

please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. The agency plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving

quality, accessibility, and affordability in healthcare. CMS also aims to put patients first in the delivery of their health care needs.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete Survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is an in-person, nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (e.g., fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 25 years, encompassing over 1 million interviews and more than 100,000 survey participants. Respondents participate in up to 11 interviews over a three and a half year period. This gives a comprehensive picture of health care costs and utilization over a period of time.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. Beginning in 2019, this proposed revision to the clearance will eliminate or streamline some questionnaire sections, add a few new measures, take advantage of administrative data to reduce the number of survey questions in some long term care facilities, and discontinue the 12th interview as had previously been collected. The revisions will result in an overall reduction in respondent burden by 25%. *Form Number:* CMS-P-0015A (OMB control number: 0938-0568); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 14,146; *Total Annual Responses:*

37,407; *Total Annual Hours:* 44,817. (For policy questions regarding this collection contact William Long at 410-786-7927.)

Dated: May 18, 2018.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-11056 Filed 5-22-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICE

### Food and Drug Administration

[Docket No. FDA-2010-D-0509]

#### Enforcement Policy—Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application." This guidance describes FDA's approach to enforcement for over-the-counter (OTC) sunscreen products marketed without approved applications before a final OTC sunscreen drug monograph becomes effective. This guidance finalizes the draft guidance of the same name issued June 17, 2011.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 23, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2010-D-0509 for “Enforcement Policy—Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 20993-0002, 240-402-4246.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application.” This guidance applies to OTC sunscreen products marketed without approved applications and describes FDA’s approach to enforcement for these products until a final OTC sunscreen monograph becomes effective. This guidance finalizes a draft guidance that was issued under the same title on June 17, 2011 (76 FR 35665) and reflects FDA’s consideration of public comments on the draft guidance.

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 enforcement

policy for OTC sunscreen drug products marketed without an approved application. 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. This guidance is not subject to Executive Order 12866.

##### II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) and under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.327 and 201.66, and 21 CFR part 330 have been approved under OMB control numbers 0910-0717, 0910-0340, and 0910-0688, respectively.

##### 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 <https://www.regulations.gov>.

Dated: May 17, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-1456]

#### Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; 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 “Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.” This draft guidance addresses FDA’s current thinking on the conduct of in vivo absorption trials for topical active ingredients that are under