(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.

1. Neale *et al., Archives of Dermatology,* 138:1319–25, 2002.

2. Autier *et al., British Journal of Dermatology,* 144:288–91, 2001.

3. Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038): C712, Schering Plough.

4. Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038): FDA List of Docket Submissions Regarding Dosage Forms Issues: C683, C712, C716, EC2720.

This ANPR is issued under 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 and under the authority of the Commissioner of Food and Drugs.

Dated: June 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–14768 Filed 6–14–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038]

RIN 0910–AF43

Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to limit the maximum labeled SPF value for over-the-counter (OTC) sunscreen drug products to ''50+.'' We are issuing this proposed rule after reviewing data and information we received on the safety and effectiveness of OTC sunscreen drug products after publication of our 2007 proposed rule. The record does not currently contain sufficient data to indicate that there is additional clinical benefit above SPF 50. This proposal is part of FDA's ongoing review of these products to ensure their safety and effectiveness.

DATES: Submit either electronic or written comments on the proposed rule by September 15, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by July 18, 2011, (see the ''Paperwork Reduction Act of 1995'' section of this document). See section VII of this document for the proposed effective date of a final rule based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–1978–N–0018 and RIN number 0910–AF43, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–1978–N–0018, and RIN 0910–AF43 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Overview of This Document

A. Summary of Proposal

This document proposes to specify one of the conditions under which OTC sunscreen products are considered to be generally recognized as safe and effective (GRASE) and not misbranded. We are proposing a maximum labeled sun protection factor (SPF) value of ''50+'' for all monograph sunscreen products. In a final monograph issued in 1999, and stayed prior to becoming effective, we determined that the maximum SPF permitted under the monograph should be ''30+'' (64 FR 27666 at 27674 through 27675, May 21, 1999). In a 2007 proposed rule, we proposed to amend the sunscreen monograph in part 352 to permit products marketed under the monograph to be labeled with SPF values up to ''50+,'' and we expressed particular concern that sunscreen products with SPF test values above 50 could not be tested with acceptable accuracy and reproducibility (72 FR 49070 at 49085 through 49087, August 27, 2007) (the 2007 proposed rule). Although submissions in response to the 2007 proposed rule demonstrated the accuracy and reproducibility of such tests at values as high as SPF 80, we are again proposing a maximum labeled SPF value of ''50+'' for sunscreen products marketed without approved applications, because the record continues to lack data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit compared to SPF 50 products. In this document, we are inviting the submission of data demonstrating additional clinical benefit provided by sunscreen products with SPF values greater than 50.

B. Enforcement Policy

Elsewhere in this issue of the **Federal Register**, we are issuing a final regulation establishing effectiveness

testing and labeling requirements for OTC sunscreen products containing specified active ingredients and marketed without approved applications. This regulation will become effective 1 year after its date of publication in the **Federal Register**. However, because we are considering certain active ingredient safety issues further, there is not yet a sunscreen final monograph in effect that specifies which sunscreen active ingredients may be included in a sunscreen product that is determined to be GRASE and not misbranded. Our further consideration of these active ingredient issues does not preclude us from identifying in this document an additional condition that is necessary for a sunscreen product to be GRASE and not misbranded. In a forthcoming rulemaking, we intend to request additional data regarding the safety of the individual sunscreen active ingredients. The issuance of the final labeling rule for certain OTC sunscreen products marketed without approved applications combined with the absence of an effective final monograph for OTC sunscreen products may give rise to questions regarding FDA's enforcement policy for OTC sunscreen products marketed without approved applications. To clarify expectations for industry, we are issuing a draft guidance document explaining our intended enforcement policy for these products in the absence of an effective sunscreen final monograph.

II. Maximum Labeled SPF

In this document, we propose to set an upper limit for labeled SPF values at ''50+,'' as proposed in the 2007 proposed rule. This limit would permit sunscreen products with SPF test results above 50 to be labeled with a ''50+'' value, but would not allow the specific values above 50 to be listed on the label. The remainder of this section of the document summarizes the public submissions regarding the maximum SPF value, most of which support this maximum specific SPF value of 50. We also summarize how the maximum SPF value has increased over the history of sunscreen rulemakings and discuss the two criteria for allowing these increases:

- *First Criteria:* Does the SPF test provide accurate and reproducible results for sunscreen products with higher SPF values?
- *Second Criteria:* Do sunscreen products with higher SPF values provide additional clinical benefit?

The first criterion has been met for sunscreen products with SPF values up to 80. However, we are proposing that the maximum specific labeled SPF be 50, unless we receive data to meet the second criterion that products with SPF values higher than 50 provide additional clinical benefit. These data are critical to show that SPF values measured in the laboratory setting correspond to additional clinical benefit in actual use conditions. We do not have sufficient data to establish that products with SPF values higher than 50 provide additional clinical benefit over SPF 50 sunscreen products. We describe the types of additional studies that would need to be submitted to support increasing the maximum specific SPF value above 50.

A. Summary of Public Submissions

In response to the 2007 proposed rule, we received 13 submissions concerning the upper limit for the SPF value (Ref. 1):

- Four submissions disagreed with the proposed upper limit of ''50+'' and argued that the upper limit should be decreased to ''30+''
- Six submissions supported raising the upper limit from 30 to ''50+''
- Three submissions disagreed with the proposed upper limit of ''50+'' and argued that FDA should not specify an upper limit

The submissions requesting that the upper limit be decreased to ''30+'' argued that consumers would not benefit significantly from the availability of higher SPF sunscreen products. The submissions noted that consumers might reapply higher SPF sunscreen products less frequently than SPF 30+ sunscreen products and, therefore, would not derive the additional protection that higher SPF products are claimed to provide. One of the submissions provided data showing that increases in the concentrations of ingredients in higher SPF products might lead to increases in skin sensitization and/or irritation problems. Another one of the submissions submitted data to demonstrate that an increase in SPF value from 28 to 50 requires roughly twice the amount of active ingredients in a sunscreen product and suggested that this result may lead to increases in skin sensitization and/or irritation problems. The submission argued that the safety risks associated with increased exposure to sunscreen active ingredients were not justified in light of what it defined as a small increase in UV protection.

The submissions that support our raising the proposed upper limit from 30+ to 50+ came from the American Academy of Dermatology, the American Society of Dermatologic Surgery, two sunscreen manufacturers, the Personal Care Products Council, and a consumer. These submissions collectively made the following arguments:

- The increased protection provided by an SPF 50 sunscreen product compared to an SPF 30 sunscreen product is important and necessary for some consumers (*e.g.,* those with skin type I, a history of skin cancer, or an immunosuppression condition).
- Increasing the upper limit from ''30+'' to ''50+'' compensates for inadequate application of sunscreen by consumers.
- The SPF test has been validated to ensure accuracy and reproducibility for sunscreen products with SPF 50, but not for sunscreen products with SPF above 50.
- An SPF upper limit of ''50+'' is harmonized with many other countries, including Japan and those in the European Union.
- An SPF 50 sunscreen product provides the maximum protection needed by consumers.

The submissions requesting that FDA not establish an upper limit on the SPF value argued that some consumers may need more sun protection than that provided by SPF 50 sunscreen products (*e.g.,* lifeguards and athletes who cannot reapply sunscreen products frequently). Two of the submissions submitted data that they argue support an upper limit for SPF values above 50. One submission included data intended to validate that the SPF test can accurately and reproducibly measure sunburn protection for sunscreen products with SPF values as high as 80. The other submission included data intended to demonstrate that sunscreen products with SPF values above 50 provide additional protection under actual use conditions.

B. Discussion of Maximum SPF Values in Previous Sunscreen Rulemakings

We have addressed the issue of establishing maximum SPF values in many earlier sunscreen rulemakings. We have raised the maximum SPF value over time in the rulemakings in accordance with the two previously mentioned criteria:

- Does the SPF test provide accurate and reproducible results for sunscreen products with higher SPF values?
- Do sunscreen products with higher SPF values provide additional clinical benefit?

Maximum SPF values were first addressed in an advance notice of proposed rulemaking (ANPRM) published in 1978 (43 FR 38206 at 38213 through 38214, August 25, 1978). A panel of sunscreen experts recommended categorizing products based upon the protection they

provided against sunburn. Products that provided the most protection from sunburn were those with SPF values of 15 or higher. The panel recommended the use of these higher SPF products for individuals with skin types that always burn easily. In the 1993 proposed rule, we considered raising the maximum SPF value to a value higher than 15 (58 FR 28194 at 28221 through 28225, May 12, 1993). Based on the data available at that time, we stated that sunscreen products with SPF values higher than 15 are beneficial to consumers and proposed increasing the maximum value to 30. We focused on the question of whether there was additional benefit from these sunscreen products with higher SPF values. We were not concerned about the accuracy of SPF testing because available data demonstrated that the SPF test was accurate and reproducible for sunscreen products with SPF values as high as 30.

In the stayed 1999 final rule, we considered increasing the SPF maximum value from 30 to 50 (64 FR 27666 at 27674 through 27675). We discussed both the question of additional benefit and the question of testing accuracy and reproducibility in deciding not to increase the maximum SPF value to 50. We expressed concern about the ''extremely small'' additional sunburn protection afforded by an SPF 50 sunscreen product compared to an SPF 30 sunscreen product (64 FR 27666 at 27675). We explained that the increase in sunburn protection becomes increasingly small with increasing SPF values. We stated that this nonlinear nature of SPF rating system is difficult to translate to labeling. We also expressed concern about the ''ability of current testing methods to accurately and reproducibly determine SPF values for high SPF products'' (64 FR 27666 at 27675). The higher UV test doses required to test high SPF products can make it difficult to obtain accurate and reproducible results. Therefore, because we did not have data validating testing for SPF 50 sunscreen products, we retained a maximum SPF value of 30 in the 1999 final rule, which is currently stayed.

In the 2007 proposed rule, we proposed increasing the maximum labeled SPF value to ''50+'' based on our receipt of sufficient supporting data (72 FR 49070 at 49085 through 49087). Our decision to limit the labeled SPF values to 50+ was based primarily on concerns about expected increased SPF test variability for sunscreen products with SPF values higher than 50 and the lack of validation data for these products. We stated that we would consider SPF values above 50 upon receipt of validation data demonstrating that accurate and reproducible test results could be obtained. We further specified that these data should include SPF test results from multiple laboratories testing the same sunscreen formulations with statistical analyses of the overall results. We also discussed the clinical benefits provided by SPF 50 sunscreen products for ''those sun-sensitive consumers who require such products based upon personal knowledge, planned sun exposure, geographical location, or advice of a health professional'' (72 FR 49070 at 49086). We explained in the 2007 proposed rule that SPF 50 sunscreen products are expected to provide additional benefit by compensating for inadequate application and infrequent reapplication of sunscreen products (72 FR 49070 at 49086).

C. Validity of Testing Sunscreen Products With SPF Values Higher Than 50

We now have data demonstrating that the SPF test can be accurately and reproducibly performed for sunscreen products with SPF values as high as 80. The data were included in one of the submissions requesting an upper limit above SPF 50 (Ref. 2). Multiple laboratories, testing multiple sunscreen formulations, determined the same SPF values for the same sunscreen products.

D. Insufficient Evidence of Additional Benefit at SPF Values Higher Than 50

Despite the new testing, the record does not contain adequate data demonstrating that a sunscreen product with an SPF value over 50 provides an increase in clinical benefit over a sunscreen product with an SPF value of 50. For reasons explained in the remainder of this section, it is critical that the data demonstrate that SPF values measured in the laboratory setting correspond to additional clinical benefit in actual use conditions. Consumers have become familiar with SPF values because SPF values have appeared on sunscreen product labels for many decades. Consumers have learned to associate higher SPF values with greater sun protection. Consumers would likely assume that a product with an SPF value higher than 50 provides greater protection than a product with an SPF value of 50 (*e.g.,* assume that an SPF 80 sunscreen provides greater protection than an SPF 50 sunscreen). However, we lack evidence that a product with an SPF value higher than 50 provides additional clinical benefit compared to a product with an SPF value of 50. In the absence of data demonstrating additional clinical benefit, we are concerned that labeling a product with a specific SPF value higher than 50 would be misleading to the consumer.

It is important to understand that SPF values are determined in a laboratory where human subjects are given ultraviolet (UV) radiation doses produced by a solar simulator (*i.e.,* a UV lamp). Under those circumstances, products with increasingly higher SPF values are shown to prevent sunburn against increasingly higher UV doses produced by the solar simulator. However, because the solar simulator can produce far higher UV radiation doses than a consumer would ever receive even under the most severe sun exposure situations (*i.e.,* locations and times associated with the most intense sun exposure), the theoretical increase in protection implied by higher SPF values generated in the lab does not necessarily correspond to meaningful additional sunburn protection for consumers in actual use conditions, where a consumer may be receiving effectively maximal protection against their actual UV exposure with a lower SPF product.

We are only aware of one study that examined the relative effectiveness of sunscreen products with SPF values of 50 compared to products with SPF values above 50. Russak *et al.* compared the sunburn protection provided by an SPF 85 sunscreen product compared to an SPF 50 sunscreen product (Ref. 3). In the double-blind study, each subject was randomly assigned to apply the SPF 85 product to one side of the face and the SPF 50 product to the other. Following a one-time morning application, subjects went skiing or snowboarding during a bright, sunny day at a well-known ski resort.

Nine of 56 subjects, who averaged 5 hours of sun exposure, developed sunburn. Eight of the sunburned subjects developed sunburn on the SPF 50 product side of the face but not on the SPF 85 side of the face. The remaining sunburned subject developed sunburn on both sides of the face. The study authors concluded that these results demonstrate that an SPF 85 sunscreen product provides significantly better sunburn protection than an SPF 50 sunscreen product. However, this single study summary is not an adequate basis upon which we may conclude that sunscreen products with SPF values above 50 provide additional sun protection compared to an SPF 50 sunscreen product. For example, we cannot determine from the study summary the amounts of sunscreen products applied, length of sun exposure for individual subjects, or

the time of day during which subjects were exposed to the sun. Furthermore, although current sunscreen directions instruct consumers to reapply sunscreen products no less frequently than every two hours, the subjects in this study were explicitly told not to reapply sunscreen products. Therefore, we do not have adequate data to conclude that sunscreen products with SPF values above 50 provide additional clinical benefit when compared to SPF 50 sunscreen products.

The requirement that higher SPF sunscreen products provide additional clinical benefit when compared to lower SPF sunscreen products also flows from the principle that the GRASE determination requires consideration of the benefit-to-risk ratio for the drug (21 CFR 330.10(a)(4)(ii) and (iii)). If the addition of ingredients to a drug does not provide additional clinical benefit, but potentially increases the risk associated with the drug (*e.g.,* increased skin irritation), then this benefit-risk calculation shifts, and the drug is not GRASE. For the reasons noted above, the record does not currently contain sufficient data to indicate that there is additional clinical benefit above SPF 50.

Our combination policy also illustrates this principle. As stated in 21 CFR 330.10(a)(4)(iv), active ingredients should not be combined in a drug product unless ''each active ingredient makes a contribution to the claimed effect(s).'' An active ingredient should not be added to a drug product unless the combination with the active ingredient has additional benefit. Similarly, increased concentrations of active ingredients should not be included in sunscreen products unless there is evidence that these increases result in improved effectiveness under conditions of actual use. Therefore, we are requiring data sufficient to support a general conclusion that sunscreen products with specific SPF values above 50 provide additional protection over SPF 50 sunscreen products. If we receive such data, and sufficient accompanying data regarding accuracy and reproducibility of testing, we may be able to allow those specific SPF values to be included in labeling. For example, as we now have data addressing the reproducibility of SPF testing up to SPF 80, if we received sufficient clinical data demonstrating additional clinical benefit for products with specific SPF values between 50 and 80, we may include those products under the monograph. However, the final determination may also depend on safety data on those products, and the question of whether the benefit-risk calculation remains favorable to finding them GRASE.

E. Data Necessary To Demonstrate Additional Benefit

To increase the maximum specific SPF value above 50, we would need data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit relative to SPF 50 sunscreen products. The study by Russak *et al.* described earlier in this section of the document is one type of study that we would accept for consideration, if it would have contained the detail required to make a determination of its adequacy. There may be other types of studies that would support such an increase. However, it is important that any such studies be well-designed so that we can draw conclusions from them. We recommend that anyone interested in conducting these types of studies contact FDA before beginning the studies.

We recognize that sunscreen products with SPF values above 50 could have utility for consumers in certain settings, such as skiing at high altitudes, or with certain conditions that predispose them to developing skin cancer. If such products are needed in unique situations but not in typical situations of sunscreen use (*e.g.,* beach or gardening), it is possible that different labeling may be necessary for these unique situations. Possibly, sunscreen products with specific SPF values above 50 should be labeled only for certain situations or populations, while sunscreen products with SPF 50 or lower could contain the labeling included in the 2011 final rule published elsewhere in this issue of the **Federal Register**. Additional data would enable us to identify the appropriate target population (*e.g.,* high altitude skiers or people diagnosed with skin cancer) for sunscreen products with SPF values above 50.

F. Alternatives for Addressing Maximum SPF Value

In this and prior rulemakings, we have proposed monograph conditions addressing SPF labeling, which would have the effect of limiting the maximum SPF value that can be declared on the label of a sunscreen under the monograph. As we have described, we are concerned that in the absence of data supporting additional clinical benefit for products with specific SPF values above 50 (but below 80, the current limit of validated testing), declaring specific SPF values higher than 50 would mislead consumers into thinking that they are obtaining superior protection from these products, which has not been substantiated. Similarly, we solicit comment on whether, absent data demonstrating additional clinical benefit, allowing a product with a tested SPF value above 50 to be labeled as ''SPF 50 plus'' is itself misleading, in suggesting a greater level of protection than a product labeled simply as ''SPF 50.''

In addition to our proposals to limit the maximum SPF value stated in labeling to ''50'' or ''50 plus,'' we solicit comment on whether we should establish a maximum SPF value for sunscreen formulations marketed under the monograph. If a maximum SPF value were established, a product with a tested SPF above that value would no longer be permitted to be marketed under the monograph. For example, if the maximum SPF value were set at 50, then a product with a tested SPF value of 65 would no longer be permitted under the monograph, even if labeled as ''SPF 50 plus'' or ''SPF 50.'' We seek comment on this alternative because, as noted previously, FDA's general approach to combination drugs prohibits the inclusion of additional active ingredients if they do not provide additional benefit. More specifically, if having an SPF above 50 does not confer additional clinical benefit in a sunscreen, the risk benefit-assessment for these sunscreens may no longer be favorable. Manufacturers may have economic incentives to limit their formulations to the minimum necessary active ingredients if they were limited to labeling their product as ''50'' or ''50 plus.'' However, we solicit comment on whether FDA should address this issue through a direct limit on product formulation rather than through labeling. We also solicit comment and data on how to establish the maximum SPF value as a formulation limit (if one were to be set).

III. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866. Consistent

with Executive Order 13563, the approach taken here maintains ''flexibility and freedom of choice for the public,'' above all by providing ''information for the public in a form that is clear and intelligible.''

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would lead to at most a small one-time relabeling cost for some small businesses, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Background

This proposed rule would require that ''SPF 50+'' be the maximum labeled SPF value for sunscreens marketed under the monograph because products with SPF values above 50 have not been shown to provide additional clinical benefit. Currently, about 2 percent of all products are labeled with SPF values above 50. Manufacturers of broad spectrum products that have products labeled with SPF values greater than 50 will have to relabel the SPF value on their products to ''50+.''

The science regarding the sun's harmful effects on skin has evolved in recent years, and we now know that protection from sunburn is not enough to prevent harmful or undesirable long-term effects from too much sun exposure, such as skin cancer and premature skin aging. We also now have evidence to demonstrate that when used as directed with other sun protection measures, products with Broad Spectrum SPF values of 15 or higher reduce the risk of skin cancer and premature skin aging, as well as helping prevent sunburn. No evidence, however, indicates that SPF values above 50 provide additional protection.

B. Cost To Relabel SPF 50+ Products

Broad spectrum products labeled with SPF values greater than 50 would have to relabel the SPF value to ''50+''. We estimate that about 2 percent of the SKUs, or a total of 72, have SPF values greater than 50 (Ref. 4). We used the new FDA labeling cost model to estimate the costs of relabeling these products. The estimated total one-time costs for relabeling, range from about $200,000 to $650,000 (see table 1 of this document).

TABLE 1—TOTAL COST TO RELABEL SPF 50+ PRODUCTS

	Low	Medium	High
SKUs relabeling SPF 50+	72	72	72
Total Costs ($)	$208,327	$381,287	$657,108

The principal alternative to this proposed rule would be allowing claimed SPF values as high as 80, which would reduce costs by 80 percent or more because most marketed products labeled with SPF values higher than 50 are in the 50 to 80 range. The SPF test has not been validated for values over 80. Another problem with this alternative is that we lack the evidence of additional clinical benefit from these higher SPF ratings.

C. Small Business Analysis

Most major suppliers of sunscreen products are drug manufacturers, for which the Small Business Administration (SBA) defines a small entity as having fewer than 750 employees. The U.S. Census, however, classifies sunscreen firms as Toilet Preparation Manufacturers under code number 325620 under the North American Industry Classification System (NAICS), where the SBA's definition of a small business is fewer than 500 employees. Census data from 2002 indicate that about 97 percent of the establishments in NAICS 325620 would be considered small using the SBA definition. A casual analysis of the sunscreen manufacturers suggests, however, that there are a higher percentage of large firms manufacturing sunscreens than indicated by using all manufacturers classified in NAICS 325620. We estimate that about 78 of 100 manufacturers of sunscreen products would be considered small under the SBA definitions. Some of these firms may be currently marketing products that would have to be relabeled as a result of this rule. If the relabeling cannot be coordinated with scheduled labeling changes, the FDA labeling cost model estimates the one-time labeling cost per Universal Product Code (UPC) to range from $3,028 to $9,555. If labeling changes can be coordinated with other scheduled changes, the cost per UPC ranges from $140 to $270. Because small manufacturers would on average be marketing few affected UPCs and only 72 UPCs in all would need changing, FDA concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities. FDA requests comments on this tentative conclusion.

IV. Paperwork Reduction Act of 1995

This proposed rule contains certain information collection provisions addressing SPF labeling and associated testing that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Specifically, if finalized, this rule would modify the information collection associated with § 201.327(a)(1), which is based on testing in § 201.327(i), by requiring that products with tested SPF values above 50 be labeled as ''50+'' or ''50 plus,'' rather than with the specific numerical SPF value that results from the testing under § 201.327(i) (21 CFR 201.327(i)). Elsewhere in this issue of the **Federal Register**, in accordance with section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), we are publishing a 60-day notice soliciting public comment on the collections of information resulting from § 201.327(a)(1) and (i) as established in the 2011 final rule published elsewhere in this issue of the **Federal Register** and will then submit these information collection provisions to OMB for approval. Those requirements will not be effective until we obtain OMB approval.

A description of the information collection provisions in this proposed rule, which would modify those resulting from § 201.327(a)(1) and (i), is

given in this section with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite 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 With SPF Values Greater Than 50

In this proposed rule, we propose that the maximum labeled SPF value for any product marketed under the OTC monograph for sunscreens be ''50+'' or ''50 plus.'' Under § 201.327(a)(1), a final rule published elsewhere in this issue of **Federal Register** which will be become effective 1 year after its date of publication, these products are required to be labeled with the numerical SPF value resulting from testing under § 201.327(i)), resulting in a third party disclosure. If the proposal included in this document is finalized, that requirement would be amended so that products with tested SPF values above 50 would no longer include that specific numerical SPF value in their labeling, but instead would substitute the statement ''SPF 50+'' or ''Broad Spectrum SPF 50+'', as applicable.

We believe that this proposed rule, if finalized, would modify the information collection associated with the present version of § 201.327, in that currently marketed sunscreens labeled with specific SPF values above 50 would be required to make a one-time revision to their labeling to replace the specific SPF value with the ''50+'' statement. In our PRA estimate for the current version of § 201.327(a)(1), we estimate that manufacturers would require 0.5 hours per SKU to insert the tested SPF value, and we believe this is therefore also an appropriate estimate of the time that would be required to revise those labels to include the term ''50 plus''. We estimate that there are a total of 3,600 currently marketed SKUs, of which 2 percent, or a total of 72, are products with SPF values above 50. We estimate that these 72 SKUs are manufactured by 50 firms (respondents). While manufacturers would need to examine all their products in order to determine which ones to revise, we estimate that the amount of time needed to accomplish this review is negligible, as SPF values would be apparent on the face of existing labels, and manufacturers are likely to have existing data compiled for their own business needs on which of their products are labeled with SPF values above 50. As a result, we include in our estimate of burden only the labels actually requiring revision. We annualize this one-time burden of 36 hours (0.5 hours per label times 72 labels) across the 3-year period for which we are seeking approval, for an annualized burden of 12 hours.

We note that no additional product testing under § 201.327(i) would be required to support this relabeling; existing products would merely reexamine their prior test values in light of the new labeling requirement.

With respect to new sunscreen products entering the market after the effective date of a final rule based on this proposal, we believe that the effect of this rule would be either to leave unchanged or slightly reduce the information collection burden associated with § 201.327(a)(1). The burden of SPF testing of all new formulations in order to ascertain the content of the SPF labeling statement (third party disclosure) is already accounted for in the estimate of burden for the 2011 final rule and would not be changed by this rule. If this proposal is finalized, new products with tested SPF values above 50 will simply create labeling that states ''SPF 50+'' or ''Broad Spectrum SPF 50+'' instead of including their specific tested value. We estimate that approximately 60 new products will be introduced each year, and based on currently marketed products, that 2 percent of these will have SPF values greater than 50, for a total of 1 such product per year. This labeling is estimated to require no more than the 0.5 hours estimated for creating labeling bearing a specific SPF value, which is already included in the estimate for the 2011 final rule.

In sum, we estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Labeling new sunscreen products with SPF values greater than 50 with ''Broad Spectrum SPF 50 plus'' or ''SPF 50 plus'' in lieu of specific SPF values	1	1	1	0.5	0.5
Reexamining/relabeling of effectiveness statement on existing sunscreen PDPs to replace specific SPF values above 50 with the phrase ''50+'' or ''50 plus'' in accordance with revisions to 201.327(a)(1)[2]	17	1.4	24	0.5	12
Total					12.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Actual first year burden hours have been divided by 3 to avoid double counting in OMB's tracking system.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by (see **DATES**) to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on 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:* 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the

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.

[FR Doc. 2011–14769 Filed 6–14–11; 8:45 am]

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.*

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