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 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 ''Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process.'' This 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 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This guidance finalizes the draft guidance that was issued under the same title on November 23, 2015 (see 80 FR 72972), and reflects FDA's consideration of public comments on the draft guidance. The draft guidance and related public comments are publicly available in Docket No. FDA–2015–D–3990. In addition to minor editorial changes, we have clarified the information in section III of the guidance on when to submit a request for an NDAC meeting.

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 process by which the Agency will carry out section 586C(c) of the SIA (21 U.S.C. 360fff–3). 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 guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This 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: October 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24460 Filed 10–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4012]

Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request; 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 ''Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request.'' This guidance provides recommendations for the process for withdrawing a 586A request submitted under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), and withdrawing a pending request, as defined by the SIA. The recommendations in this guidance apply to 586A requests and pending requests that seek a determination from FDA of whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is generally recognized as safe and effective (GRASE) for use under specified conditions and should be included in the over-the-counter (OTC) sunscreen drug monograph. We are issuing this guidance under the SIA, which directs FDA to issue guidance on various topics, including guidance on the process by which a request under section 586A or a pending request is withdrawn. This guidance finalizes the draft guidance issued on November 23, 2015.

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–4012 for ''Sunscreen Innovation Act; Withdrawal of a 586A Request or Pending Request.'' 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 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 ''Sunscreen Innovation Act; Withdrawal of a 586A Request or Pending Request.'' This guidance provides background information on the sunscreen OTC monograph process and the new procedures under the SIA (21 U.S.C. 360fff), 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 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 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 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 guidance finalizes the draft guidance that was issued under the same title on November 23, 2015 (see 80 FR 72970), and reflects FDA's consideration of public comments on the draft guidance. The draft guidance and related public comments are publicly available in Docket No. FDA–2015–D–4012. In addition to minor editorial changes, we have clarified the use of publicly available data and information submitted to the docket as it pertains to the withdrawal process.

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 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 guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This 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: October 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24459 Filed 10–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1446]

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' This document describes studies and criteria that FDA recommends be used when submitting premarket notifications (510(k)s) for self-monitoring blood glucose test systems (SMBGs) intended for over-the-counter (OTC) home use by lay-users.