

manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2015-D-4012 for “Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993, 240-402-4246.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request.” This draft guidance provides background information on the sunscreen OTC monograph process and the new procedures under the SIA (Pub. L. 113-195, enacted November 26, 2014), for reviewing 586A requests (requests made under section 586A of the FD&C Act (21 U.S.C. 360fff-1) and pending requests for nonprescription sunscreen active ingredients (the SIA process). This draft guidance provides recommendations for the general withdrawal process for 586A requests and pending requests. At certain stages of the SIA process, a sponsor who submitted the 586A request or pending request might seek to have it withdrawn, or a request may be withdrawn due to the sponsor’s failure to act on the request and failure to respond to communications from FDA. This draft guidance addresses the expected effect of a withdrawal on key phases of the SIA process, including withdrawals made prior to or after the initial eligibility determination, the submission of safety and efficacy data, the filing determination, or the GRASE determination. This draft guidance also discusses the submission of a new 586A request for the same sunscreen

ingredient for which a 586A or pending request had been previously submitted and withdrawn.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the withdrawal of 586A requests and pending requests under the SIA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

##### III. Paperwork Reduction Act of 1995

This draft guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA). Section 586D(a)(1)(C) of the FD&C Act (21 U.S.C. 360fff-4(a)(1)(C)) states that the PRA shall not apply to collections of information made for purposes of guidance under section 586D(a).

Dated: November 16, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Orthopaedic and Rehabilitation 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:** Orthopaedic and Rehabilitation 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 Friday, February 19, 2016, from 8 a.m. to 6 p.m.

**Location:** Hilton Washington, DC/ North, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

**Contact Person:** Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm.1643, 10903 New Hampshire Ave., Silver Spring, MD 20993, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301 796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The Committee will discuss the premarket application for the DIAM Spinal Stabilization System. The DIAM Spinal Stabilization System is indicated for skeletally mature patients that have low back pain (with or without radicular pain) with current episode lasting less than 1 year in duration secondary to moderate lumbar degenerative disc disease (DDD) at a single level from L2-L5. DDD is confirmed radiographically with one or more of the following factors: (1) Patients must have greater than 2 millimeters of decreased disc height compared to the adjacent level; (2) scarring/thickening of the ligamentum flavum, annulus fibrosis, or facet joint capsule; or (3) herniated nucleus pulposus. The DIAM device is implanted via a minimally invasive posterior approach.

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/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting 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 February 12, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 February 4, 2016. 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 February 5, 2016.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at 301-796-5966 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: November 13, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-29768 Filed 11-20-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-3990]

#### Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process." This draft guidance explains the process by which FDA intends to carry out the section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), which governs the convening of advisory committees and the number of requests to be considered per meeting. The recommendations in this draft guidance apply to 586A requests submitted under the FD&C Act and to pending requests as defined by the SIA that seek a determination from FDA on whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is generally recognized as safe and effective for use under specified conditions and should be included in the over-the-counter (OTC) sunscreen drug monograph. The SIA describes specific circumstances under which FDA is "not" required to convene or submit requests to the Nonprescription Drugs Advisory Committee (NDAC). We are issuing this draft guidance pursuant to the SIA, which directs FDA to issue four guidances on various topics, including this draft guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 22, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the