UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control No. 0910-0717

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the labeling of over-the-counter sunscreen products. The Food and Drug Administration's (FDA, us or we) 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 (FD&C 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 in the Federal Register of June 17, 2011 (76 FR 35620, "*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 part 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 with the Drug Facts regulation results in an additional third-party disclosure burden for manufacturers of OTC sunscreen products covered by the final rule.

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).

We therefore request extension of OMB approval for the information collection provisions associated with the product development protocol codified for OTC sunscreen products and discussed in this supporting statement.

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

The SPF value for a sunscreen drug product depends on the identity and concentration of the

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.

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

We do not believe the information collection imposes undue burden on small entities. At the same time, we assist small businesses in complying with regulatory requirements through the our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is determined by respondents engaged in the testing and marketing of over-the-counter sunscreen products and subject to the applicable regulations. We believe review of the disclosures consistent with the regulatory requirements best enables our ability to ensure products are safe and effective, as labeled.

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

There are no special circumstances relating to this information collection.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of August 22, 2018 (83 FR 42509). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

Any labeling developed under an OTC monograph is not considered confidential. The confidentiality of information received by FDA is handled consistently with the requirements of the Freedom of Information Act (FOIA) and FDA's published regulations under 21 CFR part 20, which generally prohibit FDA from releasing to the public any information that is considered confidential commercial information.

In developing this proposed IC, staff from FDA's Center for Drug Evaluation and Research (CDER) consulted the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA in association with the IC if finalized as proposed. Through this consultation, FDA determined that the subject IC does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of

FDA/CDER. Specifically, FDA/CDER does not intend to collect PII and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this proposed collection.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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 regarding SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications (2011 60-day notice). In that notice, we stated that § 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 sunscreen final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i).

Therefore, that provision resulted in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the 2011 sunscreen rule. We determined that products need only complete the testing and labeling required by the 2011 sunscreen rule once and then continue to use 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 sunscreen 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 2011 sunscreen rule was based on: (1) An estimate 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) the conduct of SPF testing based on the estimated number of existing formulations; (3) an estimate of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day notice was a total of 30,066 hours in years 1 and 2, and a total of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are already required to comply with the SPF labeling requirements specified by the 2011 sunscreen final rule. However, our original estimate also 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 must 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 received only two comments on our estimated information collection burden (FDA-2011-N-0449-0002 and FDA-2011-N-0449-0003). These comments were already addressed in FDA's notice entitled "*Agency 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 in the Federal Register of May 9, 2012 (77 FR 27230).

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

Activity	No. of Respondents	No. 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

Drug Facts Labeling for OTC Sunscreens

Because the 2011 sunscreen final rule also lifted the delay of implementing the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modified the information collection associated with § 201.66 (currently approved under OMB control number 0910-0340) and added a third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the 1999 Drug Facts 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, codified in § 201.66. This section establishes 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, OTC sunscreen products already on the market at that time incurred a one-time burden to comply with the requirements in § 201.66(c) and (d). In the 60-day notice, the burden was estimated as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 sunscreen final rule that lifted 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 the 2012

extension date notice. All currently marketed sunscreen products are, therefore, already required to comply with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 Drug Facts 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 notice, we estimated that as many as 60 new product SKUs marketed each year must comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers, which will spend approximately 12 hours 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. This is equal to 720 hours annually (60 SKUs, 12 hours per 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 considered this 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 Drug Facts labeling 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.

Table 2.--Estimated Annual Third-Party Disclosure Burden1

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 § 201.66(e)	1	0.125	8	24	3
Total					723

12b. Annualized Cost Burden Estimate

We assume an average wage rate for the sunscreen industry as a whole of $34.76 per hour to prepare and submit the ICR as specified in Section 12b above. When multiplied by the burden hours above (1,689) the cost to respondents is estimated at $5,870,964.

The average wage rate is based on the Chemical Manufacturing Industry (NAICS 3250A2) from the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics: https://www.bls.gov/oes/current/naics4_3250A2.htm.

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 the Federal Government will expend any costs associated with the labeling requirements.

15. Explanation for Program Changes or Adjustments

The burden for the information collection remains unchanged. In the Federal Register of February 26, 2019 (84 FR 6204), however, we issued a proposed rule (RIN 0910-AF43) to finalize protocol requirements for non-prescription sunscreen products and, when finalized, will revise the information collection as appropriate.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules.

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

Display of the OMB expiration date, as required by 5 CFR 1320.5, is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.