

instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the 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must include the Docket No. FDA-2015-D-3990 for "Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process; Draft Guidance for Industry."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.

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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: Section 586C(c) Advisory Committee Process." This draft guidance provides background information on the sunscreen OTC monograph process, as well as on the Agency's intended process for convening the NDAC. It also recommends procedures for sponsors of 586A requests (submitted under section

586A of the FD&C Act (21 U.S.C. 360fff-1)) and for sponsors of pending requests (as defined by section 586(6) of the FD&C Act (21 U.S.C. 360fff (6))) to follow in requesting an NDAC meeting. This draft guidance also explains how FDA intends to process these requests and describes the factors the Agency may consider in determining whether and when to refer such requests to the NDAC.

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 process by which the Agency will carry out section 586C(c) of the SIA (Pub. L. 113-195). 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 document 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 SIA 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.*

[FR Doc. 2015-29635 Filed 11-20-15; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2015-D-4033]

#### Sunscreen Innovation Act: Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions; 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 “Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act”. This draft guidance addresses FDA’s current thinking on how we will determine whether a sponsor’s submission of safety and efficacy data is sufficiently complete to support a substantive review and determination under the Sunscreen Innovation Act (SIA) that an active ingredient is or is not generally recognized as safe and effective (GRASE) for use in nonprescription sunscreen products. This guidance is being issued in accordance with the SIA.

**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*

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- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

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**Instructions:** All submissions received must include the Docket No. FDA-2015-D-4033 for “Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions; Draft Guidance for Industry; Availability”. 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.

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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 “Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act”.

This draft guidance is being issued in accordance with the SIA (21 U.S.C. Ch. 9 Sub. 5 Part I), enacted November 26, 2014, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 586D(a)(1)(A)(i) of the FD&C Act (21 U.S.C. 360fff-4(a)(1)(A)(i)), as added by the SIA, directs FDA to issue guidance on the format and content of information submitted to FDA in support of a request for a determination whether a sunscreen active ingredient or combination of active ingredients is GRASE and not misbranded for use in nonprescription sunscreen products. The information in this guidance is intended to help sponsors and manufacturers prepare a GRASE data submission that is sufficiently complete (including being formatted in a manner that enables FDA to determine its completeness) to enable FDA to conduct a substantive GRASE review, as required by section 586B(b)(2) of the FD&C Act (21 U.S.C. 360fff-2(b)(2)).

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 format and content of GRASE data submissions 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. The Paperwork Reduction Act of 1995

This guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). Section 586D(a)(1)(C) of the FD&C Act (21 U.S.C. 360ff–4(a)(1)(C)) states that the PRA shall not apply to information collected under this guidance.

## III. Electronic Access

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

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–D–4021]

### Over-the-Counter Sunscreens: Safety and Effectiveness Data; 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 “Over-the-Counter Sunscreens: Safety and Effectiveness Data.” This draft guidance addresses FDA’s current thinking about the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients evaluated under the Sunscreen Innovation Act (SIA) is generally recognized as safe and effective (GRASE) and not misbranded when used under specified conditions. The guidance also addresses FDA’s current thinking about an approach to safety-related final formulation testing that it anticipates adopting in the future.

**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*

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**Instructions:** All submissions received must include the Docket No. FDA–2015–D–4021 for “Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability.” 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.

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