received substantial assistance from the Rivers, Trails and Conservation Assistance Program or the Federal Lands to Parks Program during

the prior Fiscal Year (October 1 through September 30).

*Estimated average number of responses:* 150 per year.

*Frequency of response:* 1 per respondent.

*Estimated average time burden per respondent:* 10 minutes.

*Estimated total annual reporting burden:* 25 hours per year.

*Comments are invited on:* (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: March 31, 2009.

**Cartina A. Miller,**

*Information Collection Clearance Officer,  
National Park Service.*

[FR Doc. E9-7717 Filed 4-6-09; 8:45 am]

#### BILLING CODE

### DEPARTMENT OF THE INTERIOR

#### Fish and Wildlife Service

[FWS-R9-FHC-2008-N0328; 94300-1124-0000-T5]

#### Coastal Barrier Resources System Digital Mapping Pilot Project

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** This notice announces the availability of the *Report to Congress: John H. Chafee Coastal Barrier Resources System Digital Mapping Pilot Project* and draft maps for public review and comment. This notice also advises the public where the report and draft maps may be obtained and where comments should be sent.

**DATES:** We must receive comments on or before July 6, 2009.

**ADDRESSES:** Mail or hand-deliver (during normal business hours)

comments to Katie Niemi, Coastal Barriers Coordinator, Division of Habitat and Resource Conservation, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 860A, Arlington, VA 22203 or send comments by electronic mail (e-mail) to [CBRAComments@fws.gov](mailto:CBRAComments@fws.gov). For information about how to get copies of the pilot project report and maps or where to go to view them, see **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Katie Niemi, Coastal Barriers Coordinator, (703) 358-2161.

#### SUPPLEMENTARY INFORMATION:

#### Background

The Coastal Barrier Resources Act (CBRA) of 1982 (16 U.S.C. 3501 et seq.) established the John H. Chafee Coastal Barrier Resources System (CBRS) to minimize the loss of human life; reduce wasteful Federal expenditures; and minimize the damage to fish, wildlife, and other natural resources associated with coastal barriers. Most new Federal expenditures and financial assistance that have the effect of encouraging development are prohibited within the CBRS. In the Coastal Barrier Improvement Act of 1990 (Pub. L. 101-591), Congress amended CBRA to add new units, enlarge some previously designated units, add Otherwise Protected Areas (OPAs) as a new category of lands, and approve a series of maps entitled "John H. Chafee Coastal Barrier Resources System" and dated October 24, 1990. These maps identify and depict those coastal barriers located on the coasts of the Atlantic Ocean, Gulf of Mexico, Great Lakes, Virgin Islands, and Puerto Rico that are subject to the Federal funding limitations outlined in CBRA.

The Secretary of the Interior (Secretary), through the U.S. Fish and Wildlife Service (Service), is responsible for administering CBRA, which includes: maintaining the official maps of the CBRS; consulting with Federal agencies that propose spending funds within the CBRS; and making recommendations to Congress regarding whether certain areas were appropriately included in the CBRS. Aside from three minor exceptions, only Congress through new legislation, can modify the CBRS boundaries to add or remove land. These exceptions include: (1) The CBRA 5-year review requirement that solely considers changes that have occurred to the CBRS by natural forces such as erosion and accretion; (2) voluntary additions to the CBRS by property owners; and (3) additions of excess Federal property to the CBRS.