4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0449]

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

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 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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-New and title "SPF Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7651,

juanmanuel.vilela@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.

SPF Labeling and Testing Requirements for Over-the-Counter Sunscreen Products Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All Over-the-Counter Sunscreen Products--21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)

In the Federal Register of June 17, 2011 (76 FR 35620), FDA published a final rule establishing labeling and effectiveness testing requirements for certain over-the-counter (OTC) sunscreen products containing specified active ingredients and marketed without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). The rule also lifts the delay of implementation date of the Drugs Facts regulation (21 CFR 201.66) for all OTC sunscreens. This rule is not yet in effect. It is intended to be effective June 18, 2012.

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

Section 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the rule to include the sun protection factor (SPF) value determined by conducting the SPF test outlined in § 201.327(i). Therefore, this provision will result in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the rule. 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.

In the Federal Register of June 17, 2011 (76 FR 35665), we announced the availability of a draft guidance and stated that we do not intend to initiate enforcement action before June 17, 2013, if an OTC sunscreen subject to § 201.327 that was initially marketed prior to June 17, 2011, the date of publication of the final rule, continues to include an SPF value in its labeling that was determined prior to that date according to either the SPF test method described in the May 21, 1999, final rule (64 FR 27666 at 27689 through 27693) or the SPF test method described in the August 27, 2007, proposed rule (72 FR 49070 at 49114 through 49119). We believe that the majority of currently marketed OTC sunscreen formulations will meet this standard and, therefore, may defer their conduct of new SPF testing. However, this one-time testing will nonetheless 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 therefore do not anticipate that the draft guidance will alter the annualized burden associated with § 201.327(a)(1) and (i) as estimated here. We provide a separate PRA analysis in the notice of availability for the draft guidance to address the information collections provisions that result from it.

Our estimate of third-party disclosure burden includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. We have estimated that there are approximately 100 manufacturers of OTC sunscreen drug products. We estimate that these 100 manufacturers are currently producing as many as 2,350 OTC sunscreen formulations and that these formulations are available in approximately 3,600 stock keeping units (SKUs) (see 2010 sunscreen final rule--indicating recent data supports estimate of up to 2,348 formulations and 3,591 SKUs).[1]

Our estimates on the conduct of SPF testing are based on the estimated number of formulations because, if the same formulation is sold under different SKUs, the formulation will only have to be retested one time in order to develop the labeling for multiple marketed SKUs. However, our estimates on labeling are based on the number of SKUs because, although each SKU will not need to be tested to establish its SPF value, the labeling of each SKU has to be considered.

To determine the SPF value required in § 201.327(a)(1), manufacturers will have to conduct SPF tests according to § 201.327(i). We estimate that all 100 manufacturers will have to retest currently marketed sunscreen formulations. We estimate that there are approximately 2,350 existing sunscreen formulations that will require retesting. We further estimate that it will take 24 hours (i.e., three 8-hour days) to complete SPF testing for each of the formulations. This estimate assumes SPF testing of a high SPF sunscreen that includes 80 minutes of water resistance testing, which reflects products requiring the most time to test. Therefore, a total of 56,400 hours will be required as the one-time burden to retest existing sunscreen products in

[1] Document No. FDA-1978-N-0018-0693 in Docket No. FDA-1978-N-0018.

accordance with § 201.327(i) to provide the SPF value required to be disclosed to the public in labeling under § 201.327(a)(1). In accordance with FDA's enforcement policy guidance, retesting of currently marketed sunscreen products should be completed within 2 years after the date of publication of the final rule, so if this one-time burden is annualized across that time period, the result is a burden of 28,200 hours in each of the first 2 years to complete retesting of existing sunscreen products.

Once manufacturers have tested their products to determine the SPF value, to comply with the third party disclosure (labeling) requirements in § 201.327(a)(1), the manufacturers will need to insert the SPF value after the term "SPF" in either the statement "SPF" or "Broad Spectrum SPF," as applicable. We estimate that each of the 100 manufacturers will spend no more than 0.5 hours per SKU to prepare, complete, and review the labeling for each of 3,600 currently marketed SKUs. Therefore, we estimate that a total of no more than 1,800 hours will be required as a one time burden to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications (3,600 SKUs times 0.5 hours per SKU). In accordance with FDA's enforcement policy guidance, relabeling of currently marketed sunscreen products should be completed within 2 years after the date of publication of the final rule, so if this one-time burden is annualized across that time period, the result is a burden of 900 hours in each of the first 2 years to complete relabeling of existing sunscreen products.

In addition, new products may also be introduced each year, and these products will have to be tested and labeled with the SPF value determined in the test. We estimate that as many as 60 new OTC sunscreen products (SKUs) may be introduced each year. As discussed in this document, there are currently approximately 1.53 SKUs marketed for every sunscreen spray

formulation (3,600 SKUs divided by 2,350 formulations). Therefore, we estimate that the 60 new sunscreen SKUs will represent 39 new formulations annually. We expect the burden of testing the 39 new formulations marketed each year will require 936 hours per year (39 formulations times 24 hours testing per formulation). We estimate that labeling of the 60 new SKUs marketed each year will require 30 hours per year (60 SKUs times 0.5 hours per SKU).

The sunscreen 2011 final rule 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 June 17, 2011, concerning the collection of information imposed by the final rule and allowed 60 days for public comment on the notice (76 FR 35678–35681). 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 sunscreen 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 of the Consumers Union comments), which publishes Consumer Reports and (2) The Personal Care Products Council (PCPC) jointly with The Consumer Healthcare Products Association (CHPA) (see Attachment 3 of the PCPC/CHPA comments), 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 sunscreen final rule is practical and necessary for FDA's functions. Although the comment disagrees with the 2011 sunscreen final rule's removal of a proposed in vivo ultraviolet A (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, "the burden to industry" is not the same as "the third-party disclosure burden." This document only addresses the third-party disclosure burden. Table 1 of this document compares PCPC/CHPA's estimates with FDA's estimates.

Table 1.--Comparison of PCPC/CHPA's and FDA's Estimates

	PCPC/CHPA	FDA
Sunscreen product manufacturers	>364	100
Existing sunscreen products (SKUs formulations)	4,528; 2,943	3,591; 2,350
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., 1,262 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 sunscreen final rule (76 FR 35620 at 35678 through 35681).

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 were 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 following paragraphs.

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., 1,262 products per year) is much higher than FDA's estimate (i.e., 60 products per year). PCPC/CHPA states that its estimate of 1,262 new products includes "new products," "new variety/range extensions," "new formulations," "new packaging," and "relaunches." 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 fluid ounce size bottle of a brand-name 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, and 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 sunscreen 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 hours/SKU) differs from PCPC/CHPA's estimate (70.5 hours/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 hours/SKU) differs from PCPC/CHPA's estimate of (70.5 hours/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 are 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.

FDA estimates 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
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	180	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 years one and two					30,066
Total burden in each subsequent year					966

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden for each of first and second years for currently marketed OTC sunscreens.

Drug Facts Labeling for OTC Sunscreens

Because the 2011 sunscreen final rule also lifts the delay of implementation date for Drug Facts regulations (21 CFR 201.66) for OTC sunscreens, the rule will also modify the information collection associated with § 201.66 (currently approved under OMB control number 0910-0340) and result in additional third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the Federal Register of March 17, 1999 (64 FR 13254), 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 (the 1999 Drug Facts labeling final rule). Section 201.66 sets 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. In the Federal Register of September 3, 2004 (69 FR 53801), we delayed the § 201.66 implementation date for OTC sunscreen products indefinitely, pending future rulemaking to amend the substance of labeling for these products. The 2011 sunscreen final rule lifts this stay for OTC sunscreens. Therefore, currently marketed OTC sunscreen products will incur a one-time burden to comply with the requirements in § 201.66(c) and (d).

We estimate that there are 3,600 currently marketed OTC sunscreen drug product SKUs, and we assume for purposes of this estimate that none of them have yet complied with the 1999 Drug Facts labeling final rule. These 3,600 SKUs will need to implement the new labeling format by the implementation date included in the 2011 sunscreen final rule. We estimate that these 3,600 SKUs are marketed by 100 manufacturers and that approximately 12 hours will be spent on each label. The number of hours per label (response) is 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. If an average of 12 hours is spent preparing, completing, and reviewing each of the estimated 3,600 sunscreen SKUs, the total number of hours dedicated to the one-time relabeling of currently marketed OTC sunscreen products, as necessary to comply with § 201.66 would be 43,200 (3,600 SKUs times 12 hours/SKU).

In addition to this one-time burden, we estimate that 60 new sunscreen SKUs marketed each year will have a third-party disclosure burden to comply with Drug Facts regulations equal to 720 hours annually (60 SKUs times 12 hours/SKU). We estimate that these new SKUs will

be marketed by 20 manufacturers. We do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e).

FDA estimates the burden of this collection of information as follows:

Table 3.--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[3]	20	3	60	12	720
Total first year burden					43,920
Total burden for each subsequent year					720

[1] FDA estimates a one-time medium capital cost of 6.1 million dollars will result from preparing labeling content and format for OTC sunscreens in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.

[2] First-year burden for currently marketed OTC sunscreens.

[3] Burden for first and second years for currently marketed OTC sunscreens.

With the exception of the PDP statement of SPF value in § 201.327(a)(1), the labeling requirements in § 201.327(a) through (h), which provide other elements of the PDP, as well as specific content for indications, directions, and warnings, are a "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, are not collections of information. These provisions are thus not subject to OMB review under the PRA.

Dated: May 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-11067 Filed 05/08/2012 at 8:45 am; Publication Date: 05/09/2012]