information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–08684 Filed 4–15–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0672]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 18, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0577. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prominent and Conspicuous Mark of Manufacturers On Single-Use Devices (OMB Control Number 0910–0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250) amended section 502 of the FD&C Act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (Pub. L. 109–43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 67 establishments that distribute approximately 427 reprocessed SUDs. Each response is anticipated to take 0.1 hours (6 minutes) resulting in a total burden to industry of 43 hours.

In the **Federal Register** of December 30, 2014 (79 FR 78445), 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] [2]

Type of respondent	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Establishments listing fewer than 10 SUDs	58	2	116	0.1 (6 minutes)	12
Establishments listing 10 or more SUDs	9	34	306	0.1 (6 minutes)	31
Total					43

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

[2] Numbers have been rounded.

Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08749 Filed 4–15–15; 8:45 am]

BILLING CODE 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 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