

one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/ucm094137.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0823]

Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

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 the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

DATES: Submit either electronic or written comments on the collection of information by May 31, 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-2013-N-0823 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling." 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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@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.

Format and Content Requirements for OTC Drug Product Labeling—21 CFR Part 201 (OMB Control Number 0910-0340)—Extension

In the **Federal Register** of March 17, 1999 (64 FR 13254) (the 1999 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 in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. 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.

On June 20, 2000 (65 FR 38191), we published a **Federal Register** final rule that required all OTC drug products marketed under the OTC monograph system to comply with the labeling requirements in § 201.66 by May 16, 2005, or sooner (65 FR 38191 at 38193). Currently marketed OTC drug products are already required to be in compliance with these labeling requirements, and thus will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Modifications of labeling already required to be in Drug Facts format are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the PRA. Therefore, the burden to comply with the labeling requirements in § 201.66 is a one-time burden applicable only to new OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in “convenience size” packages.¹ New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on a March 1, 2010, estimate provided by the Consumer Healthcare Products Association (75 FR 49495 at 49496, August 13, 2010), we estimated that approximately 900 new OTC drug product stock-keeping units (SKUs) are introduced to the marketplace each year. We estimated that these SKUs are marketed by 300 manufacturers. We estimated that the preparation of labeling for new OTC drug products would require 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 10,800 hours.

All currently marketed sunscreen products are required to be in compliance with the Drug Facts labeling requirements in § 201.66, and thus will incur no further burden under the information collection provisions in the 1999 labeling final rule. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate that 60 new SKUs of OTC sunscreen drug products would be marketed each year (77 FR 27234). We estimate that these 60 SKUs would be marketed by 20 manufacturers. We estimate 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 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens.

In determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). Since publication of the 1999 labeling final rule, we have received only one request for exemption or deferral. One response over a 10-year period equates to an annual frequency of response equal to 0.1. In the 1999 labeling final rule, we estimated that a request for deferral or exemption would require 24 hours to complete (64 FR 13254 at 13276, March 17, 1999). We continue to estimate that this type of response will require approximately 24 hours. Multiplying the annual frequency of response (0.1) by the number of hour per response (24) gives a total response time for requesting exemption of deferral equal to 3 hours.

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

TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
201.66(c) and (d) for new OTC drug products	300	3	900	12	10,800
201.66(c) and (d) for new OTC sunscreen products	20	3	60	12	720
201.66(e)	1	0.125	0.125	24	3
Total					11,523

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

¹ In a final rule published in the **Federal Register** of April 5, 2002, the Agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require

more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The Agency issued this delay in order to develop

additional rulemaking for these “convenience size” products (December 12, 2006; 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.

Dated: March 29, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-07369 Filed 3-31-16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2012-N-0471, FDA-2012-N-0294]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control number	Date approval expires
Prescription Drug User Fee Cover Sheet; Form FDA 3397	0910-0297	3/31/2019
Food Additives; Food Contact Substances Notification System	0910-0495	3/31/2019

Dated: March 28, 2016.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016-07363 Filed 3-31-16; 8:45 am]
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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 ICR should be received no later than May 31, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 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 Early Childhood Home Visiting Program Funding Opportunity Announcement for Formula Grant Awards OMB No. 0906-xxxx—New.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Federal 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. Formula grant awards support Federal Home Visiting Program grantees in meeting statutory and programmatic objectives for

implementing high quality home visiting programs and coordinating with comprehensive statewide early childhood systems. All fifty states, the District of Columbia, five territories, and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible to receive formula grant awards. There are currently 56 entities with formula grant awards.

Need and Proposed Use of the Information: This information collection is requested for eligible entities to submit applications in response to annual formula Funding Opportunity Announcements (FOA) beginning in Fiscal Year (FY) 2017.

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 creation of the Federal Home Visiting Program. A portion of funding under this program is awarded to participating states and eligible jurisdictions using a funding formula. Formula funding is the main funding mechanism used by HRSA to provide support to eligible entities for the provision of voluntary high-quality home visiting services to families living in at-risk communities.

The information collected will be used to provide guidance to eligible entities on how to prepare and submit applications in response to annual