Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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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 and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 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 June 15, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All OTC Sunscreen Products—21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d) (OMB Control Number 0910–0717)—Extension

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, this sunscreen final rule lifts the delay of implementation of the prior 1999 sunscreen final rule (published May 21, 1999, at 64 FR 27666 and stayed December 31, 2001, 66 FR 67485) from complying with the 1999 labeling final rule (published 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 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products. We specifically exempted OTC sunscreen products from complying with the 1999 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 on May 11, 2012 (77 FR 27591).

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 in regard to SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications. In that notice, we stated that § 201.327 (a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, this provision results in information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the rule. We determined that products need only complete the testing and labeling required by the rule one time, and then continue to utilize 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 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 rule was based on an estimate: (1) 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) on the

conduct of SPF testing based on the estimated number of existing formulations; (3) of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) on testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day PRA notice was a total of 30,066 hours in years one and two and a total burden of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are required at this time to be in compliance with the SPF labeling requirements specified by the 2011 final rule. However, our original estimate 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 will have to 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 have received no further comments on our estimate of burden for the collection of this information other than two comments (FDA–2011–N–0449–0002 and FDA–2011–N–0449–0003). These comments were already addressed in FDA's notice of ''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 on May 9, 2012 (77 FR 27230).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number 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 min.) ...	30
Total	.....	.....	.....	.....	966

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

Drug Facts Labeling for OTC Sunscreens

Because the 2011 final rule also lifts the delay of implementation of the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modifies the information collection associated with § 201.66 (currently approved under OMB control number 0910–0340) and adds an additional third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the **Federal Register** of March 17, 1999 (64 FR 13254), 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 (the 1999 Drug Facts labeling final rule). Section 201.66 sets 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, currently marketed OTC sunscreen products will incur a one-time burden to comply with the requirements in § 201.66(c) and (d). The burden was estimated in the 60-day PRA notice published in the **Federal Register** of June 17, 2011 (76 FR 35678) as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 final rule lifting 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 an extension date notice on May 11, 2012 (77 FR 27591). All currently marketed sunscreen products are, therefore, already required to be in compliance with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 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 PRA, we estimated that as many as 60 new product SKUs marketed each year will have to comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers. We estimated that approximately 12 hours would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the 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/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 took this into consideration 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 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.

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number 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.

Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 15, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program fiscal year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Progress Report for Formula Grant.

OMB No. 0915–0355—Extension.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA), in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. Fifty states, the District of Columbia, 5 territories, and eligible nonprofit organizations are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions/entities eligible for formula awards, and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection is needed for grantees to report progress under the Home Visiting Program annually. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the ACA amended title V of the Social Security Act by adding a new section, 511, which authorized the Home Visiting Program (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf*, pages 216–225). Congress extended funding for the Home Visiting Program by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93). A portion of funding provided under this program is awarded to participating states, jurisdictions, and entities by formula.

The information collected will be used to review grantee progress on proposed project plans to assess whether the project is performing adequately to achieve the goals and objectives that were previously approved. This report will also provide implementation plans for the upcoming year, to permit assessment of whether the plan is consistent with the grant as approved, and is expected to, will result in, implementation of a high-quality project that will complement the Home Visiting Program as a whole. Progress Reports are submitted through the Electronic Handbooks. Failure to collect this information would impair federal monitoring and oversight of the use of grant funds in keeping with legislative and policy requirements. Grantees are required to provide a performance narrative with the following sections: Project identifier information; accomplishments and barriers; Home Visiting Program goals and objectives; update on the Home Visiting Program promising approach; implementation of the Home Visiting Program in targeted at-risk communities; progress toward meeting legislatively-mandated reporting on benchmark areas; home visiting quality improvement efforts; and updates on the administration of the Home Visiting Program.

Likely Respondents: Grantees with Home Visiting Formula Awards Awarded in Federal FY 2013–FY 2017.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the