

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 201 and 310**

**[Docket No. FDA-2010-D-0509]**

**Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Enforcement Policy--OTC Sunscreen Drug Products Marketed Without an Approved Application.” The draft guidance is intended to inform manufacturers of over-the-counter (OTC) sunscreen products about our enforcement policy for certain OTC sunscreen products marketed without an approved new drug application. The draft guidance describes our intended approach to enforcement for certain OTC sunscreen products prior to an effective final monograph.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers all comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit written comments on the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Enforcement Policy--OTC Sunscreen Drug Products Marketed Without an Approved Application.” Certain

OTC sunscreen products without an approved new drug application<sup>1</sup> have been marketed under our enforcement discretion while we work to establish a final monograph for OTC sunscreen products. These products are not yet the subject of an effective final monograph.

We continue to evaluate information to determine appropriate conditions for OTC sunscreen products to be generally recognized as safe and effective (GRASE) and not misbranded. In a final rule published elsewhere in this issue of the Federal Register, we establish in § 201.327 (21 CFR 201.327) and § 310.545 (21 CFR 310.545) labeling and testing requirements for OTC sunscreen products that contain certain active ingredients and are marketed without approved applications. We are also publishing a proposed rule elsewhere in this issue of the Federal Register that would, if finalized, limit the maximum labeled sun protection factor (SPF) value for OTC sunscreen products to “50 +” or “50 plus.” In addition to both rules mentioned previously, we are publishing an ANPRM where we are asking sunscreen manufacturers and other interested parties to submit data on OTC sunscreen drug products marketed without approved applications that are formulated in certain dosage forms. For spray dosage forms, we are requesting data to resolve specific questions about both effectiveness and safety. We are also inviting comment on possible labeling and testing requirements for spray dosage forms.

Because of this complex regulatory backdrop, we are developing a guidance to clarify our enforcement policy towards certain OTC sunscreen products before a final monograph becomes effective. The draft guidance applies only to OTC sunscreen products marketed without an approved application that contain only active ingredients or combinations of active ingredients

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<sup>1</sup> See section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355). Approved applications under section 505 include both new drug applications (NDAs) and abbreviated new drug applications (ANDAs).

identified as GRASE in a 1999 sunscreen final rule published in the Federal Register of May 21, 1999 (64 FR 27666) (the 1999 final rule) that was stayed before becoming effective (69 FR 53801, September 3, 2004);

The draft guidance states our intention to continue to exercise enforcement discretion for these types of products under certain circumstances. The draft guidance addresses OTC sunscreen products subject to the final rule codified in § 201.327 (i.e., products with Broad Spectrum SPF values of 15 or higher, products that do not provide broad spectrum protection, and products with Broad Spectrum SPF values between 2 and 14). The draft guidance also indicates the Agency's enforcement approach for sunscreen products labeled with specific SPF values higher than 50, sunscreens formulated in various dosage forms, and products that contain an insect repellent active ingredient registered with the Environmental Protection Agency. In addition, the draft guidance addresses enforcement policy with regard to the continued labeling of certain OTC sunscreens with SPF values determined using the SPF test methods contained in either the Agency's 1999 final rule (64 FR 27666 at 27689 through 27693) or a proposed rule that published in the Federal Register of August 27, 2007 (the 2007 proposed rule) (72 FR 49070 at 49114 through 49119).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Enforcement Policy--OTC Sunscreen Drug Products Marketed Without an Approved Application." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This draft guidance discusses our intended enforcement policy for OTC sunscreen products marketed without approved applications, including recommendations for labeling and testing of these products. Certain of these provisions are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.). These provisions are discussed further in the following paragraphs.

The draft guidance also references submissions under 21 CFR 330.14. The information collections provisions of that regulation have been submitted to OMB for approval, in accordance with the PRA (76 FR 6801, February 8, 2011).

Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information that 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 for each proposed collection of information before submitting the collection to OMB for approval.

This draft guidance refers to labeling and testing requirements applicable to certain OTC sunscreen products under § 201.327. Elsewhere in this issue of the Federal Register, in accordance with section 3506(c)(2)(A) of the PRA, we are publishing a 60-day notice soliciting public comment on the collections of information in that regulation and will then submit these information collection provisions to OMB for approval. These requirements will not be effective until we obtain OMB approval.

This draft guidance also contains additional information collection provisions that are not addressed by the notice regarding the provisions of § 201.327. To comply with the requirements of the PRA, we are publishing this notice of the additional proposed collection of information set forth in this guidance document and inviting comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Collections Applicable to Sunscreens That Choose to Defer Retesting of SPF Values and Continue Labeling With a Previously-Calculated SPF Value

As already noted, the information collection provisions resulting from § 201.327 addressed in this draft guidance are the subject of a 60-day PRA notice published elsewhere in this issue of the Federal Register. This draft guidance proposes to temporarily modify that information collection by stating that we do not intend to initiate enforcement action before [INSERT DATE 2 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], if an OTC sunscreen subject to § 201.327 that was initially marketed prior to [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the date of publication of the 2011 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 1999 final rule (64 FR 27666 at 27689 through 27693) or the SPF test method described in the 2007 proposed rule (72 FR

49070 at 49114 through 49119). We believe that the majority of currently-marketed sunscreen formulations will meet this standard and, therefore, may defer their conduct of new SPF testing. However, this one-time testing will need to be conducted within 2 years after publication of the 2011 final rule (§ 201.327), which is within the period addressed in the PRA notice for that regulation. We, therefore, do not expect this draft guidance will alter the burden calculated for SPF testing under 201.327(i) or calculated for developing the PDP (principal display panel) label in compliance with 201.327(a)(1), as indicated in that document.

Under the draft guidance, manufacturers who do choose to delay SPF testing in accordance with 201.327(i) would nonetheless be expected to include on their product's PDP the effectiveness statement required by 201.327(a)(1)--either "Broad Spectrum SPF" or "SPF", as applicable--followed by the numerical SPF value resulting from prior testing. This creates a burden for third-party disclosure. With respect to the 2011 final rule, we estimated that there are approximately 100 manufacturers of sunscreens (respondents) and we anticipated that it would require no more than 0.5 hours per stock keeping units (SKU) for these manufacturers to prepare and review labeling that inserts the SPF value into the effectiveness statement provided by 201.327(a)(1).<sup>2</sup> We anticipate that manufacturers will choose to avail themselves of the delay of SPF testing provided for under the guidance for as many as half (1,175) of the 2,350 formulations estimated in the 2011 final rule. Based on the estimate that there are about 1.53 SKUs for every formulation, we estimate that as many as 1,798 SKUs may have to be re-labeled. For these 1,798 SKUs, we estimate that it will take no more than 0.5 hours per SKU to prepare and review labeling that inserts a previously derived SPF value into the effectiveness (SPF)

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<sup>2</sup> By the terms of our enforcement policy, such manufacturers would be employing an existing test value, and thus would not incur any additional burden of testing associated with this information collection provision.

statement required under 201.327(a)(1). Therefore, the total burden is estimated be 899 hours (1,798 SKUs times 0.5 hours per SKU).

The final rule becomes effective 1 year after its date of publication, so that firms that seek to fall within the enforcement policy described in the guidance will need to begin labeling products with their previously-derived SPF value within the first year after publication of the rule. (Under the enforcement policy guidance, labeling bearing a previously derived SPF value will have to be discontinued and replaced by the labeling required by 201.327(a)(1) no later than 2 years after the date of publication of the final rule.) We therefore assume that the entire burden of labeling products with previously derived SPF values will be incurred in the first year, with no recurrence. This burden estimate is presented in table 1 of this document.

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
Create PDP labeling statement “Broad Spectrum SPF [fill in value]” based on existing SPF test results <sup>2</sup>	100	17.98	1,798	0.5	899
Total first-year burden					899

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

<sup>2</sup> First-year burden.

We conclude that other labeling recommendations of the draft guidance are not subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The labeling statements for additional directions and warnings recommended in the guidance for sunscreens formulated as sprays 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.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.