Labeling and Testing Requirements for OTC Sunscreen Products

SUPPORTING STATEMENT A

0910-AF43

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 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).

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 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

[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.

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

6. Consequences of Collecting the Information Less Frequently

Not applicable.

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

The 2011 final rule on OTC sunscreen drug products published on June 17, 2011. In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of 06/17/2011 concerning the collection of information imposed by the final rule and allowed 60 days for public comment on the notice (Federal Register, June 17, 2011, vol. 76, No. 117, pp. 35620 – 35665). FDA created a public docket for submission of these comments (i.e., FDA-2011-N-0449). FDA received three comments to this docket, but only two of them concerned the collection of information in the 2011 final rule (i.e., FDA-2011-N-0449-0002, FDA-2011-N-0449-0003). These comments were submitted by 1) Consumers Union; (see Attachment 2), which publishes Consumer Reports; and 2) The Personal Care Products Council (PCPC) jointly with The Consumer Healthcare Products Association (CHPA) (see Attachment 3), which are trade associations for the OTC personal care products industry and the cosmetics industry in the United States, respectively.

The Consumers Union comment states that the collection of information in the 2011 final rule is practical and necessary for FDA's functions. Although the comment disagrees with the 2011 final rule's removal of a proposed in vivo UVA protection test, that test has no bearing upon FDA's estimate of the third-party disclosure burden. Therefore, FDA is not making any modifications to our estimates of burden based upon the Consumers Union comment.

The PCPC/CHPA comment states that FDA underestimated the burden to industry, including the third-party disclosure burden. However, we understand "the burden to industry" to be the full compliance burden of the regulation, which is not the same as "the third-party disclosure burden" under the Paperwork Reduction Act. This document, and any associated approval, only addresses the third-party disclosure burden. The table below compares PCPC/CHPA's estimates with FDA's estimates.

Comparison of PCPC/CHPA's and FDA's Estimates		
	PCPC/CHPA	FDA
Sunscreen product manufacturers	>364	100
Existing sunscreen products (SKUs[3];	4,528; 2,943	3,591; 2,350

formulations)		
New sunscreen products (SKUs; formulations)	1,262; 824 per year	60; 39 per year
Hours per response (SPF testing)	170.5 per formulation	24 per formulation
Hours per response (principal display panel label)	70.5 per SKU	0.5 per SKU
Hours per response (Drug Facts label)	70.5 per SKU	12 per SKU

PCPC/CHPA's estimates of the number of sunscreen products and sunscreen product manufacturers are taken from brief letters submitted to PCPC/CHPA from the three market research organizations (Symphony IRI Group, The NPD Group, and Mintel). These letters are included in PCPC/CHPA's comment. PCPC/CHPA's estimated number of existing sunscreen products and sunscreen product manufacturers were calculated by adding the estimated numbers from the Symphony IRI Group letter (i.e., 3,289 products, 197 manufacturers) and The NPD Group letter (i.e., 1,239 products, 167 manufacturers). PCPC/CHPA's estimated number of new sunscreen products is taken from Mintel's letter (i.e., 1262 products). However, how the exact numbers were derived from their databases was not provided nor were any potential references that may have been used for their calculations and estimates. PCPC/CHPA's estimate of the hours required to conduct SPF testing and create principal display panel labels are based upon PCPC/CHPA's survey of its members. FDA describes the bases for its estimates in the 60-day notice concerning the collection of information imposed by the 2011 final rule (Federal Register, June 17, 2011, vol. 76, No. 117, pp. 35620 – 35665).

In conclusion, FDA does not consider the data submitted sufficient to merit revising its estimates of third-party disclosure burden as described in the following paragraphs. Details on how the survey was conducted and the number of hours required to conduct SPF testing and create principal display panel labels was not provided. In addition, no data was submitted to support their conclusions. The market research organizations letters provided little information about how they derived their data regarding number of products and manufacturers. Market research organizations also explicitly state that there is no guarantee of the accuracy of their numbers. Therefore, FDA cannot assess the quality of the data upon which PCPC/CHPA's estimates were based. FDA discusses its consideration of PCPC/CHPA's estimates in the paragraphs below.

Estimates of sunscreen products and sunscreen product manufacturers. FDA notes that all of PCPC/CHPA's estimates of sunscreen products and sunscreen product manufacturers are higher than FDA's estimates. The disparity between PCPC/CHPA's estimates and FDA's estimates remain unclear due to the lack of information about how their numbers were derived. PCPC/CHPA's estimate of new sunscreen products (i.e., 1262 products per year) is much higher than FDA's estimate (i.e., 60 products per year). PCPC/CHPA states that its estimate of 1262 new products includes "new products," "new variety/range extensions," "new formulations," "new packaging," and "relaunches."

[3] SKU = stock keeping units

Many of these products may not be considered new products (i.e., new SKUs) by FDA. For example, FDA would consider a minor labeling change on a particular 8 fl.oz. size bottle of a brandname product to be a replacement of the same SKU, whereas PCPC/CHPA considers the relabeled product to be a "new product" due to "new packaging" as stated in their submission. Because the submitted data do not allow for verification of PCPC/CHPA's higher estimates and the market research organizations themselves will not guarantee the accuracy of these estimates, FDA is not revising its estimates of sunscreen products and sunscreen product manufacturers.

Estimate of time required for SPF testing. FDA also notes that PCPC/CHPA's estimate of the time required to conduct SPF testing is much higher than FDA's estimate. PCPC/CHPA explains that FDA's estimate failed to consider the time required by good clinical practices (e.g., quality assurance testing, revision control, internal release of samples, documentation release, shipment authorization). However, PCPC/CHPA does not provide time estimates for these procedures. Also, compliance with good clinical practices is a standard regulatory requirement and does not constitute an additional burden resulting from the 2011 final rule. Regulations controlling paperwork burdens on the public in 5 CFR 1320.3(b)(2) state that the "time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary." PCPC/CHPA also explains that conducting the SPF test for a water-resistant product requires 3 to 4 weeks, instead of FDA's estimate of 24 hours (i.e., 3 days, 8 hours/day). However, PCPC/CHPA does not adequately describe the "testing timelines" section for conducting the SPF test. Even consideration of extra time required for data analysis fails to account for the difference between PCPC/CHPA's and FDA's estimate. Therefore, FDA is not revising its estimate of the time required to conduct SPF testing.

Estimate of the time required to create principal display labeling. FDA's estimate of the time required to create principal display panel labeling (e.g., 0.5 hrs/SKU) differs from PCPC/CHPA's estimate (70.5 hrs/SKU) because the estimates are based upon different tasks. FDA's estimate refers to the time required to insert the SPF value on the principal display panel, whereas PCPC/CHPA's estimate appears to be the time required to create the entire principal display panel and the Drug Facts panel. Only the insertion of the SPF value constitutes a third-party disclosure burden. The remainder of the principal display panel labeling constitutes "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)), and, therefore, is not considered a collection of information. Therefore, FDA is not revising its estimate.

Estimate of the time required to comply with Drug Facts labeling requirements. FDA's estimate of the time required to comply with Drug Facts labeling requirements (12 hrs/SKU) differs from PCPC/CHPA's estimate of (70.5 hrs/SKU). FDA's estimate is based upon estimated times to comply with Drug Facts requirements that were submitted in public comments for various OTC drug products, including OTC sunscreen products.

PCPC/CHPA breaks down its estimate for complying with Drug Facts requirements into 12 sequential steps and provides a one-sentence description of each step. Presumably, the time estimated for each step represents the average reported by PCPC/CHPA's members. Obtaining averages for data has the potential for changing the outcome due to outliers. In addition, the individual estimates from each of PCPC/CHPA's members is not provided in the PCPC/CHPA's comment in order to validate calculations made. Therefore, FDA cannot determine how representative PCPC/CHPA's estimate is of its members or how variable the estimate is between its members. In summary, FDA does not have sufficient data to assess the validity of the estimated times for each of these steps. Therefore, FDA does not consider the currently available data adequate to revise its estimate.

There have been no consultations with other government agencies.

9. Explanation of Any Payment or Gift to Respondents

This section is not applicable.

10. Assurance of Confidentiality Provided to Respondents

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

11. Justification for Sensitive Questions

This section is not applicable. FDA does not ask questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Estimated Annual Third Party Disclosure Burden[1]

For currently marketed OTC sunscreen products, FDA estimated that retesting according to SPF test requirements in 21 CFR 201.327(i) would result in a burden of 28,200 hours and labeling of these products with the SPF value determined by SPF testing would result in a burden of 900 hours in each of the 2 years allowed to complete retesting (76 FR 35678 at 35679). For new sunscreen products, SPF testing would result in a burden of 936 hours per year and labeling with the SPF value would result in a burden of 30 hours per year (76 FR 35678 at 35680). See Table 1.

In Table 1, the "No. of Respondents" column refers to the estimated number of manufacturers of existing OTC sunscreen formulations (Rows 1 and 3) or new OTC sunscreen formulations (Rows 2 and 4). The "Total Annual Responses" column refers to the estimated number of existing or new formulations that require SPF testing (Rows 1 and 2) or the estimated number of existing or new stockkeeping units of a formulation that require labeling with an SPF value (Rows 3 and 4). The "Average Burden per Response" column refers to the estimated time required to SPF test a formulation (Rows 1 and 2) or the estimated time required to label a stockkeeping unit with an SPF value

(Rows 3 and 4). These estimates are based upon our most recent data, including an OTC sunscreen market survey by the Eastern Research Group and data submitted in public comments.

The "No. of Responses per Respondent" column is obtained by dividing "Total Annual Reponses" by "No. of Respondents." The "Total Hours" column is obtained by multiplying "Total Annual Responses" by "Average Burden per Response."

For example, in the first row, the "100" refers to the number of manufacturers of existing OTC sunscreen formulations; the "1,175" refers to the number of existing OTC sunscreen formulations that will require SPF testing in each of the next 2 years; the "24" refers to the number of hours required to SPF test a formulation; the "11.75" refers to the number of existing formulations per manufacturer that require SPF testing; and the "28,200" refers to the number of hours required to SPF test all existing formulations.

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

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 existing sunscreen formulations[2]	100	11.75	1,175	24	28,200
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 existing sunscreen SKUs[2]	100	18[3]	1,800	0.5	900
Create PDP labeling in accordance with §201.327(a)(1) for new sunscreen SKUs	20	3	60	0.5	30
Total burden in					30,066

years one and two					
Total burden in each subsequent year					966

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

[2] Burden for each of first and second years for currently marketed OTC sunscreens.

[3] The number was wrongly published as "180" in Table 1 of the June 17, 2011 60 day comment request (76 FR 35678 at 35680). The actual number should be 1,800 Total Annual Responses divided by 100 Number of Respondents to equal 18 Annual Frequency per Response.

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). See Table 2. The derivation of numbers in Table 2 is similar to Table 1, Rows 3 and 4.

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 existing sunscreen SKUs[2]	100	36	3,600	12	43,200
Format labeling in accordance with 201.66(c) and (d) for new sunscreen SKUs	20	3	60	12	720
Total first year burden					43,920
Total burden for each subsequent year					720

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

[2] Burden for each of first and second years for currently marketed OTC sunscreens.

12b. Annualized Cost Burden Estimate

See section A.13.

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 (see Tables 1 and 2 above in section 12.a.).

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

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This section is not applicable.

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

This section is not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.