products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA's cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

In the **Federal Register** of April 17, 2014 (79 FR 21766), 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]

21 CFR Section/Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.3/Ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11/Statement of identity	1,518	24	36,432	1	36,432
701.12/Name and place of business	1,518	24	36,432	1	36,432
701.13/Net quantity of contents	1,518	24	36,432	1	36,432
Total					141,174

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

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

The estimated annual third party disclosure is based on data available to the Agency, our knowledge of and experience with cosmetic labeling, and our communications with industry. We estimate there are 1,518 cosmetic product establishments in the United States. We calculate label design costs based on stock keeping units (SKUs) because each SKU has a unique product label. Based on data available to the Agency and on communications with industry, we estimate that cosmetic establishments will offer 94,800 SKUs for retail sale in 2014. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that we discuss in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. We estimate that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the Agency's experience with other products, we estimate that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, we estimate that the number of disclosures per respondent will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

We estimate that each of the required label elements may add approximately 1 hour to the label design process. We base this estimate on the burden hours the Agency has previously estimated for food, drug, and medical device labeling and on the Agency's knowledge of cosmetic labeling. Therefore, we estimate that the total burden hours on members of the public for this information collection are 141,174 hours per year.

Dated: June 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14768 Filed 6–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0493]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

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 July 25, 2014.

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 0910–0688. 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.

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded—(OMB Control Number 0910–0688)—Extension

In the **Federal Register** of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded (2002 time and extent application (TEA) final rule). These regulations state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain ''time and extent'' criteria outlined in § 330.14(b). The regulations allow a TEA to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data includes the data and information listed in 21 CFR 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred, and an official or proposed compendial monograph. We published the Guidance for Industry ''Time and Extent Applications for Nonprescription Drug Products'' on September 29, 2011 (76 FR 60504).

In the **Federal Register** of October 8, 2010 (75 FR 62404), we published a 60-day notice requesting public comment on the proposed collection of information. In that notice, we stated that based on the number of submissions we had received in the 8 years following publication of the TEA final rule, we expected to receive an average of two TEAs and two submissions of safety and effectiveness data each year. In the same document, we stated in our estimate that approximately 1,525 hours are required to prepare a TEA and approximately 2,350 hours to prepare a safety and effectiveness submission. This estimate is based on a comment from a manufacturer that filed two TEAs that was submitted to the Agency in response to the 60-day notice requesting public comment on this proposed collection of information in the **Federal Register** of October 8, 2010. The commenter included, as part of the estimated burden of safety and effectiveness data submission, an estimated burden to submit environmental data to conduct an environmental assessment as required by the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) (see 21 CFR 25.1), or the application of any categorical exclusion that may be warranted (21 CFR 25.20(f)). Because the information provided in the submission is based on actual experience by a TEA applicant and included an estimated burden to comply with NEPA, we agreed with the submission and adjusted our estimates accordingly. Based on our experience since the October 2010 notice, we continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year, and that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission, to include environmental data.

In the **Federal Register** of March 24, 2014 (79 FR 16007), 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 REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
330.14(c)—Time and Extent Application and (d) [2]—Submission of Information; Confidentiality	2	1	2	1,525	3,050
330.14(f)—Request for Data and Views and (i) [3]—Compendial Monograph	2	1	2	2,350	4,700
Total					7,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] TEA.
[3] Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: June 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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