Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Products

SUPPORTING STATEMENT

0910-0717

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This collection is associated with FDA's regulations for labeling and testing of over-the-counter (OTC) sunscreen products. FDA's legal authority to modify and simplify the manner in which certain information is presented in OTC drug product labeling derives from sections 201, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetics Act (the Act). Regulating the order, appearance, and format of OTC drug product labeling is consistent with FDA's authority to ensure that drug labeling conveys all material information to the consumer (sections 201(n) and 502(a) of the act), and that labeling communicates this information in a manner that is ''likely to be read and understood by the ordinary individual under customary conditions of purchase and use'' (section 502(c) of the act).

A final rule published on June 17, 2011 (76 FR 35620 through 35665, "2011 final rule") included testing and labeling requirements for OTC sunscreen products marketed containing specified active ingredients and marketed without an approved new drug application or abbreviated new drug application. Under the 2011 final rule, OTC sunscreen products are required to be tested according to the SPF test procedure in 21 CFR 201.327(i). The SPF test demonstrates a product's effectiveness in protecting against sunburn. A product's numerical SPF value, as determined by the SPF test, reflects the level of sun protection provided by the product. The 2011 final rule requires that an OTC sunscreen product be labeled with its SPF value on its principal display panel according to labeling requirements in 21 CFR 201.327(a)(1).[1] Requiring labeling with SPF values allows consumers to compare the levels of sunburn protection between sunscreen products. The requirement to label OTC sunscreen products with an SPF value determined by the SPF test results in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreen products covered by the final rule.

The 2011 final rule also lifts the delay of implementation date of the Drug Facts regulation (21 CFR 201.66) for all OTC sunscreens effective June 18, 2012. Compliance

[1] The rule also required that if the principal display panel includes broad spectrum or water resistance claims, those must be presented in a particular way. (See 21 CFR 201.327(a)(1). FDA has determined that these statements are not subject to the Paperwork Reduction Act because they are "[t]he public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." 5 CFR § 1320.3(c)(2).

with the Drug Facts regulation results in an additional third-party disclosure burden for manufacturers of OTC sunscreen products covered by the final rule.

2. Purpose and Use of the Information Collection

Consumers have become accustomed to seeing sunscreen products labeled with SPF values, which have appeared on sunscreen product labels for decades. The SPF value is a primary factor in consumers' selection of a sunscreen product.[2] Consumers are aware that the SPF value indicates the level of sunburn protection a sunscreen product provides. The only accurate, reliable, and validated method for determining the level of sunburn protection that a sunscreen product provides is an in vivo SPF test method that determines an SPF value by measuring the ratio between the minimal erythemal dose (MED) that causes sunburn on sunscreen-protected skin and the MED that causes sunburn on unprotected skin.

The 2011 final rule requires that all OTC sunscreen products be tested according to the in vivo SPF test procedure in 21 CFR 201.327(i). Labeling sunscreen products with SPF values determined by this test, as required by 21 CFR 201.327(a)(1), is necessary to inform consumers about the level of sun protection a sunscreen product provides. Established standards for SPF testing and labeling are necessary to ensure consistent labeling between sunscreen products, which allows consumers to compare the levels of sun protection sunscreen products provide. Failure to obtain adequate sun protection leads to sun-induced skin damage that includes sunburn, skin cancer, and premature skin aging.

The Drug Facts regulation in 21 CFR 201.66 establishes standards for labeling content and format for the Drug Facts panel on labels for all OTC drug products. This standardized labeling helps consumers understand the information that appears on the labels of OTC drug products. Consistent language used in headings and subheadings helps consumers comprehend labeled information, and consistent formatting helps consumers locate information.

3. Use of Improved Information Technology and Burden Reduction

The process of determining an SPF value depends on a subjective assessment of reddening of the skin and may, therefore, be time consuming. However, currently available software and hardware greatly simplify the process of integrating SPF values into product labeling. The availability of these software and hardware products is a result of decades of experience in performing the in vivo SPF test method.

4. Efforts to Identify Duplication and Use of Similar Information

[2] Wang, S.Q. and S.W. Dusza, "Assessment of Sunscreen Knowledge: A Pilot Survey," British Journal of Dermatology, 161 (Supplement 3): 28 – 32, 2009.

The SPF value for a sunscreen drug product depends on the identity and concentration of the product's active ingredients as well as the product's final formulation and, therefore, is unique for each sunscreen.

5. Impact on Small Businesses or Other Small Entities

There would be no exceptions for small businesses/marketing enterprises.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 4/16/2015 (80 FR 20499). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Any labeling developed under an OTC monograph is not considered confidential.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

For currently marketed OTC sunscreen products, FDA 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. 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 is estimated as follows:

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Conduct SPF testing in accordance with §201.327(i) for new sunscreen formulations	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 burden					966

Drug Facts Labeling for OTC Sunscreens

Manufacturers of currently marketed OTC sunscreen products will incur a one-time burden to comply with the Drug Facts content and format requirements in 21 CFR 201.66(c) and (d). The compliance dates for the 2011 final rule lifting the delay of the Sec. 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 data notice on May 11, 2012 (77 FR 27591). Therefore, all currently marketed sunscreen products are already required to be in compliance with the Drug Facts labeling requirements in Sec. 201.66. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in Sec. 201.66. We estimate 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 Sec. 201.66(e)	1	24	24	0.125 (7 min.)	3
Total burden					723

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

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We do not anticipate that any costs associated with the labeling requirements will be borne by the federal government.

15. Explanation for Program Changes or Adjustments

FDA originally estimated a one-time burden for manufacturers to relabel their currently marketed products, plus a third-party disclosure burden to comply with Drug Facts regulations for new sunscreen SKUs marketed thereafter. In this estimate FDA did not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in Sec 201.66(e). However, the extension of the 60 day PRA published on April 13, 2015 provides for an estimated 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. The total response time for requesting an exemption or deferral was estimated as three hours (as shown in Table 2 above).

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.