



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Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry;
Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period provided in the notice entitled "Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability" that appeared in the **Federal Register** on November 23, 2015 (80 FR 72975). That notice announced the availability of a draft guidance for industry and requested comments to that draft guidance by January 22, 2016. FDA is extending the draft guidance's comment period by 30 days (to February 22, 2016) in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the draft guidance by an additional 30 days. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to permit the Agency to consider your comments before issuing the final version of the guidance, submit either electronic or written comments on the draft guidance by February 22, 2016.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 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 "Over-the-Counter Sunscreens: Safety and Effectiveness Data; 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 the 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 20993-0002, 240-402-4246.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 23, 2015 (80 FR 72975), FDA published a notice of availability with a 60-day comment period for the draft guidance for industry entitled "Over-the-Counter Sunscreens: Safety and Effectiveness Data." Publication of that draft guidance was mandated by the Sunscreen Innovation Act (SIA), which also requires FDA to publish the final guidance no later than November 26, 2016.

The Agency has received a request for a 30-day extension of the comment period to provide more time for regulated industry to prepare a detailed and meaningful response to the

draft guidance. FDA has considered the request and is extending the comment period for 30 days, until February 22, 2016. The Agency believes that a 30-day extension will allow adequate time for interested persons to submit comments without compromising timely publication of the final guidance as mandated by the SIA.

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>.

Dated: January 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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