4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0449]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements for Over-the-Counter Sunscreen Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on sun protection factor (SPF) labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and comments on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2011-N-0449 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products." Received comments, those filed in a timely manner (see ADDRESSES), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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. "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 provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

SPF Labeling and Testing Requirements for OTC Sunscreen Products--21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)

OMB Control Number 0910-0717--Extension

I. Background

In the *Federal Register* of June 17, 2011 (76 FR 35620), we published a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). In addition to establishing testing requirements, the 2011 sunscreen final rule lifted the delay of implementing the prior 1999 sunscreen final rule (published in the *Federal Register* of May 21, 1999 (64 FR 27666) and stayed in the *Federal Register* of December 31, 2001 (66 FR 67485) from complying with the 1999 Drug Facts labeling final rule (published in the *Federal Register* of March 17, 1999 (64 FR 13254)), in which we amended our regulations governing requirements for human drug products to establish

standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). Specifically, the 1999 Drug Facts labeling final rule added new § 201.66 to part 201. Section 201.66 establishes content and format requirements for the Drug Facts portion of OTC drug product labels. We specifically exempted OTC sunscreen products from complying with the 1999 Drug Facts labeling final rule until we lifted the stay of the 1999 sunscreen final rule. The 2011 sunscreen final rule became effective December 17, 2012, for sunscreen products with annual sales of $25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than $25,000 when we published an extension date notice in the *Federal Register* of May 11, 2012 (77 FR 27591) (2012 extension date notice).

II. SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and Marketed Without Approved Applications

In the *Federal Register* of June 17, 2011 (76 FR 35678), we published a 60-day notice requesting public comment on the proposed collection of information regarding SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications (2011 60-day notice). In that notice, we stated that § 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 sunscreen final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, that provision resulted in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the 2011 sunscreen rule. We determined that products need only complete the testing and labeling required by the 2011 sunscreen rule once and then continue to use the resultant labeling (third-party disclosure) going forward without additional burden. This one-time testing would need to

be conducted within the first 3 years after publication of the 2011 sunscreen final rule for all OTC sunscreens covered by that rule.

We determined that the third-party disclosure burden by manufacturers of OTC sunscreens covered by the 2011 sunscreen rule was based on: (1) an estimate of the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information; (2) the conduct of SPF testing based on the estimated number of existing formulations; (3) an estimate of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day notice was a total of 30,066 hours in years 1 and 2, and a total of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are already required to comply with the SPF labeling requirements specified by the 2011 sunscreen final rule. However, our original estimate also included the burden of new products introduced each year. We estimated that as many as 60 new OTC sunscreen products stock keeping units (SKUs) may be introduced each year, which must be tested and labeled with the SPF value determined in the test. We estimated that the 60 new sunscreen SKUs represent 39 new formulations. The burden for testing and labeling these formulations was estimated at 30 hours per year.

We received only two comments on our estimated information collection burden (FDA-2011-N-0449-0002 and FDA-2011-N-0449-0003). These comments were already addressed in FDA's notice entitled "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sun Protection Factor Labeling and

Testing Requirements and Drug Facts Labeling for Over-the Counter Sunscreen Drug Products" published in the *Federal Register* of May 9, 2012 (77 FR 27230).

In the *Federal Register* of April 16, 2015 (80 FR 20499), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden[1]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Conduct SPF testing in accordance with § 201.327(i) for new sunscreens	20	1.95	39	24	936
Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs	20	3	60	0.5 (30 minutes)	30
Total					966

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Drug Facts Labeling for OTC Sunscreens

Because the 2011 sunscreen final rule also lifted the delay of implementing the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modified the information collection associated with § 201.66 (currently approved under OMB control number 0910-0340) and added a third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the 1999 Drug Facts labeling final rule, we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products, codified in § 201.66. This section establishes requirements for the Drug Facts portion of labels on OTC drug products requiring such labeling, to include uniform headings and subheadings, presented in a standardized order with minimum standards for type size and other graphical features. Therefore, OTC sunscreen products already on the market at that time incurred a one-time

burden to comply with the requirements in § 201.66(c) and (d). In the 60-day notice, the burden was estimated as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 sunscreen final rule that lifted the delay of the § 201.66 labeling implementation data for OTC sunscreen products were December 17, 2012, for sunscreen products with annual sales of $25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than $25,000, respectively, when we published the 2012 extension date notice. All currently marketed sunscreen products are, therefore, already required to comply with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 Drug Facts labeling final rule. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. In the 2011 60-day notice, we estimated that as many as 60 new product SKUs marketed each year must comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers, which will spend approximately 12 hours on each label based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. This is equal to 720 hours annually (60 SKUs, 12 hours per SKU). We stated that we do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e). However, we considered this in 2013 and estimated the burden for an exemption or deferral by considering the number of exemptions or deferrals we have received since publication of the 1999 Drug Facts labeling final rule (one response) and estimating that a request for deferral or exemption would require 24 hours to complete. Multiplying the annual

frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting an exemption or deferral equal to 3 hours.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs	20	3	60	12	720
Request for Drug Facts exemption or deferral § 201.66(e)	1	0.125	0.125	24	3
Total					723

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

We note that these estimates may be adjusted in the future development of an upcoming rulemaking on over-the-counter sunscreen products (RIN 0910-AA01). FDA intends to amend this information collection and/or seek approval of additional information collections, as appropriate, concurrent with this rulemaking.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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