DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 23, 2009, from 8:30 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4050, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by Atritech, Inc., for the WATCHMAN® Left Atrial Appendage (LAA) Closure Technology. The WATCHMAN® device, a percutaneously placed permanent implant, is intended as an alternative to warfarin therapy for patients with non-valvular atrial fibrillation. The WATCHMAN® LAA Closure Technology is designed to prevent embolization of thrombi that may form in the left atrial appendage thereby preventing the occurrence of ischemic stroke and systemic thromboembolism.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 16, 2009. Oral presentations from the public will be scheduled approximately 30 minutes at the beginning of committee deliberations and approximately 30 minutes near the end of the deliberations. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 8, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 9, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–7726 Filed 4–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0146]

Sodium Shale Oil Sulfonate Eligibility for Inclusion in Monograph; Over-the-Counter Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Human Use; Request for Safety and Effectiveness Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: As part of our ongoing review of over-the-counter (OTC) drug products, we (Food and Drug Administration (FDA)) are announcing a call-for-data for safety and effectiveness information for sodium shale oil sulfonate (SSOS), 0.5 to 2.0 percent, as a rinse-off treatment for dandruff. We have reviewed a time and extent application (TEA) for SSOS and determined that it is eligible for consideration in our OTC drug monograph system. We will evaluate the submitted data and information to determine whether SSOS can be generally recognized as safe and effective (GRASE) as an OTC rinse-off treatment for dandruff.

DATES: Submit data, information, and general comments by July 6, 2009.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0146, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, we are no longer accepting

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*. 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*. 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.