

title “SPF Labeling and Testing Requirements for OTC Sunscreen Products with SPF Values Greater Than 50.”

## V. Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” The sole statutory provision giving preemptive effect to the proposed rule is section 751 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r).

We believe that the preemptive effect of this proposed rule, if finalized, would be consistent with Executive Order 13132. Through the publication of this proposed rule, we are providing notice and an opportunity for State and local officials to comment on this rulemaking.

## VII. Proposed Effective Date

Any final rule based on this proposal would become effective 1 year after the date of its publication in the **Federal Register**.

## VIII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**), under Docket No. FDA-1978-N-0018 (formerly Docket No. 1978N-0038) unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. FDA List of Docket Submissions Addressed in This Proposed Rule.

2. Comment C716 from Playtex Products, Inc., Docket No. FDA-1978-N-0018.

3. Russak, J. E. *et al.*, “A Comparison of Sunburn Protection of High-Sun Protection Factor (SPF) Sunscreens: SPF

85 Sunscreen Is Significantly More Protective Than SPF 50,” *Journal of the American Academy of Dermatology*, 62:348–9, 2010.

4. Eastern Research Group, “Sunscreen Drug Formulations for Over-the-Counter Human Use,” Task Order No. 21, Contract No. 223-03-8500, 2010.

## List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201, as amended June 17, 2011, effective June 18, 2012, be further amended as follows:

## PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.327 is amended by revising paragraph (a) introductory text and paragraphs (a)(1)(i)(A) and (a)(1)(ii) to read as follows:

### § 201.327 Over-the-counter sunscreen drug products; required labeling based on effectiveness testing.

\* \* \* \* \*

(a) *Principal display panel.* In addition to the statement of identity in paragraph (b) of this section, the following statements shall be prominently placed on the principal display panel:

(1) *Effectiveness claim.*—(i) *For products that pass the broad spectrum test in paragraph (j) of this section.* (A) The labeling states “Broad Spectrum SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section. For values over 50, insert “50+” or “50 plus”].”

\* \* \* \* \*

(ii) *For sunscreen products that do not pass the broad spectrum test in paragraph (j) of this section.* The labeling states “SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section. For values over 50, insert “50+” or “50 plus”].” The entire text shall appear in the same font style, size, and color with the same background color.

\* \* \* \* \*

Dated: June 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

## 21 CFR Parts 201 and 310

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

### SPF Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products; Agency Information Collection Activities; Proposed Collection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Comment request.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on SPF labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

**DATES:** Submit either electronic or written comments on the collection of information by August 16, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

### FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**SPF Labeling and Testing Requirements for OTC Sunscreen Products Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All OTC Sunscreen Products—21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)—(OMB 0910–New)**

Elsewhere in this issue of the **Federal Register**, we (FDA) are publishing a final rule establishing labeling and effectiveness testing requirements for certain 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 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 a draft guidance published elsewhere in this issue of the **Federal Register**, we state 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).<sup>1</sup>

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 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

<sup>1</sup> Document No. FDA-1978-N-0018-0693 in Docket No. FDA-1978-N-0018.

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 section of the document, there are currently approximately 1.53 SKUs marketed for every sunscreen 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).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Conduct SPF testing in accordance with § 201.327(i) for existing sunscreen formulations <sup>2</sup> .....	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 <sup>2</sup> .....	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

<sup>1</sup> There are no capital, operating or maintenance costs associated with this collection of information.

<sup>2</sup> Burden for each of first and second years for currently marketed OTC sunscreens.

### Drug Facts Labeling for OTC Sunscreens

Because the 2011 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 21 CFR 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 21 CFR 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 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 21 CFR 201.66(e).

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Format labeling in accordance with 201.66(c) and (d) for existing sunscreen SKUs <sup>2</sup> .....	100	36	3,600	12	43,200

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>—Continued

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
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

<sup>1</sup> We estimate 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.

<sup>2</sup> First-year burden 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: June 9, 2011.

**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
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