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'').

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–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.

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 20993–0002, 240–402–4246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data.'' This guidance replaces a draft

guidance entitled ''Over-the-Counter Sunscreens: Safety and Effectiveness Data'' that was issued on November 23, 2015 (see 80 FR 72975) 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–4021.

This guidance addresses the current thinking of FDA about the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients evaluated under the SIA (Pub. L. 113–195), enacted November 26, 2014, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351 *et seq.*), is 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. FDA is issuing this guidance in partial implementation of the SIA which, among other things, established new procedures and review timelines for FDA to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients is GRASE and not misbranded when used under the conditions specified in a final sunscreen order, in accordance with sections 586A, 586B, and 586C of the FD&C Act (21 U.S.C. 360fff–1, 360fff–2, and 360fff–3). The SIA directed FDA to issue guidance on four topics, including guidance regarding safety and effectiveness data in accordance with section 586D of the FD&C Act (21 U.S.C. 360ffff–4). Many of the safety topics addressed in this guidance were discussed at a public Nonprescription Drug Advisory Committee meeting held on September 4 and 5, 2014, *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/ucm380890.htm.*

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on the topics it addresses. This guidance 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 (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 made for purposes of guidance under that subsection.

III. 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.*

Dated: November 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28124 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–2016–N–3389]

Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for scientific data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting scientific data, information, and comments that would help us evaluate the beneficial physiological effects to human health of isolated or synthetic non-digestible carbohydrates that are added to foods. We are requesting such scientific data, information, and comments to help us determine whether a particular isolated or synthetic non-digestible carbohydrate should be added to our definition of ''dietary fiber'' for purposes of being declared as dietary fiber on a Nutrition Facts or Supplement Facts label.

DATES: Submit either electronic or written scientific data, information, and comments by January 9, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic scientific data, information, and 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 comments 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–2016–N–3389 for ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments.'' 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