committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens appointed to serve on a CDC SEP and can be full-time employees of the U.S. Government. Current participation on CDC federal workgroups or prior experience serving on another federal advisory committee does not disqualify a reviewer, except for service on the Board of Scientific Counselors, NCIPC. However, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Reviewers appointed to the SEP, CDC are not considered Special Government Employees, and will not be required to file financial disclosure reports.

Nominees interested in serving as a potential reviewer on a SEP, CDC for NCIPC programs should submit the following items:

• Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, and email address).

Nomination materials must be postmarked by March 31, 2017 and sent by U.S. mail to: NCIPC Extramural Research Program Office (ERPO): Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F–63, Atlanta, Georgia 30329 or to the ERPO Mailbox *NCIPC_ERPO@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–28207 Filed 11–22–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Advisory Committee on Breast Cancer in Young Women, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through June 17, 2018.

For information, contact Temeika L. Fairley, Ph.D., Designated Federal Officer, Advisory Committee on Breast Cancer in Young Women, HHS, CDC, 4770 Buford Highway NE., Mailstop K52, Atlanta, Georgia 30341, telephone 770/488–4518, fax 770/488–4760.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–28206 Filed 11–22–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4033]

Nonprescription Sunscreen Drug Products—Format and Content of Data Submissions; 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 guidance for industry entitled ''Nonprescription Sunscreen Drug Products—Format and Content of Data Submissions.'' This guidance addresses FDA's current thinking on the format and content of information provided to support a request for a determination whether a nonprescription sunscreen active ingredient is generally recognized as safe and effective (GRASE), as provided under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA).

DATES: Submit either electronic or written comments on Agency guidances at any time.

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 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–4033 for ''Nonprescription Sunscreen Drug Products—Format and Content of Data Submissions; 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.

- *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 the 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 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 guidance for industry entitled ''Nonprescription Sunscreen Drug Products—Format and Content of Data Submissions.'' This guidance replaces a draft guidance that was issued on November 23, 2015, under the title ''Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act'' (see 80 FR 72973), and incorporates editorial changes and clarifying language based on FDA's consideration of comments received on that draft guidance. The draft guidance and related public comments are available at *http://www.regulations.gov* by searching Docket No. FDA–2015–D–4033.

This guidance addresses FDA's current thinking on the format and content of information provided to support a request submitted under section 586A (586A request) of the FD&C Act (21 U.S.C. 360fff–1), as amended by the Sunscreen Innovation Act (SIA) (21 U.S.C. Ch. 9 Sub. 5 Part I, enacted November 26, 2014), or in support of a pending request, as defined under section 586(6) of the FD&C Act (21 U.S.C. 360fff(6)).[1] The requests addressed in this guidance seek a determination from FDA of whether an over-the-counter (nonprescription) sunscreen active ingredient,[2] or a combination of nonprescription sunscreen active ingredients, is GRASE for use under specified conditions and should be included in the over-the-counter sunscreen drug monograph.[3] The GRASE determination is primarily based on FDA's review of safety and effectiveness data and other information submitted by the request's sponsor (GRASE data submission) but also on information and comments submitted to the public docket by other interested parties.[4] Before that review may begin, however, FDA must review the GRASE data submission for completeness and determine accordingly whether to file or refuse to file it for substantive review. If the submission is not sufficiently complete to enable the Agency to conduct a substantive GRASE review, including being formatted in a manner that will enable the Agency to evaluate the submission's completeness, FDA will refuse to file the submission (section 586B(b)(2) of the FD&C Act).

FDA is issuing this guidance in partial implementation of the SIA, which, among other things, added section 586D(a)(1)(B) of the FD&C Act (21 U.S.C. 360fff–4(a)(1)(B)) and directed FDA to finalize guidance on the implementation of and compliance with the SIA requirements for nonprescription sunscreens, including the Agency's guidance on the format and content of information submitted by a sponsor in support of a 586A request or a pending request. The information in this guidance is intended to provide recommendations to help sponsors 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 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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. A sponsor or member of the public can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

[1] The SIA defines a *pending request* to mean a request for a nonprescription sunscreen active ingredient to be included in the over-the-counter monograph that was originally submitted as a time and extent application under 21 CFR 330.14 and that was determined to be eligible for review and for which safety and effectiveness data were submitted prior to the enactment of the SIA (section 586(6) of the FD&C Act).

[2] As defined in the SIA, *sunscreen* means a drug containing one or more sunscreen active ingredients (section 586(9) of the FD&C Act (21 U.S.C. 360fff(9)), and the term *sunscreen active ingredient* means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation (section 586(10) of the FD&C Act (21 U.S.C. 360fff(10)).

[3] See section 586(4) of the FD&C Act (21 U.S.C. 360fff(4) (definition of ''GRASE determination''). Under the SIA, FDA must also make an initial determination on whether a nonprescription sunscreen ingredient or combination of sunscreen ingredients that is the subject of a 586A request has been marketed for a material time and to a material extent and thus whether that ingredient or combination of sunscreen ingredients is eligible for review under the SIA (section 586B(a) of the FD&C Act (21 U.S.C. 360fff–2(a))).

[4] Section 586B(b)(1) of the FD&C Act. An SIA *sponsor* is a person who has submitted a 586A request, a pending request, or any other application subject to the SIA (section 586(8) of the FD&C Act (21 U.S.C. 360fff(8)).

II. The Paperwork Reduction Act of 1995

This guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Section 586D(a)(1)(C) of the FD&C Act, as amended by the SIA, states that the PRA shall not apply to collections of information for purposes of guidance under that subsection.

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 17, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28121 Filed 11–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4021]

Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data; 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 guidance for industry entitled ''Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data.'' This guidance addresses FDA's current thinking on 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 the Agency anticipates adopting in the future.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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 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'').

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- *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–4021 for ''Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data; 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.

- 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/regulatory&information/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.

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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 20993–0002, 240–402–4246.

SUPPLEMENTARY INFORMATION:

I. Background

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