COMMENTS SUBMITTED BY

Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application
Docket No. FDA-2010-D-0509

August 16, 2011

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application; Availability; Docket No. FDA-2010-D-0509

The Personal Care Products Council (the Council) and the Consumer Healthcare Products Association are pleased to provide these comments in response to the Food and Drug Administration's (FDA) draft guidance document "Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application" (Draft Guidance) which FDA published on June 17, 2011, as well as the final rule "Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use," 76 Fed. Reg. 35620 (2011 Final Rule).

Based in Washington, D.C., the Council (formerly the Cosmetic, Toiletry and Fragrance Association) is the leading national trade association for the cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo, to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

The Consumer Healthcare Products Association (CHPA) is the 130-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines.

INTRODUCTION

Our members market or manufacture the majority of sunscreen products sold in the U.S., as well as a large number of OTC drugs and OTC drug-cosmetic combination products. Our members export sunscreen products throughout the world, and many members have manufacturing facilities located outside the U.S. We believe sunscreens are important to public

health in helping to prevent sunburn, skin cancer, and other significant detrimental effects of ultraviolet (UV) radiation.

Specifically, these comments on the Draft Guidance request:

I) additional time for the implementation of the 2011 Final Rule;
II) that FDA not require retesting of sunscreen products to determine SPF values;
III) modifications to the water resistance testing methods;
IV) modifications to the test methodology supporting "Broad Spectrum" claims;
V) modifications to the labeling of sunscreen products; and
VI) that FDA permit continued marketing of sunscreen powders.

We believe the recommended changes to FDA's enforcement of the 2011 Final Rule under the Draft Guidance outlined in these comments are necessary to ensure the continued availability of sunscreen products to promote the public health.

As time is of the essence, <u>we respectfully request that FDA respond to our requests herein as soon as possible</u>. To the extent that FDA grants the requests, *e.g.* to permit the proposed labeling modifications, sunscreen manufacturers should be informed at the earliest practical time to avoid unnecessary substantial investments in new labeling and packaging design.

I. <u>Request for Additional Time for Implementation</u>

A. <u>Action Requested</u>

The 2011 Final Rule is currently scheduled to become effective on June 18, 2012.[1] 76 Fed. Reg. at 35620. We request that FDA extend this date via enforcement discretion by 6 months, to December 18, 2012.

[1] The compliance date for all products subject to the 2011 Final Rule with annual sales of less than $25,000 is June 17, 2013.

B. Statement of Grounds and Further Information

When FDA published the 2011 Final Rule, it stated: "We are requiring that this final rule become effective in 1 year, even though we considered 18 months in the 2007 proposed rule [72 Fed. Reg. 49070, 49110 (August 27, 2007)]." 76 Fed. Reg. at 35623. We respectfully request that FDA permit an effective date based on the 18-month period it originally proposed in 2007 for the following reasons:

- the complexity of relabeling does not provide a reasonable opportunity for all affected products to be brought into compliance with the new rule by June 18, 2012;
- to avoid consumers needing to transition to the new label during the height of the sun season;
- to help avoid a shortage of sunscreen products in the marketplace during 2012;
- to mitigate the environmental impact of returned product; and
- such action will be consistent with past FDA practice and in the public interest.

1. The complexity of relabeling does not provide a reasonable opportunity for all affected products to be brought into compliance with the new rule by June 18, 2012

In its 2007 proposed rule, FDA said:

> FDA understands the seasonal nature of the sunscreen industry and the time required for product testing and relabeling. FDA is also aware that more than 1 year may be needed for implementation. FDA is proposing an 18- to 24-month implementation date and will try to have it coincide with the June/July time period.

Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph, 72 Fed. Reg. 49070 (Aug. 27, 2007) (2007 proposed rule).

The 2011 Final Rule requires labeling be revised for the entire U.S. sunscreen marketplace consisting of thousands of products with many different uses (ranging from "beach" products to cosmetic-sunscreen combinations) in many different package shapes, sizes and materials. The industry is already working diligently to accomplish this relabeling as quickly as possible, but there are two categories of products for which complete implementation most likely

cannot occur by June 18, 2012: products with complex label redesign issues and products requiring broad spectrum testing.

A majority of sunscreen products will be affected by label redesign issues that are complex and/or require long lead times. These include, for example:

- products packaged in glass or plastic tubes or bottles that require embossing or other special production techniques;
- products that require complete package redesign in order to accommodate the Drug Facts panel (e.g., the new use of cards or fold-out labels); and
- products in lines with many variants, all of which need to be coordinated for relabeling in tandem.

A significant number of products will need broad spectrum testing, which will take longer than 3 months. Although FDA has permitted use of the an *in vitro* test to demonstrate broad spectrum protection, there are nevertheless a limited number of testing facilities that will be able to accommodate many product tests in an exceedingly short time. In addition, other testing facilities perform many types of testing in addition to broad spectrum testing, and are not staffed to meet the requirements of their other testing obligations in addition to FDA's increased broad spectrum testing requirements. This process could take a few weeks to a few months, depending on where products fall in the testing queue. As illustrated in the industry operational timeline in Appendix A, products that take longer than approximately 3 months for testing will not be able to be relabeled by June 18, 2012.

We are providing below (Figure 1) and in Appendix A an industry operational timeline demonstrating that for sunscreen products, including the above groups of products, label redesign will take at least 18 months. This operational timeline reflects the industry at large and provides an illustrative overview of the steps that companies typically take in order to comply with the testing and labeling changes of the kind and scope required by the 2011 Final Rule. We have overlapped steps to demonstrate portions of activities that can run in parallel.

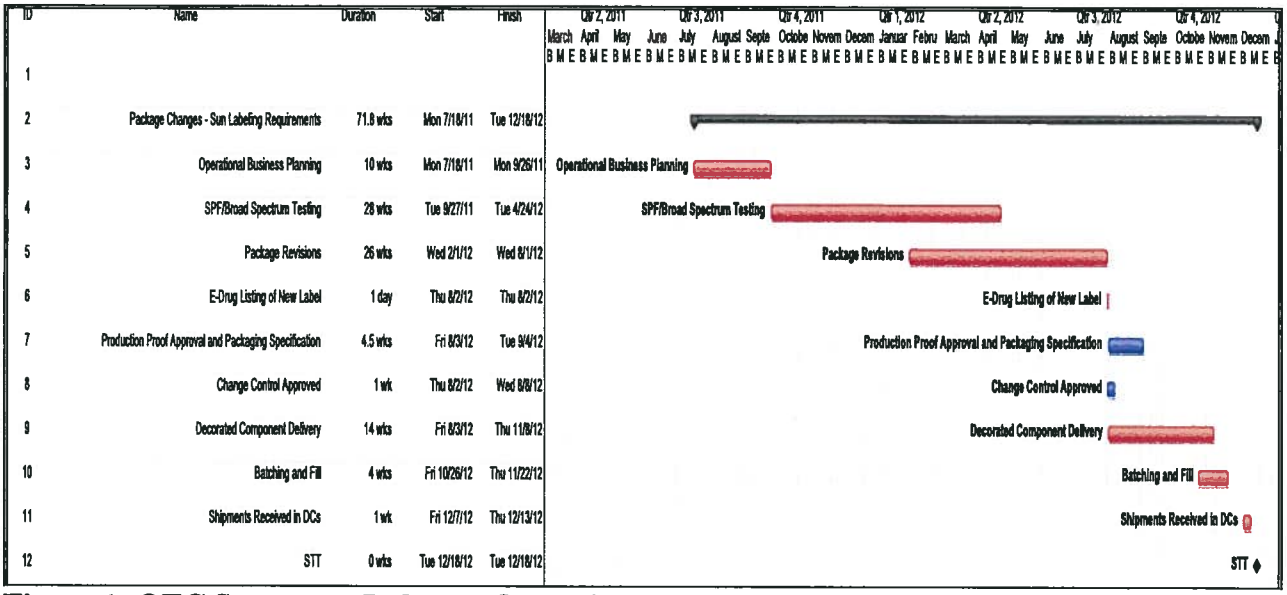

Figure 1: OTC Sunscreen Industry Operational Timeline

The major stages of implementation of the 2011 Final Rule, and their estimated time frame, are outlined below. Please note that we determined estimates for approximate time, number of sunscreen manufacturers, and number of products based upon information from industry and third parties. For further information regarding these estimates, see our comments to FDA's notice of SPF Labeling and Testing Requirements and Drug Facts Labeling for OTC Sunscreen Drug Products; Agency Information Collection Activities, provided in Appendix B.

Based on an average of our member companies' estimates to implement the 2011 Final Rule, we are confident that a request for an additional six months is necessary and practicable. We have extrapolated these estimates and applied them to the industry at large for illustrative purposes. Smaller manufacturers may have different production timelines. In some instances, these will require coordination with contract manufacturers and fillers as well.

- Operational business planning (10 weeks): This stage involves a business assessment of the 2011 Final Rule and an analysis of the financial impact to the company, including a formal budgetary review, analyzing of the number of impacted codes, and outlining the project management timeline for the June 18, 2012 compliance deadline. The operational business plan also factors inventory availability, production schedules, additional organization resources, and facilities needed for SPF testing.

- SPF and Broad Spectrum testing (28 weeks): Each product with SPF is required to undergo broad spectrum testing under new FDA guidelines as well as retest on SPF metrics.

- Prior to sending products to a testing laboratory for human clinical testing (SPF test), Good Clinical Practices must be followed, including internal release of samples (i.e. toxicology testing, safety testing), batch documentation release, shipment authorization, etc. These regulatory requirements can take at least 6 weeks.

- Testing facilities need time to recruit subjects and each subject will only need to come to the facility for 3 days (baseline MED determination at day 1, sunscreen application and UV irradiation on day 2 and final erythema reading on day 3). The entire testing for water resistance of a SPF 30 sample on 10 subjects will typically take 3-4 weeks, including data analysis and excluding the final report. This timeline cannot be shortened as there are at least 364 companies utilizing the same clinical testing facilities.

- Estimating 2,943 formulations will need testing with approximately 7 laboratories that are able to test simultaneously, that leads to 420 formulations (2,943 formulations divided by 7 laboratories) for each lab, three formulations per subject. If we assume that we can overlap some of the process time between different samples, then the independent process and testing time for each code is 6 weeks. Therefore, sample production through final report generation requires at least 6 weeks.

- While the critical wavelength test method is much quicker to conduct and does not require adherence to GCP's (*in vivo* vs. *in vitro*), many of the testing facilities need additional time to order equipment to perform the test. An estimated 3 months will be required to be fully operational. It appears that currently, there are only 5 labs able to perform the critical wavelength test described in the 2011 Final Rule. Some of the testing facilities that were surveyed are not planning on offering these services, which could further reduce the number of available resources for the industry.

- The new UVA test method requires approximately 1.5 hours for preparing the sample, running the test, and summarizing the results. Therefore, it is possible to complete testing on at least 50 samples per month. Using the same numbers for formulations currently on the market (2,943) plus those that will be introduced to the market between June 17, 2011 and June 18, 2012 (XX) and with only 5 laboratories available to perform the testing, it would require approximately 10 months for industry to complete the UVA testing.

- <u>Packaging and labeling revisions (26 weeks)</u>: A company's Creative team must develop package designs to integrate and comply with FDA requirements.

    - The Creative and Design teams then must ensure that the packaging is consistent with the brand equity as well as provide clarity on packaging communication to the consumer. Marketing, Regulatory Affairs, & Legal teams are consulted throughout the process for alignment so that the Creative team can make

appropriate modifications before the extensive internal approval routing process begins.

- A majority of the SPF SKU's in the market have small packages (less than 3 ounces), as they are color cosmetics, trial sizes, or skin care products. As a result, the extensive labeling that is now required will not fit on current package designs for these products, and so the packaging must be redesigned to accommodate the additional labeling space necessary. There are a number of ways to do this (*e.g.*, header card, wrap around labels, 5th panel, etc.), but each product shape and size will require a different solution. Therefore, redesigning many different packages for many different products will take up to 20 weeks. Additionally, once that is done, drug facts labeling must be created for each product, and that will take up to 6 weeks, for a total of 26 weeks.

- E-Drug listing of new labels (1 day): Product/labeling submission is expected to take one day, however, additional time for follow up and possible corrections may be required.

- Production proof approval & packaging specifications (4.5 weeks): This phase requires component specifications to be written & released to both the printed component supplier and manufacturing site with the approved artwork mechanical. The printed component supplier then reviews the component specification and creates a production proof. The production proof is then reviewed & approved by the Print Production Manager. A signed production proof is released to the printed component supplier. The Package Engineer attaches the approved production proof to the component specification and routes it through the internal routing systems.

- Approval of change control (1 week): During this phase, component specification & approved production proof routes in internal system for final approval.

- Decorated component delivery (14 weeks): In this phase, Supply Chain orders packaging components across various global suppliers (*e.g.*, tube, tube caps, aerosol components, aluminum cans, aluminum caps, sticks, cartons). Global suppliers place orders and ship components to printed component supplier. Once the production proof has been approved, the printed component suppliers begin printing the unfilled white components (tubes, cans, cartons) with the new artwork graphics. Final packaging components are then delivered to the manufacturing site and QA completes incoming inspection on each batch shipped.

- Batch & fill (4 weeks): Supply Chain requests fill and batch time on line production schedules at various Plant locations.

  - Manufacturing site produces the bulk, fills printed components, packs the shippers, and then, places components onto pallets. Quality Assurance must then test each batch for active and preservatives issues on both the bulk and filled finished goods before releasing product to Distribution Centers.

- Production schedules are routinely locked one week in advance to ensure a facility is used efficiently. Therefore, it would most likely be the second week after component release when a batch is filled. Depending on the Lot size and batch order or cleaning requirements, each batch may take an average of 1 to 4 shifts to be filled, labeled, and placed on hold. There is then typically a 2-week period during which release testing is performed, batch paperwork is reviewed, and the lot is released for distribution. The average batch and fill time has therefore been estimated as 4 weeks.

- Shipments received in distribution centers (1 week domestically, 8 weeks internationally): During this phase, filled finished goods are air shipped or driven by truckers to internal distribution centers.

  - The pallets are unloaded from the trucks & entered into internal systems before final retailer release of finished goods. Final finished goods are then air shipped or driven by truckers to retailer distribution or warehouse centers.

  - For products manufactured in the U.S., it should only take about 1 week for shipping to distribution centers across the country. However, there are many manufacturers located outside the U.S. For these foreign manufacturers, it takes up to 8 weeks to ship product by ocean to the US and to clear customs here.

The addition of six months to the effective date in order to permit an orderly transition would be reasonable and appropriate, and would not add significantly to the time already taken by this process.

2. Permitting a December 18, 2012, effective date will avoid requiring consumers to transition to the new label during the height of the sun season

Most of the sunscreen products that are sold in the summer of 2012 will need to be produced, labeled and shipped well before the summer. In many cases, products will need to be shipped, or ready for shipment, no later than March or April 2012. Most companies will not be able to ship by this date, and will be forced to ship product with existing labels.

As indicated in the timeline in Figure 1, above, and Appendix A, virtually all products shipped by March or April 2012 – and most products shipped by June 18, 2012 – will continue to

bear old labeling. Because these products can continue to be sold in the marketplace,[2] they will comprise the preponderance of sunscreens available for sale during 2012. Thus, most sunscreens available for sale in 2012 will not be relabeled under the new rule.

However, to the extent that the new sunscreen product labeling will be introduced on store shelves, this "new label transition" will commence at the height of the sun season. There will be consumer confusion on account of seeing the old and new labels on the shelf at the same time. We believe it is in keeping with the Agency's public health goals to allow for an additional 6 months (shifting the implementation date in to December 2012) to avoid having "new label transition" phase during the sun season.

3. *A 6-month extension will help avoid a shortage of sunscreen products in the marketplace during 2012*

Revising the effective date to December 18, 2012 will also help avoid a shortage of sunscreen products in the marketplace during the critical spring and summer months of 2012. Currently, any sunscreen products labeled on or after June 18, 2012 must comply with all of the labeling requirements of the 2011 Final Rule. Some manufacturers may not be able to meet this compliance date for some or all of their sunscreen products. We anticipate this situation will lead to decrease availability in the market for these affected products. Thus, some consumers could experience a shortage and/or an interruption in the availability of the sunscreens to which they are accustomed. Extending the effective date as we have requested would protect the public health by avoiding this result.

4. *Allowing for an additional six months to comply with the 2011 Final Rule will mitigate the environmental impact of returned noncompliant product*

Because most of the recreational sunscreen products currently on the market and products shipped prior to the compliance date cannot all be sold in 2013, the extra products will be returned to manufacturers and destroyed. In addition to the waste of the destroyed product, the

[2] FDA stated, "... [W]e do not expect non-compliant products introduced or delivered for introduction into interstate commerce prior to the compliance dates specified for this final rule to be removed from the market." 76 Fed. Reg. at 35624.

process of returning and destroying this additional product will have a significant impact through their transportation and handling. These products, which are safe and effective albeit noncompliant with the new labeling requirements, will be replaced by new product associated with greater packaging. An orderly transition to the new labeling requirements prior to the 2013 spring and summer season will reduce the potential for consumer confusion and significant disruption in the manufacturers/retail supply chain.

5. *A 6-month extension is consistent with past FDA practice and in the public interest*

We have already noted that FDA's 2007 proposed rule provided for an 18-month implementation period. In that rule, FDA acknowledged that "more than 1 year may be needed for implementation." 72 Fed. Reg. at 49073. This proposal was consistent with FDA's approach in its earlier 1999 final rule. Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999). In that rule, after having proposed a 1-year implementation period in 1993, Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph 58 Fed. Reg. 28194, 28195 (May 12, 1993), FDA rejected the 1-year period in favor of 2 years. FDA said:

> Generally, the agency allows only a 1-year implementation period for final monographs. However, because most sunscreen products are produced seasonally, the 2-year period will substantially enhance the ability of the industry to relabel and reformulate its products, if necessary, and sell its existing product inventories. The 2-year period will also allow sunscreen manufacturers to coordinate the required labeling changes with routine industry-initiated labeling changes and changes required by the new OTC drug product labeling final rule (64 FR 13254). ... [T]he agency determined that a 2-year period provides sufficient time to allow the required relabeling and product retesting to be completed.

64 Fed. Reg. at 27686.[3] Revising the 2011 Final Rule to permit a December 18, 2012 effective date would therefore be consistent with past FDA practice.

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[3] FDA established a 1-year effective date for 21 CFR 740.19 (discussed in the 1999 final rule), which requires a warning statement on the labeling of cosmetic suntanning preparations that do not contain a sunscreen active ingredient. *See* 72 Fed. Reg. at 49073. However, this does not establish a precedent for (continued...)

Further, it is consistent with FDA's normal practice to permit an extension of the effective date or compliance date for a final rule, where justified. For example, FDA granted a 1-year extension of the compliance date for certain products to comply with the Drug Facts final rule. Over-the-Counter Human Drugs; Labeling Requirements; Partial Extension of Compliance Dates, 65 Fed. Reg. 38191 (June 20, 2000); *see also* Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use; Final Rule, 75 Fed. Reg. 9767 (Mar. 4, 2010) (setting a later compliance date by three years for certain products that required relabeling).

A 6-month extension would be in the public interest because it provides a reasonable opportunity for all products to be systematically brought into compliance with the new requirements during 2012, would not have an adverse effect on the public health, and would help avoid reduced availability of sunscreen products during 2012. FDA's unexpected decision to require a 1-year effective date after proposing 18 months in the 2007 proposed rule is questionable and considered as being arbitrary and capricious.

6. Conclusion

For the reasons discussed above, a 6-month extension of the effective date of the 2011 Final Rule would:

- provide a reasonable opportunity for all affected products to be brought into compliance with the new rule, which, due to the complexity of relabeling, is not provided by the current effective date of June 18, 2012 date;
- avoid consumer confusion as consumers would otherwise have to transition to the new label in the middle of the sun season;
- help avoid a shortage of sunscreen products in the marketplace during 2012;
- mitigate the environmental impact of returned noncompliant product; and
- be consistent with past FDA practice and in the public interest.

FDA's 2011 Final Rule because the products subject to the 2011 Final Rule are sunscreen drug products and do not present the same safety issues as cosmetic suntanning preparations that contain no sunscreen active ingredients.

Therefore, we respectfully request that FDA establish an effective date based on the 18-month transition period it originally proposed in 2007, *i.e.*, December 18, 2012.

Because this requested action would extend the effective date in a manner consistent with the effective date proposed in FDA's 2007 proposed rule, there is good cause to dispense with a notice of proposed rulemaking, under 5 U.S.C. § 553(b)(3)(B), as impracticable and unnecessary. Thus, the extension may be published as a final rule.

II. Request the FDA Not Require SPF Retesting of Formulations That Already Have Valid Supporting Data

A. Action Requested

We request that FDA allow for existing sunscreen formulations that have been fully tested by the 1999 or 2007 SPF test methods on or before June 17, 2011 to not be required to be retested by the 2011 SPF test method. Further, with respect to water resistant testing, we request that the Agency return the rest period between immersions to 20 minutes.

B. Statement of Grounds and Further Information

FDA has made changes to the SPF testing methodology thereby requiring that all sunscreen formulations on the market be tested for effectiveness by the SPF methods published in the 2011 Final Rule. In its Draft Guidance, FDA has informed manufacturers that it will employ enforcement discretion for those products already on the market prior to the publication of the Final Rule (June 17, 2011) until June 18, 2013 relative to retesting those products for SPF by the 2011 SPF method.

In its commentary on the 2011 Final Rule, FDA noted that it had evaluated the need for panels of 20-25 subjects versus 10 subjects, and by examining 10 random results from panels of 20-25 subjects, found that the mean SPF and standard error of the mean were comparable for these two panel sizes, thus allowing them to reduce the panel size to 10 subjects "without compromising SPF test accuracy or precision." 76 Fed. Reg. at 35646-47.

While we agree with the Agency and support the reduction in panel size to 10 subjects, we believe that results obtained using panels of 20-25 subjects under the 1999 and/or 2007 SPF methods remain valid and formulations already tested using these methods should not need to be retested to support the label SPF claim.

Other than subject panel size, the differences in methodology are very small, and should not affect the outcome of the SPF test. In its Draft Guidance document, FDA states that products on the market prior to June 17, 2011 should be retested by the 2011 method even if they have full panels of valid results obtained by the 1999 or 2007 SPF testing methods, but may be marketed based on results of the 1999 or 2007 methodology until June 17, 2013. If FDA is allowing the SPF determined by the 1999 or 2007 methods to support the label claim for the next 2 years for those products, it is assumed that the efficacy determined by the 1999 and/or 2007 SPF methods is not in question.

By requiring that products and formulations now ready to go to market later in 2011 or early 2012 that already have valid and complete panels of SPF results be retested, FDA is not only significantly impacting many new, fully developed products, but also is mandating that additional human subjects be exposed to UV radiation without a reasonable scientific justification. The SPF results already obtained for these formulations should be accepted as valid as well as for products already on the market as of June 17, 2011. Manufacturers and testing laboratories had no reason to expect that this extra testing would be required to be considered compliant, just before they begin manufacturing for next year. More importantly, there is no public health or safety reason to require retesting of such formulations.

Data are presented herein that illustrate these points. Results supporting products tested on panels of subjects that utilized the SPF 4 as well as the SPF 15 control formulation demonstrate that the choice of control formulation does not alter the outcome of the result for the test panel.

Formulations that were tested by both the 1999/2007 FDA SPF methods (20 subjects) as well as by the International SPF method (10 subjects) are presented to show that the results for the same formulation, regardless of whether panels of 20-25 subjects or 10 subjects were tested,

result in the same outcome, regardless of the control formulation utilized. The control formulas are controls on laboratory procedure only; the results of testing the control formulations are not used to alter the results of the test product and do not figure into the mathematics of calculating the test product's SPF. Thus, the use of an SPF 4 or SPF 15 control formulation for panels of data completed prior to June 17, 2011 do not negate the validity of the test results, and should not be a reason to mandate retesting of products and formulas already supported by valid SPF results.

Another change the Agency has now formally adopted is harmonization with the COLIPA specifications for the solar simulator waveband energy limits. We agree, as recommended in our response to the 2007 Proposed Rule, that these specifications are more technically descriptive than the original solar simulator descriptions that appeared in the 1978 Proposed Rule, the 1993 Tentative Final Monograph and 1999 Final Monograph. The COLIPA specifications, which were adopted into the International SPF Method (2006), have set the standard for solar simulators.[4] Solar simulators in the U.S. have also met the COLIPA requirements for many years, as the testing laboratories in the US have been conducting SPF testing for global clients using the 2006 International SPF Method as well as conducting the FDA SPF test methods. All of these tests have been using the identical solar simulators.

We are providing several solar simulator certifications that illustrate that solar simulators in use prior to publication of the 2011 Final Rule already meet not only the FDA's previous requirements, but also meet COLIPA/International requirements. Thus, the formal adoption by FDA of the COLIPA/International solar simulator requirements would have no affect on SPF test results that have been conducted using the existing 1999/2007 SPF methods prior to June 2011. Solar simulators already currently meet the COLIPA/International specifications.[5]

In summary, the tables of SPF data provided in Appendix C illustrate the following points:

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[4] Sayre RM, Dowdy JC. Spectral Standardization of Sources Used for Sunscreen Testing: 5 Years of Compliance. In: Sunscreens, Regulations and Commercial Development. Third edition. Edited by Nadim Shaath. Taylor and Gump Publishers, Boca Raton, FL, 2005.

[5] Id at 843-851.

- Testing the same formulation by either the 1999 FDA Monograph Method (20-25 subjects) or by the International SPF Method (10 subjects) results in the same outcome. There is no reason based on panel size to require that existing product formulations fully tested by the 1999 or 2007 FDA SPF methods be re-tested by the 2011 FDA SPF method.

- The use of either the SPF 4 or SPF 15 control (reference) lotion does not influence the outcome of the test panel. Products that were fully tested by the 1999 or 2007 FDA SPF methods along with the SPF 4 control lotion do not need to be retested by the 2011 method and with the SPF 15 control lotion, as the choice of control formulation does not impact the outcome of the test product's results.

- Adoption of the COLIPA/International solar simulator specifications will not affect SPF results for products tested by the 1999/2007 SPF test methods. Current solar simulators already meet both existing FDA and COLIPA/International Method requirements.

For these reasons, we recommend that SPF testing by the new 2011 method be required for all new formulations entering the marketplace after the implementation date. Existing products and formulations that already have been fully tested by the 1999 or 2007 SPF test methods before June 17, 2011 and which have valid results supporting their SPF claim should to be required to be retested.

III. Request that FDA modify the water resistance testing methods

A. Action Requested

We request that FDA modify the water resistance testing methods in the 2011 Final Rule by returning the rest period between immersions to 20 minutes.

B. Statement of Grounds and Further Information

In the 2011 method for water resistance testing, FDA has specified that the rest period between water immersions shall be 15 minutes, a change from the 20-minute rest period that has been in place since the 1978 Proposed Rule. In its discussion of changes to the SPF method, the Agency stated its intention to make the method as similar to the COLIPA SPF test methods as possible. However, in making the change to a 15-minute rest period, the Agency has inadvertently created a water resistance protocol that is *less* harmonized with the COLIPA method, in which the rest period between water immersions is 20 minutes. This change has also created problems at laboratories where multiple subjects may be immersed in large whirlpool baths at one time. If some subjects are being tested by the COLIPA method and others by the

new FDA method, they will now be out of sync as to when they get in and out of the water, to the point that it will now be impossible to conduct the water resistance portion of the test for multiple subjects unless they are all being tested under the same methodology at one time.

To resolve this issue and to restore harmonization between methods, we recommend that the Agency either return the rest period between immersions to 20 minutes.

IV. Request Modifications to UVA Test Methodology for "Broad Spectrum" Claims

A. Action Requested

We request that FDA exercise enforcement discretion to allow for modifications to the test for "Broad Spectrum" as outlined below.

B. Statement of Grounds and Further Information

In the 2011 Final Rule for labeling and effectiveness testing for sunscreen products, FDA published methodology for evaluating the Critical Wavelength value used to determine if the product is qualified for "Broad Spectrum" protection claims. This methodology is significantly closer to methods currently in practice globally and validated for *in vitro* sunscreen spectral analysis compared to the proposed *in vitro* UV spectrum analysis proposed in the 2007 proposed rule. In an effort to further align the FDA Critical Wavelength test methodology and validation procedures with International *in vitro* sunscreen techniques, we are offering the following recommendations for modification of the *in vitro* UVA "Broad Spectrum" testing methods for inclusion in the Final Monograph.

1. Specification for the Test Substrate and Application Density

The FDA 2011 Critical Wavelength test method stipulates that a polymethylmethacrylate (PMMA) plate with a surface roughness between 2 and 7 microns (Sa) may be utilized. To our knowledge, there are only two specific options available that have been validated, a 2 micron roughness plate, and a 6 micron roughness plate. Both the 2 micron and 6 micron plates have been tested in multiple ring tests, and have been shown to yield equivalent critical wavelength data. However, it must be noted that the application density appropriate for each of these two plate roughnesses are not the same, and should be adjusted according to the roughness of the

plate. Specifically, the 2 micron roughness plates were tested with 0.75 mg/cm2 product density application, while the 6 micron roughness plates were tested with 1.3 mg/cm2 product density application. Putting too little (0.75 mg/cm2) product onto the 6 micron roughness plate is inappropriate and has not been validated with cross laboratory testing. Conversely, putting 1.3 mg/cm2 onto a 2 micron roughness plate would be too much sample. The application densities have been evaluated and adjusted to each of the surface roughness parameters and have been validated at the corresponding application densities in ring test evaluations

Attached below are data from the ISO 24443 *in vitro* UVA test method Ring Test in which 9 products were tested by 12 laboratories under the same test protocol using both a 2 micron roughness plate treated with 0.75 mg/cm2 and a 6 micron roughness plate treated at 1.3mg/cm2 application density. The results show equivalent critical wavelengths for the 9 test products independent of the plate roughness. Analysis of variance testing shows statistical differences between the critical wavelengths of the test samples, but no statistical differences between the critical wavelengths as a function of the test plates. For critical wavelength testing, the two plates are equivalent when tested with their corresponding application densities.

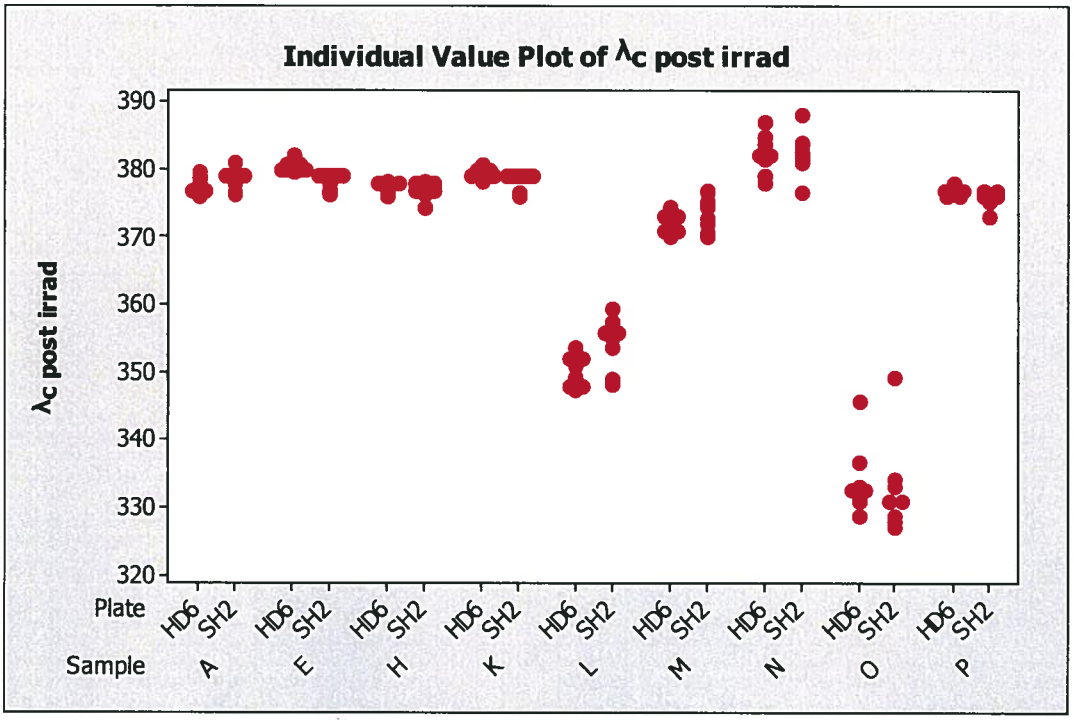

Figure 2: Analysis of Variance Analysis: General Linear Model: λc post irrad versus Sample, Plate

Factor	Type	Levels	Values
Sample	random	9	A, E, H, K, L, M, N, O, P
Plate	fixed	2	HD6, SH2

Analysis of Variance for λc post irrad, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Sample	8	43444.2	43443.6	5430.5	761.08	0.000
Plate	1	0.0	0.0	0.0	0.00	0.950
Error	167	1191.6	1191.6	7.1		
Total	176	44635.8				

We recommend that the specification for PMMA plates and the corresponding application density be revised to the following for further clarification and consistency:

Plate Roughness	**Sunscreen Application Density**
2 micron roughness	**0.75 mg/cm^2**
6 micron roughness	**1.3 mg/cm^2**

2. Spectrophotometer Input Optics

The specification for the spectrophotometer input optics defined by the FDA requires that the bandwidth of the input beam is less than or equal to 1 nm. While this specification would yield valid data, it is in fact excessively narrow, and would exclude the majority of spectrophotometers designed specifically for and utilized today on a global basis for *in vitro* thin film evaluation of sunscreen test products. Restricting the incoming light on these commercial instruments to a 1 nm bandwidth drastically reduces the amount of signal available for the measurement of the sunscreen absorbance such that the noise to signal ratio is greatly increased, degrading the quality of the measurement and significantly raising variability. This is particularly true for the UVB portion of the spectrum where sunscreen absorbance is maximal. Having such a narrow bandwidth also diminishes the valid dynamic range of the spectrophotometer, and raises the likelihood of undetected dynamic range limitations of the instrument.

Given the continuous and broad spectral peaks that are characteristic of all of the UV filters, reducing the incoming signal bandwidth to 1nm is excessive and unnecessary, degrading

the quality of the signal, and diminishing the dynamic range of the spectrophotometer without improving accuracy at all. If one is attempting to resolve narrow bandwidths of absorbance, or obtain high precision on rapidly changing absorbance spectra it is critical to use a narrow bandwidth (i.e., less than or equal to 1 nm). However, use of a narrow bandwidth is inappropriate for any of the FDA approved sunscreen filters (or in TEA submissions for approval), or any sunscreen filters permitted for use in any foreign market. Sunscreen filters are, by design and choice, intended to be broad in their absorbance characteristics and should not use a narrow bandwidth. Doing so would diminish the signal to noise ratio and lower the dynamic range of the instrument; thereby producing less reliable data.

Appendix D contains a spectra of nine sunscreen products. These spectra were obtained using a narrow 1 nm bandwidth and compared to a 4nm bandwidth. The absorbance shape using the two input bandwidths is unchanged as is also the calculated critical wavelength. We recommend that FDA's 1 nm specification be modified to permit use of spectrophotometers with input optics spectral bandwidth of up to and including 4 nm. In addition, to be capable of accurately measuring highly protective sunscreen products, the dynamic range of the spectrophotometer should be specified to be capable of greater than or equal to 2.2 Absorbance Units at any point in the test spectrum 290-400 nm.

3. Sunscreen Product Pre-irradiation

The pre-irradiation step in the Critical Wavelength procedure prescribes that the sample be exposed to 4 MEDs of radiation from a solar simulator that is compliant with the description in section 352.70(b). This specification for the erythemal spectral distribution of the irradiation light source describes the permitted ranges of RCEE values for the various spectral bandwidths. While this specification is extremely critical and appropriate for solar simulators used for conducting clinical SPF tests, it is overly restrictive as a prescription for the light source to be utilized for pre-irradiating the *in vitro* samples for Critical Wavelength determinations. In fact, the vast majority of the photostability challenge of sunscreen products is coming from the UVA region of the spectrum and is not critically dependent on the UVB content, or on a very critically shaped UVB cut-off spectrum.

Multiple ring tests have been conducted by COLIPA and ISO for *in vitro* UVA sunscreen characterization, which have utilized commercial solar "irradiators" that do not comply with the 352.70(b) RCEE specifications – and are yet more representative of real solar spectral irradiation in that they contain all the visible and infrared energy present in the solar spectrum. The difference lies in the need to eliminate both visible and infrared radiation from clinical solar simulators used for SPF determinations on human subjects to prevent thermal overload and interference with the primary erythema endpoint. The visible and IR components of the spectrum are of no concern however for the prescribed *in vitro* Critical Wavelength determination. Benchtop xenon arc solar "irradiators" do not utilize the visible light and infrared blocking filters used in clinical solar simulators, but have been successfully used and validated in the ISO *in vitro* UVA ring tests. Comparisons between labs using clinical solar simulators that would comply with 352.70(b) versus these solar "irradiators" have yielded identical Critical Wavelength values for the test products evaluated.

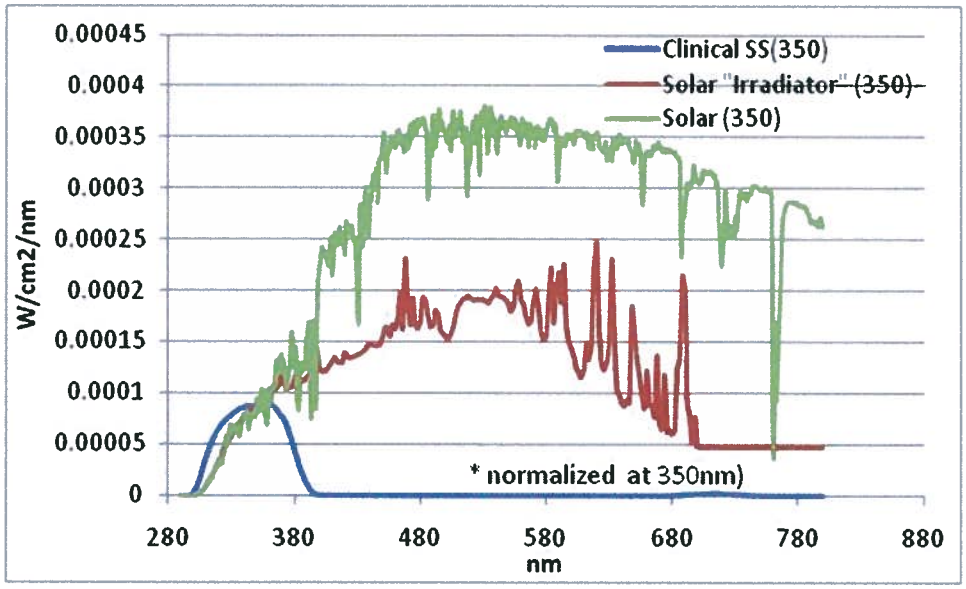

Figure 3: Comparison of Sunscreen Irradiation Sources with Actual Sunlight

We recommend that the spectral composition of the source used to pre-irradiate the *in vitro* samples be expanded beyond the § 352.70(b) specification to also include other xenon arc sources that have characteristics as described below: The source should be as similar as possible

to the irradiance at ground level under a standard zenith sun[6] as defined by COLIPA (1994)[7] or in DIN 67501 (1999)[8]. The UV irradiance must be within the following acceptance limits (measured at sample distance)."

UV exposure source specifications as measured with a spectroradiometer	
Total UV irradiance (290 to 400 nm)	**(40 – 200 W/m^2)**
Irradiance ratio of UVA$_{(320 \text{ to } 400 \text{ nm})}$ to UVB$_{(290 \text{ to } 320 \text{ nm})}$	**8 - 22**

V. Request that FDA Modify Certain Labeling Requirements

A. Action Requested

We request several modest modifications to the labeling required by the 2011 Final Rule for all sunscreen products as well as some additional modifications to the labeling for products in small packaging as further described below.

B. Statement of Grounds and Further Information

For the reasons set forth below, these modifications are necessary to ensure sunscreen labeling is supported by adequate data and to ensure the continued availability of a wide array of sunscreen products for consumer use. Furthermore, we believe it is in the best interest of public health that FDA acknowledge in the Draft Guidance the "sweat resistant" label claims for water resistant sunscreens.

We have included in the appendices graphical illustrations of labeling required by the 2011 Final Rule and as modified by the requests herein. Specifically, Appendix E includes sample labeling for two "regular size" (non-small size packages), Broad Spectrum, SPF 30, Water Resistant uncartoned sunscreen bottle and tube. Appendix F includes sample labeling for

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[6] Bernhard G, Mayer B, Seckmeyer G, Moise A "Measurement of spectral solar irradiance in tropical Australia" J Geophys Res, (1997) 102:8719–8730

[7] COLIPA (European Cosmetic Toiletry and Perfumery Association). *SPF Test Method* (1994) Brussels: COLIPA

[8] DIN 67501: Evaluation of sunscreen products (1985) Berlin: Beuth

a 0.5 oz, non-Broad Spectrum, SPF 20, non-Water Resistant uncartoned sunscreen tube. Appendix G includes sample labeling for a 0.15 oz non-Broad Spectrum, SPF 20, non-Water Resistant uncartoned lip balm sunscreen, and a 0.15 oz non-Broad Spectrum, SPF 20, non-Water Resistant blister cartoned lip balm sunscreen.

1. Requested labeling Revisions for All Sunscreen Products

We recommend that for all sunscreen products FDA:

- remove the required direction to apply "15 minutes before sun exposure;"
- replace the required direction "reapply every 2 hours" with "reapply often or as needed;"
- remove the required direction "use a water resistant sunscreen if swimming or sweating;" and
- remove the required other information "protect this product from heat and direct sun."

We believe that these labeling statements are not supported by appropriate data and are not required for the safe and effective use of sunscreen products.

a) Remove the required direction to apply "15 minutes before sun exposure."

Sunscreens are composed of active ingredient molecules that absorb, reflect and/or scatter UV rays. When applied to the skin surface, the active ingredients in the sunscreen begin to protect against UV rays penetrating through the sunscreen film by absorbing UV energy. The active ingredients work to prevent sunburn immediately when applied. They do not need to wait 15 minutes in order to function as a sunscreen. For example, when applying a lip balm with sunscreen, the product acts as a sunscreen when applied to the lips. Similarly, lotion, oil or other product type sunscreens also protect against UV when applied. There is no need to wait to obtain the sun protection benefits of such products.

Products that are water resistant also begin to function as a sunscreen immediately when applied on the skin. Because of the polymer content of most of today's water resistant sunscreens, many of these products are also water resistant right after application. However, it is the manufacturer's responsibility to determine if there is a necessity to wait before the product

can be immersed in water. There is no reason at all that all sunscreens (water resistant or not) require a waiting period before they are active sunscreens; the function of blocking UV rays is independent of the need to wait before water immersion.

Merely because the SPF testing protocol specifies that there be a waiting period after application (meant to standardize the testing conditions for all products) does not mean that there needs to be a waiting period before the sunscreen becomes "active" in consumer use. It is a fact that many consumers apply their product at the beach or pool, and they expect that the product will work when applied. To require a 15-minute waiting period when there is no scientific rationale for such a wait period is not only confusing, but it is also unsupportable from a technical perspective.

b) Remove the required direction "reapply every 2 hours" and replace with "reapply often or as needed"

The 2011 Final Rule requires that sunscreen product labeling direct consumers to "reapply every 2 hours" for both water resistant and non-water resistant products. Although FDA considered revising the 2-hour reapplication timeframe, it concluded that the timeframe remained appropriate. FDA based this conclusion on the fact that "all of the public education materials from the American Academy of Dermatology (AAD) instruct consumers to reapply sunscreen at least every 2 hours" and other public health organizations "recommend reapplication at least every 2 hours." 76 Fed. Reg. at 35638. FDA also supported this timeframe with two studies: one found that subjects who reapplied sunscreen every 1 to 2 hours were not sunburned, the second found that people who reapplied sunscreen every two hours were five times less likely to sunburn compared to those who reapplied sunscreen only after 2.5 hours or longer. *Id.*

We believe that a 2-hour reapplication direction is not supported by adequate science. AAD recognized, in its comments to the 2007 proposed rule, that it is difficult to universally recommend a specific reapplication time interval for all sunscreens because little scientific data exists on the topic of reapplication. AAD supports a direction that sunscreens be reapplied "often" and after rubbing, swimming or perspiring. Comments of AAD, Docket No. 1978N-0038, at 3 (Nov. 2, 2007).

The 2-hour reapplication direction is particularly inappropriate for daily use sunscreen products (e.g., foundations, concealers, facial and eye-area moisturizers and lotions, sunless tanners, and lip products, such as lipsticks and lip glosses). The direction to "reapply at least every 2 hours" is inconsistent with consumers' reapplication needs when using these types of daily use products. Manufacturers will therefore be discouraged from marketing these products with sunscreen, especially for long-wearing daily use cosmetic products. Thus, the 2-hour reapplication direction threatens the continued marketing and use of these products.

FDA has recognized that many consumers use facial cosmetics with sunscreen "as their primary and only source of sunscreen protection for that area of the body." 72 Fed. Reg. at 49091; *see also* 72 Fed. Reg. at 49092 ("[M]akeup with sunscreen products may be the primary sunscreen for many consumers."). FDA also recognizes that these products are important in addressing consumers' need for sunscreen for frequent incidental sun exposure as contrasted with intentional exposure such as sunbathing.[9] 72 Fed. Reg. at 49092. If daily use sunscreen products are not on the market, consumers are unlikely to replace their use of these products, particularly lip products, for daily sun protection with "beach" products. The primary driver of women's selection of daily use products is their cosmetic benefit, specifically the color shade. Women will continue to buy daily use products based on their color shade preference, even if these products no longer contain sunscreen. Furthermore, women are unlikely to use "beach" products on a daily basis with reapplications every two hours as directed in place of daily use products. Rather, consumers would forgo daily sunscreen use altogether and use only cosmetics with no sunscreen if unable to purchase daily-use products.

In addition, the data FDA cited in support of the 2-hour reapplication direction does not support a requirement for 2-hour reapplication for daily use products. FDA did not fully evaluate, when implementing the 2-hour timeframe, the differences in the way consumers use daily use sunscreen products versus "beach" sunscreen products. The references supporting this time frame addressed intentional, direct and prolonged exposure to the sun, for protection from

[9] These separate uses were originally recognized in the preamble to the 1993 tentative final monograph, in which FDA noted distinct categories of sunscreen products: traditional "beach" products use for protection from intentional sun exposure and makeup preparations used for protection from incidental daily exposure. 58 Fed. Reg. at 28195.

which consumers would typically choose a "beach" product. However, consumers typically use daily use sunscreens to protect against incidental daily sun exposure. Therefore, the 2-hour reapplication direction as applied to facial cosmetics is not supported by adequate science.

c) Remove the required direction "Use a water resistant sunscreen if swimming or sweating."

The 2011 Final Rule requires that sunscreen products that are not water resistant be labeled with the following directions for use: "use a water resistant sunscreen if swimming or sweating." We request that the regulation be revised to permit this statement to be omitted from sunscreen products.

This statement is not a direction for use of the labeled product, but rather provides educational information about a different category of sunscreen products.

Although many non-water resistant sunscreens many not be available in a water-resistant version, consumers will obtain information about the availability of other types of water resistant sunscreens from many different sources, including FDA and label statements on water resistant sunscreen products. However, a label statement referring to water resistant products could be confusing to consumers if they would not find water-resistant variants of the product in stores. Thus, omitting this statement from sunscreen labeling would minimize consumer confusion, while providing labeling flexibility that would have no detrimental effect on consumers; nor would it deprive consumers of information about water resistant sunscreens.

d) Remove the required "Other Information Protect this product from heat and direct sun"

In the 2011 Final Rule FDA stated that it received comments requesting a new statement about sunscreen storage conditions under 'Other information' in the Drug Facts label. FDA stated:

> The submissions argued that sunscreen products in containers are often exposed to heat when used at the beach, swimming pools, etc. The concern expressed in the submissions was that heat could cause sunscreen formulations inside containers to change, resulting in less sun protection.

> We agree with the submissions. Sunscreen products within containers should not be exposed to direct sun and can be protected by wrapping them in towels and/or keeping them in shaded environments (e.g., under an umbrella and/or in a purse or bag). Consumers could also store sunscreen product containers in coolers while outside during hot periods.
>
> In this final rule we are requiring the following statement in the 'Other information' section of the Drug Facts label: '[Bullet] protect the product in this container from excessive heat and direct sun' (new 21 CFR 201.327(f)).

76 Fed. Reg. at 35642. In the above commentary, no data were provided to support the need for this new storage/information statement; the concerns expressed in the comment to the Agency were not explained in detail.

Because sunscreen products are meant for use on skin outdoors during the summer, it is very possible that the instruction to "protect from heat and sun" will be confusing to consumers, who will think that the products cannot be used outside or taken to the beach or pool. They may erroneously think that they should discard a product if they have taken it to the beach for a day, based on this new "information" statement.

Because sunscreens are OTC drug products, stability studies are routinely conducted to ensure that the products will maintain their physical and chemical specifications throughout their shelf life. Pre-market accelerated stability data (3 or 6 months at 40°C) and stress data (1 month at 50°C) demonstrate that the product can be exposed to excessive heat (USP defines excessive heat as >40C) and will still meet its required specifications. In addition, sunscreens marketed in opaque packaging are designed to provide protection of the product inside from sunlight. UV testing of packaging components is a routine part of package testing and qualification.

Without data or specific examples to support the concerns, it is hard to understand why the results of stability programs routinely conducted for topical OTC drug products would not obviate the need for such a general storage statement. In cases where a stability program identifies special storage needs, that information is clearly placed on the label. A general statement that is not based on data for the specific product is not helpful to the consumer, and may only cause confusion about proper use and storage. In the case of products packaged in

cans, for example, there is no exposure of the product content to direct sunlight, and thus the instruction to protect from direct sun is unnecessary.

We ask that this general statement not be required as a mandatory part of the Drug Facts label, and that only storage statements supported by stability data for the specific product be included, where appropriate. A comprehensive stability program that includes high temperature and stress data should be adequate for confirming the heat stability of a sunscreen product.

e) The issue of the "Sweat Resistant" claim

We ask that in the Draft Guidance FDA address the "sweat resistant" claim for water resistant sunscreen products. This "sweat resistant" claim is adequately substantiated by the water resistant test method, and is truthful and not misleading. We believe it would be helpful for industry to more clearly understand that in order to make a sweat resistant label claim, a sunscreen should at least satisfy the water resistance testing requirements as outlined in the 2011 Final Rule.

Many active consumers who have purchased sunscreen products for their sweat resistant properties may not choose a "water resistant" sunscreen, because they are not going into the water, and do not believe that they need a product meant for swimming. In other words, consumers in very warm weather or engaged in strenuous outdoor activity should understand that certain sunscreen products can provide a measure of sweat resistant protection, and should be encouraged to use these sunscreen products in lieu of non-sweat/water resistant products. There is a clear public health benefit in communicating the sweat resistant properties of sunscreens.

In the 2007 proposed rule, FDA expressly acknowledged and outlined requirements for sweat resistant claim. 72 Fed. Reg. 165 at 49113. In the 1999 Final Monograph Ruling the Agency had outlined labeling claims for Sweat Resistant products based on Water Resistance SPF testing results:

> § 352.50 Principal display panel of all sunscreen drug products.
> (b) *For products that satisfy the water resistant sunscreen product testing procedures in § 352.76.*
> (1) (Select one of the following: ''Water,'' ''Water/Sweat,'' or ''Water/Perspiration'') ''Resistant.''

(2) ''SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the water resistant sunscreen product testing procedures in § 352.76).''
(c) *For products that satisfy the very water resistant sunscreen product testing procedures in § 352.76.* (1) ''Very'' (select one of the following: ''Water,'' ''Water/Sweat,'' or ''Water/ Perspiration'') ''Resistant.''
(2) ''SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the very water resistant sunscreen product testing procedures in § 352.76).''

64 Fed. Reg. 27688 (May 21, 1999).

In the 1993 Tentative Final Monograph (TFM), FDA discussed that sweat resistance claims can be substantiated by the water resistance test method (as outlined in the 1993 TFM). We agree with the Agency's discussion:

> the Agency believes it is appropriate for a product that passes the water resistance and very water resistance tests to also be permitted to make claims that satisfy the sweat resistance test. The Agency agrees that a product that passes the "water resistant" test should be permitted to use the claim "sweat resistant." The Agency has reviewed the available information and concludes that for sunscreen drug products that have passed the tests in § 352.76 of this tentative final monograph for water resistant and very water resistant claims , an additional test to support a sweat resistance claim is unnecessary and possibly hazardous."

58 Fed. Reg. 28275 (May 12, 1993).

Sweat is a fluid that is composed of >99% water. In 1993, FDA disagreed with a comment that had suggested that the difference in the chemistry of water and of sweat required two different test standards (58 Fed Reg 90 at 28275 comment 100 (May 12 1993). FDA noted that the while the composition of sweat and of water may differ, the components of each may also vary. In addition, the Agency agreed that the while the physical mechanisms by which a sunscreen product resists removal by water or sweat may be different, the "wash-off" from sweat (which emerges from the pores of the skin and then rolls down the surface of the skin) can be expected to be less than the effects of 40 or 80 minutes of constant water washing over the surface of the sunscreen product. Based on that information, FDA concluded that sunscreen

products which had passed water resistance testing did not require additional testing to be labeled as sweat resistant.

After almost two decades of acknowledging the "sweat resistant claim," in the 2011 Final Rule, FDA did not discuss the claim, nor did the Agency provide any rationale for not including its mention. However, in the 2011 Final Rule, the Agency does require the term "sweating" in the directions on the back label, stating that products that satisfy the water resistance test should state: "reapply... after 40 minutes of or 80 minutes of swimming or *sweating*..." (emphasis added). Thus the Agency recognizes that these products do resist removal by sweat as well as by water immersion.

We believe that given the importance of communicating the sweat resistant properties of a sunscreen, it would be helpful if FDA addressed the issue in the Draft Guidance. Specifically, the Agency should clarify that in order to make a sweat resistant label claim; a sunscreen should at least satisfy the water resistance testing requirements as outlined in the 2011 Final Rule.

2. Reduced Labeling for Small Size Packaging Is Appropriate and Promotes the Public Health

In the 1999 final sunscreen monograph and the 2007 proposed rule, FDA recognized that reduced labeling for certain sunscreen products in small size packages, beyond that permitted under § 201.66, would provide consumers with adequate information to use these products safety and effectively. 72 Fed. Reg. at 49077. Specifically, FDA recognized that these products meet the criteria for reduced information for safe and effective use under the OTC Drug Labeling Rule. *Id.* at 49076.

In the final monograph, FDA permitted reduced labeling for certain small size packages because "excessive labeling requirements may discourage manufacturers from marketing certain products, such as lipsticks or lip balms containing sunscreens, which provide significant public health benefit." 64 Fed. Reg. at 27681-82. In 2007, FDA reaffirmed this rationale, noting that requiring full Drug Facts labeling on these products "would discourage manufacturers from marketing some of these products" since many of these products "are sold in extremely small packages that cannot accommodate the required labeling, even with the format exemptions

allowed under § 201.66(d)(10)." *Id.* at 40977. Furthermore, FDA recognized that "removal of these products from the OTC market would have a negative impact on public health" and "the benefit of UV radiation protection provided by these products outweighs the need for manufacturers to include all sunscreen labeling information."[10] *Id.*

In the 2011 Final Rule FDA removed the labeling reductions permitted by the proposed rule and did not permit any label modifications for small packages other than those permitted by 21 C.F.R. § 201.66(d)(10). FDA based this decision on its belief that "in the last several years manufacturers have introduced new label designs that permit full Drug Facts labeling on very small packages" (for example, "some stick products ... marketed in 0.15 oz. amounts"), and therefore requiring full Drug Facts labeling "should not discourage manufacturers from including sunscreen ingredients because of limited labeling space." 76 Fed. Reg. at 35643.

However, this determination ignores the fact that sunscreen products in small size packages meet the criteria for reduced information for safe and effective use under the OTC Drug Labeling rule. FDA evinced its commitment to consider appropriate exemptions for products that require minimal information for their safe and effective use in the preamble to the OTC Drug Labeling Rule. 64 Fed. Reg. at 13270. Thus, the issue is not ultimately whether manufacturers can invent packaging such that it is physically possible to include the full Drug Facts content and formatting, but whether such a requirement is necessary for the safe and effective use of these products and is in the interest of public health. We believe, as FDA previously recognized, that sunscreen products in small size packages meet the criteria for minimal information, and that FDA should permit reduced labeling for sunscreen products with small packaging.

FDA has identified products with the following characteristics as typical of those requiring minimal information for their safe and effective use: products (1) packaged in small amounts, (2) having a high therapeutic index, (3) carrying extremely low risk in actual consumer use situations, (4) providing a favorable public health benefit, (5) requiring no specified dosage

[10] FDA also recognized, in the 1999 final sunscreen monograph, that "excessive labeling requirements may discourage manufacturers from marketing certain products, such as lipsticks or lipbalms containing sunscreens, which provide significant public health benefit." 64 Fed. Reg. at 27681.

limitation, and (6) requiring few specific warnings and no general warnings. 64 Fed. Reg. at 13270.

We believe that small size sunscreen products have all of these characteristics, justifying the requested labeling modifications. By definition, these products are packaged in small amounts. Sunscreens have a high therapeutic index in that their effective dose is substantially lower than the dose that would pose even a minimal risk of toxicity. Sunscreens carry extremely low risk in actual consumer use situations: sunscreens have a low toxicity profile and consumers have a clear understanding of when and how to use these products safety. Sunscreens provide a favorable public health benefit, as FDA has repeatedly and clearly recognized. Sunscreens require no specified dosage limitation: sunscreens may be used in unrestricted amounts on a daily basis without fear of overdose. Sunscreens require few specific warnings and only one general warning. The required specific warnings are limited to warnings that the product be kept out of eyes and that use of the product should be stopped if a rash develops. The general warning to keep out of the reach of children would remain under this proposal.

To the extent the 2011 Final Rule incorporates content and format labeling requirements beyond those that are reasonable and necessary for the safe and effective use of sunscreen products, labeling flexibility will be sacrificed without any corresponding benefit to the public health. By imposing rigid labeling requirements on products in small size packages, such as those that are designed for daily use and that offer a substantial cosmetic as well as drug benefit, FDA runs the risk of discouraging manufacturers from including sunscreen ingredients in such products. As a result, consumers will be denied access to products they have come to rely on for daily sun protection. There is no question that decreasing the array of products available for providing sun protection is contrary to the public health and does nothing to further the ability of consumers to use sunscreen products safely and effectively.

In particular, lip products, make-up products and lotions and moisturizers intended for use on the face are labeled and promoted primarily for their cosmetic purposes and are primarily sold in smaller packages. These products are labeled, promoted and used by consumers primarily for the cosmetic benefits they impart. Recognizing the importance of prevention and the daily use of sunscreen, consumers have come to rely heavily on these daily-use products that

contain sunscreen to combat the effects of chronic sun exposure. The inclusion of sunscreens in these products provides an easy method for incorporating sun protection into a consumer's daily skin routine. Consumers are well versed in the application of such products, which, as discussed above, require minimal information to use appropriately. Imposing labeling requirements that are neither necessary nor particularly helpful to consumers, who are already knowledgeable regarding the safe and effective use of these products, simply creates a disincentive for manufacturers to include sunscreen ingredients in these products. Doing so eliminates an important weapon in the arsenal of consumers concerned about combating the effects of daily, incidental exposure to UV radiation. Such a result is contrary to FDA's sound public health policy of promoting protection against the adverse effects of daily sun exposure.

a) Specific Requested Labeling Revisions for Small Size OTC Sunscreen Products

In addition to the labeling revisions requested for all OTC sunscreen products we request additional labeling relief for small size packages.[11] Specifically, we recommend that for small size packages, FDA:

- not require the term "Drug Facts" or "Drug Facts continued;"
- not require hairlines;
- for non-combination products and for sunscreen-lip protectant combination products, not require a listing of ingredient Purpose;
- not require the phrase "For external use only;"
- not require the Sunscreen Protection Measures in the skin aging/skin cancer indication;
- not require the warning "If swallowed get medical help or contact a Poison Control Center right away;" and
- for sunscreen lip products, not require the warning "When using this product keep out of eyes. Rinse with water to remove."

[11] Small size packages are those in which the required Drug Facts information requires more than 60 percent of the total surface area available to bear labeling as defined in 21 C.F.R. § 201.66(d).

Our request for modification of the labeling requirements for sunscreen products in small size packages is premised on the firm belief that the proposed modified labeling provides the consumer with the information necessary to ensure the safe and effective use of sunscreens. The proposed labeling reductions are consistent with FDA's recognition, in Over-the-Counter Human Drugs; Labeling Requirements; Final Rule, 64 Fed. Reg. 13254, 13270 (March 17, 1999) and in the sunscreen monograph regulatory history, that sunscreen products in small size packages meet the criteria for products that require minimal information for their safe and effective use.

Moreover, the proposed reduced labeling is necessary to avoid overly burdensome labeling requirements that would deter manufacturers from marketing sunscreens in small size packages, such as lip products, makeup products and other daily use products. These products, as FDA has established, are an important part of consumers' protection from daily UV exposure, and removal of these products from the market would have a negative impact on public health.

The proposed changes do not diminish the power of the format devised by FDA and implemented in the OTC Drug Labeling Rule and will not comprise FDA's goal of ensuring that consumers understand the important drug information necessary to ensure the safe and effective use of such products. The vast majority of the standard format requirements are preserved, and these modifications do not remove the important new warnings. Rather, our proposal includes all information essential for safe and effective use of sunscreens and will encourage the manufacture and use of sunscreen in the broadest array of products possible, ensuring the availability and consumer use of sunscreen.

Many of these proposals were permitted under the 1999 final sunscreen monograph and the 2007 proposed amendments to the monograph. There, FDA recognized that sunscreens in small packages met the criteria for minimal information for their safe and effective use, justifying reduced labeling to avoid overly burdensome requirements that would reduce the availability of such products. Moreover, even with this modified labeling, consumers have safely and effectively used sunscreen products. Although the final sunscreen labeling rule no longer permits reduced labeling, the Agency did not find that full Drug Facts labeling was necessary for safe and effective use (or that any of the labeling modifications it previously permitted were inappropriate). Rather the agency eliminated the modified labeling because it

believed that current technology permitted manufacturers to fit the warning onto the labeling. For all the reasons discussed above, FDA should permit the following labeling modifications for sunscreens in small packages.

(1) Do not require use of the term "Drug Facts" or "Drug Facts (continued)."

FDA should eliminate the requirement that the title "Drug Facts" or "Drug Facts (continued)" appear at the top of the information panel for small size packages but rather require a distinct shaded area to denote the drug facts panel area. The "Drug Facts" title is unnecessary and reduces the space available for important label information, both required and discretionary.

The Drug Facts title is unnecessary for sunscreens given the nature of sunscreens generally (e.g. high therapeutic index and extremely low risk) combined with the fact that the resulting label with sill preserve the essential elements of the drug facts format. Based on a long history of the safe use of sunscreens, we believe consumers already fully understand how to use such products safely and effectively and that including a title for the required information is unnecessary. Furthermore, FDA determined in the 1999 final sunscreen monograph, that the "Drug Facts" title was not necessary for the safe and effective use of sunscreen products and permitted certain sunscreen products in small packaging to omit the title. 64 Fed. Reg. at 27689. FDA retained this modification in its 2007 proposed rule. 72 Fed. Reg. at 49114.

The title is particularly inappropriate for those products which provide important cosmetic benefits because it unnecessarily narrows the product label. Such products have legitimate, beneficial cosmetic purposes which are equally recognized under the Federal Food, Drug and Cosmetic Act, in addition to their drug purposes. "Drug Facts" inappropriately denotes a single purpose to a product that provides a dual benefit. Removing Drug Facts is a reasonable accommodation to address the issue, particularly in light of the fact that it does not undermine the agency's labeling goals.

(2) Do not require hairlines within the drug facts section.

FDA should permit the use of a distinct shaded area to denote the drug facts panel area on small size packages rather than requiring hairlines. Under § 201.66(d)(10), the box enclosure

required under the OTC Drug Labeling Rule may be omitted if the drug facts panel information is set off from the rest of the label by color contrast. FDA should likewise not require hairlines within the drug facts section on small size sunscreen packages. Consumers will still be able to easily locate the OTC label format information on the product label, which will still contain the same information in the same order as other OTC drug products. FDA recognized that hairlines were not necessary for sunscreens in small packages and did not require hairlines in the labeling for such products in the final sunscreen monograph. 64 Fed. Reg. at 27689. FDA retained this reduced labeling in its 2007 proposed rule. 72 Fed. Reg. at 49114. Consumer's ability to locate important drug facts information has not changed, therefore hairlines can safely be replaced by shading on small size sunscreen packaging. Moreover, requiring hairlines would add significantly to the space required for the label and would reduce the availability of small size sunscreen products.

(3) Do not require a listing of ingredient Purpose for sunscreens that are not combined with any other OTC category of products or for sunscreen-lip protectant combinations products.

FDA should not require a listing of ingredient Purpose for sunscreens that are not combined with any other OTC category of products or for sunscreen-lip protectant combination products.

Requiring purpose information on sunscreens in small packages is unnecessary because it is duplicative of both the statement of identify requirement for the principal display panel of sunscreen products and of the "Use" statement immediately preceding the listing of active ingredient information. Furthermore, FDA recognized in the 1999 final sunscreen monograph, that Purpose information was not necessary for the safe and effective use of sunscreen products and permitted certain sunscreen products in small packaging to omit this information. 64 Fed. Reg. at 27678, 27689. FDA continued to recognize that such information was unnecessary in its proposed amendments to the monograph. 72 Fed. Reg. at 49114. The nature and consumers' use of these products has not changed, such that this information can safely be omitted from the labeling on small size sunscreen packaging.

We also propose that the Purpose information be omitted for sunscreen-lip protectant combination products. The final monograph regulating skin protectant drug products, including lip protectant products, permits manufacturers to omit the purpose information for lip protectant products in small packages. 21 C.F.R. § § 347.50(e). FDA permitted modified labeling for lip protectants because:

> Lip protectant/lip balm products are typically packaged in small amounts, applied to limited areas of the body, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings). For these reasons, the agency has concluded that minimal information is needed for the safe and effective use of such products.

Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph, 68 Fed. Reg. 33362, 33371 (June 4, 2003). FDA has therefore found that consumers can safely and effectively use lip protectant products absent a listing of ingredient Purpose. Because sunscreen products in small packages can also be safely and effectively used with minimal information, a listing of ingredient purpose should not be required for sunscreen-lip protectant combination products in small size packaging.

We recognize that when a sunscreen is marketed in other combination products (*e.g.* sunscreen-skin protectant combination products), the Purpose section importantly informs consumers which ingredients are sunscreens and which have other purposes. Therefore, we propose that the Purpose information be omitted only for sunscreens which are not combined with any other OTC drug category.

(4) Do not require the warning "For external use only."

FDA should not require on small size packages the warning "For external use only." Such a warning is unnecessary based on widespread consumer knowledge regarding the appropriate use of sunscreen products. We are not aware of any adverse event data suggesting that consumers inappropriately apply sunscreen products.

Furthermore, FDA determined in the 1999 final sunscreen monograph, that the warning was not necessary for the safe and effective use of sunscreen products and permitted certain sunscreen products in small packaging to omit this warning. 64 Fed. Reg. at 27678, 27689 (21 C.F.R. § 352.52(f)). FDA retained the reduced labeling omitting this warning in its 2007 proposed amendments. 72 Fed. Reg. at 49114. The nature of these products and consumer's understanding of how to safely use these products has not changed since FDA's proposals to omit this warning. Thus, this warning is not necessary for the safe and effective use of sunscreen products.

(5) Do not require the Sun Protection Measures as well as the parenthetical "(see Directions)" in the early skin aging/skin cancer prevention indication.

21 CFR 201.327(e)(2) requires that sunscreen products with a Broad Spectrum SPF value of 15 or higher be labeled with the following directions for use:

> "Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: [Bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses."

We request that the regulation be revised to permit this statement to be omitted from sunscreen products in small packages.

Although the statement provides information to consumers, it is not a direction for use of the labeled product but rather is educational information about the consequences of sun exposure and how to use other forms of sun protection with sunscreens. Indeed, this same educational information is provided to consumers by FDA and other public health agencies, by health care professionals, and health care associations such as the AAD, Skin Cancer Foundation, American Society for Dermatologic Surgery, etc., online on health, beauty, and parenting related websites and blogs, and on the labeling of larger-sized sunscreens. Thus, there are many other avenues to provide the consumer with such information and the omission of such information on small packages as proposed is unlikely to have any negative effect on the public health. Rather, failure to grant this exemption is more likely to have a negative effect on the public health by resulting

in products in small packages being discontinued or formulated solely as cosmetics rather than as cosmetic-sunscreen combinations – thus reducing the number and variety of sunscreens available to consumers.

If FDA determines not to permit omission of the "Sun Protection Measures" statement, we request in the alternative that the statement be permitted to be shortened on small packages to state, "[Bullet] limit time in the sun [Bullet] wear protective clothing." This shortened statement will convey the key points of the "Sun Protection Measures" statement while saving label space, reinforcing the same educational message that consumers receive from other sources.

(6) Do not require the warning "If swallowed get medical help or contact a Poison Control Center right away."

FDA should not require the warning "If swallowed get medical help or contact a Poison Control Center right away" on small size sunscreen products. Such a warning is unnecessary for the safe and effective use of such products. In the 1999 final sunscreen monograph, FDA permitted certain small size sunscreen products to omit this warning, based on its determination that these products met the criteria for minimal information for safe and effective use. 64 Fed. Reg. at 27689. Likewise, in the 2007 proposed rule, FDA recognized that this warning is not necessary for the safe use of sunscreen products in small size packages. 72 Fed. Reg. at 49114. Consumers continue to be understand the safe use of sunscreen products without this warning. Thus, this warning is unnecessary for the safe and effective use of sunscreen packages.

(7) Do not require on small size sunscreen lip products "When using this product keep out of eyes. Rinse with water to remove."

FDA should not require on sunscreen lip products in small size packages the warning "When using this product keep out of eyes. Rinse with water to remove." Such a warning is unnecessary based on widespread consumer knowledge regarding the appropriate use of lip products. Moreover, FDA recognized that such a warning was not necessary for the safe and effective use of sunscreen products in the final monograph. 64 Fed. Reg. at 27689 (21 C.F.R. § 352.52(f)). FDA omitted this warning because the agency "has received neither data concerning adverse reactions due to the use of sunscreen-containing lip balms near the eyes, nor information

that such products are normally used in the eye area." Id. at 27677. FDA retained this reduced labeling in its 2007 proposed amendments to the monograph. 72 Fed. Reg. at 49114. Thus, FDA has long recognized that this warning is not necessary for lip products.

b) Environmental Impact

Consumers and industry alike are becoming more and more aware and concerned about the environmental impact of our choices and businesses. FDA's current labeling requirements and lack of labeling relief for small size packages create a substantial tonnage of excess paper and packaging – creating an unnecessary, ongoing negative impact to the environment.

For these reasons we ask the Agency to reconsider the 2011 Final Rule labeling requirements as outlined above.

VI. FDA Should Exercise Enforcement Discretion and Allow for Continued Marketing of Powder Sunscreens

A. Action Requested

We request that FDA exercise enforcement discretion and allow for continued marketing of powder sunscreens.

B. Statement of Grounds

Prior to the Draft Guidance, FDA has never stated which sunscreen dosage forms are included or excluded from the sunscreen monograph. FDA has explicitly included all cosmetic sunscreen products, which it acknowledged encompassed makeup powders, throughout the rulemaking history. FDA's stated basis for excluding powders from the sunscreen monograph – they were not marketed prior to May 1972 – is not a legal basis for exclusion from the monograph. Furthermore, powder sunscreens, in particular cosmetic powder sunscreens, are a vital source of daily sunscreen protection, which cannot be replaced with other sunscreen products. Therefore we request that FDA exercise enforcement discretion to allow the continued marketing of powder sunscreens.

1. FDA is Not Limited to Products on the Market Before 1972

In the Draft Guidance FDA stated that powders were not eligible for review under the sunscreen monograph because the agency lacked evidence that such products existed in the OTC marketplace on or before May 1972. However, there is no legal requirement that FDA be bound by products on the market before May 1972 when considering products for inclusion in an OTC monograph. Therefore, the fact that sunscreen powders were not marketed prior to May 1972 is not a basis for their exclusion in the monograph.

While manufacturers were prohibited from bringing a drug on the market after the OTC Drug Review began in 1972 absent a pre-1972 predicate *or* a proposed monograph, tentative final monograph or final monograph specifying the product as generally recognized as safe and effective, the conditions FDA included in monographs was not so limited. Advisory panels were not bound by precedent and can recommend any condition they consider safe and effective in a proposed monograph. There is no pre-1972 marketed predicate required for an advisory panel to recommend a condition for inclusion in a monograph. In fact, the advisory panels recommended that many prescription products be included in OTC monographs. Although FDA adopted the "rush to market" regulation in 1975, 21 C.F.R. § 330.13, which prohibits the marketing of a pre-1972 prescription drug as OTC until a proposed monograph, this, again, does not prohibit the inclusion of products without a pre-1972 predicate in the monograph.

Similarly, FDA is not bound by pre-1972 marketed products and can include any condition for which there is adequate data of its safe and effective use in a tentative final monograph or a final monograph. Thus, FDA and the advisory panels retain discretion to include products marketed after 1972:

> 21 C.F.R. 330.10(a)(5) authorized a panel to recommend in a monograph any conditions of any kind relating to an OTC drug. The recommended labeling indications and other conditions need not have been marketed prior to 1972. No FDA policy has ever adopted a May 1972 cut-off for monograph approval of OTC drug conditions. Indeed, panels routinely considered and recommended approval of conditions not marketed prior to 1972. The agency's flexibility with respect to new conditions of use is limited only by the material extent or material time provision of the new drug

> definition, which FDA has liberally construed. Many final monographs recognize conditions that did not exist in 1972.

Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, *Food and Drug Law; Cases and Materials* (3d ed. 2007).

Companies are then permitted to market any Category I (generally recognized as safe and effective) products in a proposed monograph or tentative final monograph, even if there is no pre-1972 predicate, so long as FDA does not explicitly object in the preamble. Companies may not market a Category III (insufficient evidence to determine that they are safe and effective) product listed in a proposed or tentative final monograph *unless* there is a pre-1972 predicate with the same active ingredient, dosage, dosage form and direction use.

For example, FDA issued a call for data for ingredients contained in products bearing antiplaque and antiplaque-related claims, despite the fact that such products were not deemed eligible for inclusion in the monograph by the advisory panel. The original advisory panel did not review antiplaque dental products "because there were no submissions from drug companies for dental products making antiplaque claims in their labeling at that time." Over-the-Counter Dental and Oral Health Care Drug Products for Antiplaque Use; Safety and Efficacy Review, 55 Fed. Reg. 38560, 38561 (Sept. 19, 1990). In fact, the panel concluded that drug products which had antiplaque claims were not appropriate for the OTC market because "there [was] no general recognition of any such drug products as safe and effective for these indications at [that] time." *Id.* However, in 1990, FDA recognized that "recently, products with antiplaque claims have been heavily promoted, and the agency is aware that a great deal of research has been conducted in this area in recent years." *Id.*; *see also* Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Oral Antiseptic Drug Products, 59 Fed. Reg. 6084, 6086 (Feb. 9, 1994) (noting that "because of the passage of time, some antiplaque ingredients have entered the marketplace since 1975 and have been marketed for a number of years"). FDA issued a call for data "because neither the Dental Panel nor the Oral Cavity Panel reviewed in detail the safety and effectiveness data on particular ingredients for antiplaque or gingivitis indications." Thus the agency recognized that products that have come on the market after the initial advisory panel review could be eligible for inclusion in the monograph.

In addition, the Dental Plaque Subcommittee reviewed and recommended several oral health care combination products: (1) an antiplaque active ingredient combined with an anticaries active ingredient, (1) an antiplaque active ingredient combined with a tooth desensitizer active ingredient, and (3) an antiplaque active ingredient combined with an anticaries active ingredient and a tooth desensitizer active ingredient. Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Proposed Rules, 68 Fed. Reg. 32232 (May 29, 2003). The subcommittee reviewed these combinations, even though FDA was not aware of any marketing history of such combination products. FDA, however, dissented from this part of the subcommittee's recommendation, because it believed "data are needed to establish the safety and effectiveness of these combination products" and it sought supporting data and information demonstrating that these combination products can be generally recognized as safe and effective. Thus, although FDA did not believe at that time the data was sufficient to show that the combinations were safe and effective, it recognized that were there sufficient data, the combinations could be included in the monograph despite not being marketed prior to 1972.

Similarly, FDA recognized through the cough-cold monograph rulemaking several combination products that were not on the market before 1972. The panel recommended fifteen combinations, Establishment of a Monograph for OTC Cold, Cough, Allergy, Bronchodilator and Antihistamine Products, 41 Fed. Reg. 38312, 38419 (Sept. 9, 1976), while the current monograph permits twenty-eight. 21 C.F.R. § 341.40. These combinations were added at various times in FDA's ongoing review of cough-cold products, highlighting FDA's flexibility to consider conditions not marketed before 1972.

Therefore, there is no legal requirement that FDA be bound by products on the market before May 1972 when considering products for inclusion in an OTC monograph. In fact, both advisory panels and FDA have proposed products not on the market before 1972 for inclusion in OTC monographs. The fact that sunscreen powders were not marketed prior to May 1972 is not a basis for their exclusion in the monograph.

2. *Cosmetic Powder Sunscreen Products Have Been Included in the Regulatory History of Sunscreen Products*

The Draft Guidance marked the first time, in over 30 years of regulating sunscreen products, FDA stated explicitly which dosage forms of sunscreen products the agency considered eligible for inclusion in the sunscreen monograph. Since 1993, FDA has clearly and explicitly regulated *all* cosmetic sunscreen products, including makeup products, as drugs under the sunscreen monograph. FDA's regulations elsewhere define "make-up preparations (non-eye)" to include "face powders." 21 C.F.R. § 720.4(c)(7) (regarding voluntary cosmetic listing). This definition predates the 1978 panel recommendation and subsequent sunscreen rulemaking. 39 Fed. Reg. 10060 (Mar. 15, 1974). FDA itself referred to this definition of make-up preparations in the preamble to its 2007 proposed rule as defining all makeup products to which the sunscreen monograph applied. 72 Fed. Reg. at 49077. Therefore, it should be clear that sunscreen makeup powders are within the scope of the monograph and final labeling regulation.

FDA first addressed sunscreen products in August 1978, when it issued an advanced notice of proposed rulemaking that included recommendations from an advisory review panel on the safe and effective use of sunscreen products. Sunscreen Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Notice of Proposed Rulemaking, 43 Fed. Reg. 38206 (Aug. 25, 1978). The panel report did not address cosmetics containing sunscreen with SPF claims. The panel discussed the application of test materials formulated as oils, lotions, creams, heavy gels, butters, pastes, and ointments, but did not recommend classifying any specific dosage forms as safe and effective. 43 Fed. Reg. at 38266.

In May 1993, FDA published a tentative final monograph for sunscreen products. 58 Fed. Reg. 28194. The tentative final monograph did not discuss which dosage forms were considered to be safe and effective generally, nor did it discuss powders specifically. However, the proposed rule permitted additional directions "applicable to a particular product (e.g. cream, gel, lotion, oil, spray, etc.)." *Id.* at 28297. In specifying the application of test materials when testing a product's SPF value, the tentative final monograph referred to oils, lotions, creams, heavy gels, butters, pastes, and ointments. *Id.* at 28300.

In the preamble to the tentative final monograph, FDA recognized that cosmetic products containing the term sunscreen, or a similar term, "SPF," and SPF value or other terms referring to the therapeutic attributes of sunscreen ingredients were considered drugs regulated by the monograph. 58 Fed. Reg. at 28205. FDA implemented this policy by proposing to amend 21 C.F.R. part 700, "Requirements for Specific Cosmetic Products," to add a new regulation, 21 C.F.R. § 700.35, specifying that cosmetics containing a sunscreen active ingredient and using the term sunscreen or other sunscreen claims in its labeling are drugs subject to the monograph. 58 Fed. Reg. at 28301. The proposed regulation referred simply to "cosmetics" generally, and did not limit its application or exclude any type of cosmetic.

In May 1999, FDA published a final rule for sunscreen products establishing the sunscreen monograph, 21 C.F.R. part 352. 64 Fed. Reg. 27666. The final monograph did not discuss which dosage forms were included in the monograph. However, the final monograph retained additional directions "applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.)," *id.* at 27688, and referred to oils, lotions, creams, heavy gels, butters, pastes and ointments in specifying the application of test materials when testing a product's SPF value, *Id.* at 27691. The final monograph also retained 21 C.F.R. § 700.35 specifying that cosmetics containing sunscreen ingredients and including the term sunscreen or other sunscreen claims are subject to regulation as a drug, except those qualified by describing the cosmetic benefit provided by the sunscreen ingredient. *Id.* at 27693. FDA specifically noted that "the agency gave careful consideration to the wide variety of products marketed for sunscreen uses." *Id.* at 27673.

In August 2007, FDA issued a proposed rule amending the monograph. 72 Fed. Reg. 49070. FDA again permitted sunscreen labeling to include "more detailed directions applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.)." *Id.* at 49113. With regard to the application of test materials, FDA noted:

> FDA is also aware of sunscreen drug products marketed in dosage forms that may not be addressed by current SPF testing procedures. The SPF testing procedure described in § 352.72 (proposed § 352.70) references oils, lotions, creams, gels, butters, pastes, and ointments. FDA invites interested parties to submit

> SPF testing modifications for new dosage forms (e.g., mousses, foams, and towelettes) in accordance with § 352.77.

Id. at 49094. The test application rule itself was revised such that it no longer referred to any specific dosage form. *Id.* at 49120. The proposed amendments provided no further guidance as to which dosage forms FDA considered eligible for inclusion in the monograph. The proposed amendments did not revise 21 C.F.R. § 700.35, which specified that all cosmetic products containing a sunscreen ingredient and making a sunscreen or SPF labeling claim are regulated as drugs under the monograph.

Powders have been an internationally recognized sunscreen dosage form for many years. The 1999 JCIA (Japan Cosmetic Industry Association) Standard SPF Method describes two alternative methods for the applications of powders to the test site to ensure that the powder is retained on the skin.[12] Both the 2003 and 2006 (updated) International Sun Protection Factor (SPF) Test Methods recognize powders as a valid sunscreen dosage form and specifically outline the parameters for their proper application prior to UV exposures.[13]

In the 2011 Final Rule, for the first time since the tentative final monograph in 1993, FDA removed the referenced dosage forms from the directions, such that the rule states simply "more detailed directions applicable to a particular product formulation may also be included." 21 C.F.R. § 201.327(e). In addition, the testing procedures do not refer to any specific dosage forms. 21 C.F.R. § 201.327(i).

The Draft Guidance, and corresponding advance notice of proposed rulemaking requesting additional data for various sunscreen dosage forms, is the first instance in which FDA stated explicitly which dosage forms it deemed included under the sunscreen monograph. Wipes, towelettes, powders, body washes and shampoos were not considered eligible for review because FDA was not able to identify any sunscreen products in these forms that were marketed before the OTC Drug Review began. FDA further noted that the agency does not intend to withhold

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[12] Japan Cosmetic Industry Association, 1999. JCIA Standard SPF Test Method (Revised). Effective date: 1/1/2000.

[13] International Sun Protection (SPF) Test Method, CCTFA, CTFA, JCIA, COLIPA (2006), page 13.

enforcement with regard to those dosage forms not considered eligible for inclusion in the monograph.

3. *Powder Sunscreens are an Important Source of UV Radiation Protection*

FDA has recognized that many consumers use facial makeup products with sunscreen "as their primary and only source of sunscreen protection for that area of the body." 72 Fed. Reg. at 49091 FDA also recognizes that these products are important in addressing consumers' need for sunscreen for frequent incidental sun exposure as contrasted with intentional exposure such as sunbathing. *Id.* at 49092 These separate uses were originally recognized in the preamble to the 1993 tentative final monograph, in which FDA noted distinct categories of sunscreen products: "(1) beach products for occasional use to protect consumers from extreme sunlight conditions, (2) tanning products to aid consumers in acquiring a tan, and (3) non-beach products for daily use to protect consumers from chronic exposures to sunlight (e.g. make-up preparations and lipsticks)." 58 Fed. Reg. at 28195.

If sunscreen-containing powder products are not on the market, consumers are unlikely to replace their use of sunscreen-containing powders for daily sun protection for the face with "beach" products. As noted above, women are unlikely to use "beach" products on a daily basis as many view "beach" formulations as less desirable in that they have not been formulated like daily-cosmetics for frequent application to the face. Because consumers select sunscreen-containing powders primarily for their cosmetic (e.g., color shade), if sunscreen powders are removed from the market, consumers would likely forgo their daily sunscreen use altogether and use only products with no sunscreen if unable to purchase sunscreen-containing powders. The availability of powder products containing sunscreen are vital to ensuring that women get sunscreen protection for the face. Cosmetic powders are a particularly important source of sun protection for the face, as powders are most likely to be reapplied throughout the day.

FDA's recent labeling rule requiring the same labeling information for makeups and "beach products," and guidance that powders are not eligible for inclusion in the monograph, would require manufacturers to stop marketing makeup powders and other cosmetics with SPF claims. Doing so would deprive consumers of a vital source of daily protection against

incidental sun exposure. FDA should exercise its enforcement discretion to permit the continued marketing of sunscreen cosmetic powders, to ensure that women continue to have protection from daily sun exposure to the face.

CONCLUSION

We request that FDA exercise its enforcement discretion to provide:

I) additional time for the implementation of the 2011 Final Rule;
II) that FDA not require retesting of sunscreen products to determine SPF values;
III) modifications to the water resistance testing methods;
IV) modifications to the test methodology supporting "Broad Spectrum" claims;
V) modifications to the labeling of sunscreen products; and
VI) that FDA permit continued marketing of sunscreen powders.

We believe the recommended changes to FDA's enforcement of the 2011 Final Rule under the Draft Guidance outlined in these comments are necessary to ensure the continued availability of sunscreen products to promote the public health.

As time is of the essence, we respectfully restate our request that FDA respond to our request herein as soon as possible.

We look forward to an open dialogue with the Agency on these issues, which are of critical importance to our members.

Please feel free to contact me, if you have any questions or concerns.

Sincerely,

Elizabeth H. Anderson

Elizabeth H. Anderson
Executive Vice President – Legal and General Counsel

Enclosures

Cc: Michael Scott Furness, Director, Division of Nonprescription Regulation Development, Food and Drug Administration

Capt. Lydia Velazquez, Lead IDS, Senior Regulatory Review Officer, Division of Nonprescription Regulation Development, Food and Drug Administration

Reynold Tan, IDS Chemist, Division of Nonprescription Regulation Development, Food and Drug Administration

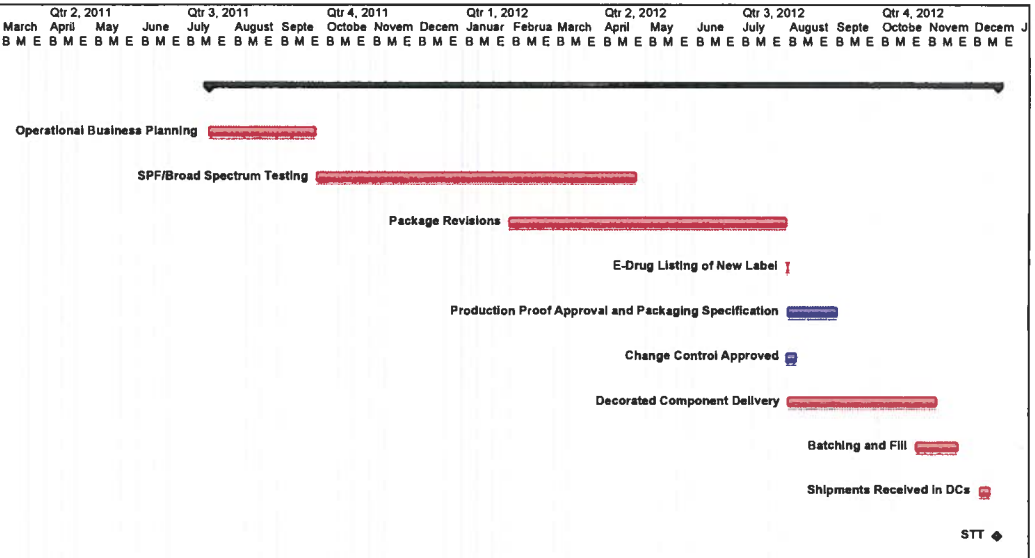
Debbie Lumpkins, Lead IDS, Acting Deputy Director, Division of Nonprescription Regulation Development, Food and Drug Administration

Farah K. Ahmed, VP – Associate General Counsel, Personal Care Products Council

Alison Manhoff, Deputy General Counsel, Consumer Healthcare Products Association

APPENDIX A: Sunscreen Product Operational Timeline

ID	Name	Duration	Start	Finish
1				
2	Package Changes - Sun Labeling Requirements	71.8 wks	Mon 7/18/11	Tue 12/18/12
3	Operational Business Planning	10 wks	Mon 7/18/11	Mon 9/26/11
4	SPF/Broad Spectrum Testing	28 wks	Tue 9/27/11	Tue 4/24/12
5	Package Revisions	26 wks	Wed 2/1/12	Wed 8/1/12
6	E-Drug Listing of New Label	1 day	Thu 8/2/12	Thu 8/2/12
7	Production Proof Approval and Packaging Specification	4.5 wks	Fri 8/3/12	Tue 9/4/12
8	Change Control Approved	1 wk	Thu 8/2/12	Wed 8/8/12
9	Decorated Component Delivery	14 wks	Fri 8/3/12	Thu 11/8/12
10	Batching and Fill	4 wks	Fri 10/26/12	Thu 11/22/12
11	Shipments Received in DCs	1 wk	Fri 12/7/12	Thu 12/13/12
12	STT	0 wks	Tue 12/18/12	Tue 12/18/12



APPENDIX B: Council/CHPA comments on SPF Labeling and Testing Requirements and Drug Facts Labeling for OTC Sunscreen Drug Products; Agency Information Collection Activities, August 16, 2011

Personal Care Products Council
Committed to Safety, Quality & Innovation

CHPA

August 16, 2011

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: SPF Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products; Agency Information Collection Activities; Proposed Collection; Docket No. FDA–2011–N–0449

To Whom It May Concern:

The Personal Care Products Council (the Council) (formerly the Cosmetic, Toiletry, and Fragrance Association) and the Consumer Healthcare Products Association provide these comments in response to the Food and Drug Administration's (FDA's) June 17, 2011 Notice regarding SPF Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products; Agency Information Collection Activities.[1]

Based in Washington, D.C., the Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

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[1] 76 Fed. Reg. 117 at 35678 (June 17, 2011): http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14771.pdf

The Consumer Healthcare Products Association (CHPA) is the 130-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines.

On June 17, 2011, 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 Final Rule).[2] The 2011 Final Rule also lifted the delay of implementation date of the Drugs Facts regulation (21 CFR 201.66) for all OTC sunscreens (effective date June 18, 2012).

1) FDA underestimated the burden of the Final Rule

As described below, FDA underestimated the burden to industry of the 2011 Final Rule. We note that the hours described below represent actual person hours, and not a calendar timeline.

a) Number of OTC sunscreen manufacturers:

FDA estimated that there are approximately 100 manufacturers of OTC sunscreen drug products. However, based on third-party market research data, we have determined that there are over 364 manufacturers. Appendix A contains information from third-party market research firms who provided information on the number of OTC sunscreen manufacturers and OTC sunscreen stock keeping units (SKUs) in the U.S. This number reflects products sold through mass and prestige channels of distribution, but does not capture products sold exclusively online, exclusively in dermatologist offices, or exclusively via direct sales.

b) Number of OTC sunscreen SKUs:

FDA estimated that there are currently as many as 3,591 OTC sunscreen SKUs in the market. However, based on third-party market data, we have determined that there are over 4,528 OTC sunscreen SKUs in the U.S. market. See Appendix A. This number reflects products

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[2] 76 Fed. Reg. 117 at 35620 (June 17, 2011).

sold through mass and prestige channels of distribution, but does not capture products sold exclusively online, exclusively in dermatologist offices, or exclusively via direct sales.

c) Number of OTC sunscreen formulations:

FDA estimated that there are currently approximately 2,350 OTC sunscreen formulations in the market. We are unable to verify this estimate using a third-party firm. Thus, for purposes of this comment, we will use the Agency's 65% ratio (65% of SKUs, or 1.53 SKUs per formulation) to reflect the number of OTC sunscreen formulations in the market. Using FDA's proportions, there are an estimated 2,943 sunscreen formulations currently in the market.

d) Number of new sunscreen products:

FDA estimated that as many as 60 new sunscreen SKUs may be introduced in to the market each year, representing 39 new formulations per year. Appendix B contains information from a third party market research firm that found 1,262 new sunscreen products (not SKUs) were introduced in 2010. A typical non-color sunscreen product can have approximately 1 – 10 SKUs, and a typical color sunscreen product (such as a lipstick or foundation) can have up to 30 SKUs. However, since we were unable to obtain third-party information on number of new SKUs prior to this comment submission, for purposes of this comment, we will assume a one-to-one ratio of product to SKU. Additionally, for purposes of this comment, we assume that the same number of new sunscreen SKUs is the same every year. However, based on historical market data, the number of new sunscreen SKUs introduced in to the market each year increases with each subsequent year.

Using FDA's 65% calculation, we found an estimated 820 new sunscreen formulations introduced each year.

e) Burden of SPF testing:

FDA estimated that it will take 24 hours (i.e., three 8-hour days) to complete SPF testing for each sunscreen formulation. The Agency did not account for the added burden of Broad Spectrum testing. The Agency stated that 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. In other words, FDA estimated that 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); 28,200 hours per year for two years when considering FDA's 1-year enforcement discretion.

We surveyed our sunscreen manufacturers and found that the time it will take to complete testing for each sunscreen formulation is 160 hours. In FDA's estimate, it does not appear that the Agency took into consideration a number of issues, including:

- Good Clinical Practices: prior to sending products to a testing laboratory for human clinical testing (SPF test), Good Clinical Practices, including quality assurance testing, revision control, as well as internal release of samples, documentation release, shipment authorization, etc.; and

- Testing Timeline: each subject will need to come to the testing facility for 3 days (baseline MED determination at day 1, sunscreen application and UV irradiation on day 2, and final erythema reading on day 3); and the entire testing for water resistance of a SPF 30 sample on 10 subjects will typically take 3-4 weeks (8 hours per day), including data analysis and excluding the final report.

- Broad Spectrum Test Method: the new Broad Spectrum test method requires approximately 1.5 hours for preparing the sample, running the test, and summarizing the results (which, for purposes of estimate comparison, we are not including in the calculation below).

When considering all factors, including those listed above (aside from Broad Spectrum testing), at least 170.5 hours are required for one formulation, which means 400,675 hours are required to test our estimated 2,943 sunscreen formulations currently in the market 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); 200,338 hours per year for two years when considering FDA's 1-year enforcement discretion.

f) Burden of label/packaging redesign for currently marketed sunscreen products:

FDA estimated approximately 12.5 hours for relabeling. The Agency estimated no more than 0.5 hours per SKU to prepare, complete, and review the labeling for each currently

marketed SKUs, plus 12 hours to implement the new Drug Facts labeling requirements. In total, FDA estimates 45,000 hours per year.[3]

The 2011 Final Rule requires considerable changes to the majority of OTC sunscreen labels; and for many, this also includes redesign of packaging. We surveyed our sunscreen manufacturers and found that it requires approximately 70.5 hours per SKU to prepare, complete, and review the labeling and implement the new Drug Facts labeling requirements for each currently marketed SKU. In total, we estimate 319,224 hours per year (4,528 SKUs x 70.5 hours). The following is a description of the implementation hours for labeling changes required by the 2011 Final Rule:

- Initial manuscript (8 hours): Creating the master document that reflects all of the required content based on each formulation.
- Packaging design and engineering (16 hours): Developing and testing the actual primary and secondary labeling components that will be used at the packaging site
- Development of component drawing (4 hours): Creating a CAD drawing of the components onto which the artwork will be designed.
- Initiation of change control (1 hour): A change control allows the manufacturing site to begin assessing the impact of the change
- Artwork design and development (12.5 hours): The graphic designer develops the full artwork (including logos, barcode placement, graphical elements, and both the PDP and Drug Facts) in accordance with individual Company Packaging Standards
- Proofreading and tracking (6 hours): A word-by-word review of each artwork component against the approved manuscript; initiation of a review of each component by the responsible departments
- Review by all required departments (7 hours): Each piece of art is reviewed by the Regulatory, Quality, Formulation, Medical, Marketing, Packaging, and Legal Departments
- Specification development and issuance (6 hours): Each printed component requires a purchasing specification to send to the supplier.
- Review of printers proofs (1 hour): A sample of the printing plate is reviewed by the

[3] (3,600 SKUs times 12 hours for Drug Facts labeling), plus (3,600 SKUs times 0.5 hours for SPF labeling) = 45,000 hours.

company prior to the production run.

- Bill of material update (6 hours): The Bill of Material documents specify which components are to be used in the manufacture of each SKU
- Batch tecord update (2 hours): The Batch Record ensures the proper documents from the BOM are delivered to the production areas at the manufacturing site.
- Close of Change Control (1 hour): This allows the plant to ship products that have been packaged with the new components.

g) Burden of label/packaging redesign for new sunscreen products:

FDA estimated that as many as 60 new sunscreen product SKUs may be introduced each year, representing 39 new formulations annually. The Agency estimated that the burden of testing and labeling the 39 new formulations marketed each year will require 1686 hours (936 hours per year for testing (39 formulations times 24 hours testing per formulation), plus 30 hours per year for labeling SPF (60 SKUs times 0.5 hours per SKU), plus 720 hours per year for Drug Fact labeling (60 SKUs times 12 hours per SKU).

As discussed above, according to our estimates, approximately 1,262 new sunscreen SKUs are introduced each year, representing 820 new formulations. This will require 228,781 hours (139,810 hours per year for testing (820 formulations times 170.5 hours per formulation), plus 88,917 hours per year for labeling SPF and Drug Facts (1,262 SKUs times 70.5 hours for SPF and Drug Facts labeling)

1) FDA should provide additional enforcement discretion on the 2011 Final Rule's SPF testing requirements to further public health and reduce burden to industry

We would like to take this opportunity to provide information on how FDA can lesson the burden of the 2011 Final Rule, while also furthering its public health mission. The 2011 Final Rule – 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). In a draft guidance, also published on June 17, 2011, FDA indicated that it does 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, 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). In other words, FDA has provided an additional year for SPF testing for certain OTC sunscreen products.

We appreciate this additional time and believe it supports public health while somewhat minimizing waste and burden to industry. However, we believe a greater public health benefit (see (a) below) and a much lower burden to industry can be achieved if the 2011 Final Rule's SPF testing requirements (or FDA enforcement discretion) allowed formulations already fully tested by the 1999 or 2007 SPF methods (as well as products currently on the market with valid SPF results to support their label claim) to continue to be marketed based on their existing SPF data. New formulations introduced after the compliance date would be required to have SPF results based on the new 2011 SPF test method.

The following further explains why we believe SPF formulations already fully tested by the 1999 or 2007 SPF methods can be marketed based on their existing data:

a) Requiring that products which already have full panels of valid results tested according to the 1999 or 2007 FDA SPF methods will expose hundreds of test subjects to unnecessary UV exposures without a scientific rationale and for no public health benefit. We ask the Agency to allow products and formulations that already have full and valid SPF results based on 1999 or 2007 SPF methods to continue to use that SPF data to support the label SPF claims, while new and untested formulations would be expected to comply with the new SPF methodology as of June 18, 2012.

b) Testing the same formulation by either the 1999 FDA Monograph Method (20-25 subjects) or by the International SPF Method (10 subjects) results in the same outcome. There is no reason based on panel size to require that existing product formulations fully tested by the 1999 or 2007 FDA SPF methods be re-tested by the 2011 FDA SPF method.

c) The use of either the SPF 4 or SPF 15 control (reference) lotion does not influence the outcome of the test panel. Products that were fully tested by the 1999 or 2007 FDA SPF methods along with the SPF 4 control lotion do not need to be retested by the 2011 method and the SPF 15 control lotion, as the choice of control formulation does not impact the outcome of the test product's results.

Appendix C contains our comments to FDA on the Agency's Guidance for Industry: *Enforcement Policy OTC Sunscreen Drug Products Marketed Without an Approved Application*[4] (submitted August 16, 2011) (Comments to the Draft Guidance) which includes discussions on a number of issues, including more detailed information on the above issue of SPF retesting (see Comments to the Draft Guidance, page 12).

In conclusion, we appreciate the opportunity to comment on FDA's collection of information activities for SPF labeling and testing requirements and Drug Facts labeling for OTC sunscreen products. We urge FDA to consider our input, especially with respect to furthering the public health impact of the 2011 Final Rule, while decreasing its burden.

Please feel free to contact me, if you have any questions or concerns.

Sincerely,

Elizabeth H. Anderson

Elizabeth H. Anderson
Executive Vice President – Legal and General Counsel

Enclosures

Cc: Michael Scott Furness, Director, Division of Nonprescription Regulation Development, Food and Drug Administration

Capt. Lydia Velazquez, Lead IDS, Senior Regulatory Review Officer, Division of Nonprescription Regulation Development, Food and Drug Administration

Reynold Tan, IDS Chemist, Division of Nonprescription Regulation Development, Food and Drug Administration

Debbie Lumpkins, Lead IDS, Acting Deputy Director, Division of Nonprescription Regulation Development, Food and Drug Administration

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[4] Draft Guidance available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf

Elizabeth Berbakos, CDER – Desk Officer, Office Chief of Information, Food and Drug Administration

Leslie Klux, Acting Assistant Commissioner for Policy, Office of Policy, Planning and Budget, Food and Drug Administration

Farah K. Ahmed, VP – Associate General Counsel, Personal Care Products Council

Alison Manhoff, Deputy General Counsel, Consumer Healthcare Products Association

APPENDIX A: Number of OTC sunscreen manufacturers and OTC sunscreen stock keeping units (SKUs) currently in the U.S.

SymphonyIRIGroup

Insight.
Innovation.
Impact.

August 10, 2011

Via email: ahmedf@personalcarecouncil.org

Farah Ahmed
Chair, Sunscreen Task Force
Personal Care Products Council
1101 17th Street, N.W.
Suite 300
Washington, D.C. 20036

Re: Disclosure of SymphonyIRI Data

Dear Ms. Ahmed:

I am responding to your request pertaining to disclosure of certain data and/or reports ("Information" and/or "Data") prepared by SymphonyIRI Group, Inc. ("SIG") for J&J. As I understand, the disclosure of such Information will be in response to the FDA's recently issued rule regarding sunscreens. As you know, the Information is proprietary to SIG.

The following is in response to your specific request:

1. Current number of manufacturers of mass market sunscreen products: _197__
2. Number of mass market sunscreen products (SKUs) currently on the market: __3,289_

SIG grants its consent to the Personal Care Products Council to disclose the Information to the FDA for the purpose stated above. SIG prohibits the disclosure or use of such Information for any other purpose (including in connection with any legal, investigatory or governmental proceedings) or to any other party, without SIG's prior written consent.

Please note that SIG compiles the Data based on data received by it from supermarkets and other retail outlets. As a result, SIG cannot guarantee the accuracy or completeness of such Data. SIG MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE DATA OR RESULTS TO BE OBTAINED BY THE COMPANY OR OTHERS FROM THE USE OF THE DATA.

If you have any questions, please call me at 312-474-3293.

Sincerely,

Finus Douglas

Finus Douglas

cc: Alison Harkins
Vice President and Corporate Counsel

NPD GROUP
Behind Every Business Decision

August 10, 2011

Ms. Farah Ahmed
Chair, Sunscreen Task Force
Personal Care Products Council
1101 17th Street, N.W., Suite 300
Washington, D.C. 20036

Dear Farah:

This will provide you with the sunscreen product information for annual 2010 as requested by PCPC. NPD's methodology for coding SPF benefits includes using item descriptions obtained via participating retailer data feeds as part of our BeautyTrends prestige universe*, coupled with the review of published marketing materials available in print or on the Internet.

Products coded with SPF in all segments in NPD's Skincare category include products designed for face, body, and suncare. This does not include sets and kits in which multiple items of similar or different products could be bundled together for sale. Also note that currently the only Makeup product type coded in our data with SPF is Foundation.

In 2010, there were 1239 products with SPF that meet the above definition and 167 companies that provide products with SPF.

**Retailers included in the NPD BeautyTrends prestige universe: Sephora, Macy's, Nordstrom, Lord & Taylor, Bloomingdales, Dillard's, Saks Fifth Avenue, Boscovs, Bon Ton, Belk, Peebles, Skinstore.com and Beauty.com. E-commerce sales are also included from the listed retailers except for Peebles & Dillard's.*

Please don't hesitate to reach out to me with any questions.

Best Regards.

Lori Monaco (V.S.)

Lori Monaco
Vice President U.S. Beauty
The NPD Group
Lori.monaco@npd.com
516-625-2287

APPENDIX B: Number of new sunscreen products introduced in to the market

MINTEL

Intelligence in time

VIA EMAIL
ahmedf@personalcarecouncil.org

15 August 2011

Farah Ahmed
Chair, Sunscreen Task Force
Personal Care Products Council
Suite 300
1101 17th Street, N.W.
Washington, DC 20036

Re: Mintel Data re: Sunscreen Products in the United States

Dear Ms. Ahmed:

I respond to the request of Personal Care Products Council ("PCPC") to disclose certain data prepared by and proprietary to Mintel Group Ltd. ("Mintel"). The data appears in Attachment A ("Data").

Mintel understands that PCPC will disclose the Data in a presentation to the United States Food and Drug Administration ("FDA"). The presentation will address a recently issued rule pertaining to sunscreen products.

Mintel consents to PCPC disclosing the Data to the FDA for the purpose stated above. Mintel prohibits the disclosure of the Data for any other purpose (including in connection with any legal, investigatory, or governmental proceeding) or to any other party, without Mintel's prior written consent.

Please note that Mintel compiled the Data according to the methodology described in Attachment B. As a result, Mintel cannot guarantee the accuracy or completeness of the Data, and Mintel excludes all warranties, express or implied.

If you have any questions, then please call me at 312.932.0400.

Sincerely,

Jenny Roock
Vice President, Product Development

MINTEL

Intelligence in time

Attachment A

Data

1. Number of new sunscreen and other beauty and personal care products containing sunscreen or sun protection factor, launched in the US from January 2010-December 2010: 1,262 mass and prestige products - 541 products below $24.99, 721 products $25 and above.

2. Number of new sunscreen and other beauty and personal care products containing sunscreen or sun protection factor, launched in the US from January 2009-December 2009: 1,436 mass and prestige products - 633 products below $24.99, 803 products $25 and above.

3. Number of new sunscreen and other beauty and personal care products containing sunscreen or sun protection factor, launched in the US from January 2008-December 2008: 1,205 mass and prestige products - 698 products below $24.99, 507 products $25 and above.

MINTEL

Intelligence in time

Attachment B

Methodology

Mintel GNPD (Global New Products Database)

Mintel GNPD offers unrivalled coverage of new consumer packaged goods product launches worldwide to facilitate competitor and trend monitoring, category awareness, and new product idea generation. Approximately 20,000 products are added every month from 48 countries, covering all food, beverage, beauty & personal care, healthcare, household and pet categories.

Mintel GNPD Overview and Coverage

The GNPD online database can be used to track the launch of new products within categories of interest and to drill down into the ingredients, nutritional information and positioning claims featured within these products. Over 80 fields are inputted, including company, brand, product, product description, category, ingredients, nutritional info, flavors, allergens, claims, price, primary and secondary packaging details, storage type, etc.

The GNPD online database includes new product information for 5 different types of new products: new products, new variety/range extensions, new formulations, new packaging and re-launches. It covers processed food and beverage products, beauty and personal care, cosmetics, healthcare, household and pet products across 49 key countries. GNPD is updated each business day with approximately 1,000 global products.

Mintel GNPD Coverage Methodology

The GNPD online database relies on Mintel's global network of field associates to identify new products in the market place. These field associates are looking for new products, new variety/range extensions, new formulations, new packaging and re-launches.

Key retail distribution channels are monitored, including grocery supermarkets, mass market, drug stores, natural food stores, convenience stores, club stores, specialty stores, other independent outlets, select mail order/internet products, and some direct to consumer products.

Field associates regularly ship products into the Mintel offices, allowing products to appear on the GNPD online database within approximately 1 month of launch or as close to launch as possible. It's important to note that a considerable number of product launches are published on the GNPD online database prior to their official launch date.

Mintel also monitors secondary sources that report on new product information, including trade publications, trade shows, company websites, press releases, and on-line/e-newsletters.

APPENDIX C: Council/CHPA comments to FDA on the Agency's Guidance for Industry*:* *Enforcement Policy OTC Sunscreen Drug Products Marketed Without an Approved Application* (submitted August 16, 2011)

[This appendix (Appendix C) has been intentionally left empty as it is contained within the primary document referenced herein.]

APPENDIX C: SPF Data and Information

Same Product Tested - Expected SPF of 15

	Final Monograph Method			International SPF Method		
	SUB #	CONTROL = 4.0	HRL PANEL 09-70119	SUB #	CONTROL = 15.0	HRL PANEL 09-70120
	01	4.00	13.65	01	15.00	18.75
	02	4.40	15.00	02	15.00	15.00
	03	4.00	18.00	03	18.75	15.00
	04	4.00	16.35	04	15.00	18.75
	05	4.40	15.00	05	15.00	18.75
	06	4.00	16.35	06	15.00	18.75
	07	4.00	16.35	07	18.75	15.00
	08	4.40	16.35	08	15.00	18.75
	09	4.00	16.35	09	15.00	15.00
	10	4.00	16.35	10	15.00	18.75
	11	4.00	16.35			
	12	4.40	16.35			
	13	4.00	16.35			
	14	4.00	16.35			
	15	4.00	16.35			
	16	4.40	16.35			
	17	4.00	16.35			
	18	4.00	18.00			
	19	4.00	15.00			
	20	4.40	16.35			
Protection Factor (Mean) = (ΣSPFi) / n		4.11	**16.17**		15.75	**17.25**
Standard Deviation (SD) = $\Sigma(SPFi^2) - ((\Sigma SPFi)^2 / (n-1))$		0.19	0.96		1.58	1.94
Standard Error = SD / √ # of subjects		0.04	0.22		0.50	0.61
Standard Error – Mean (%) SE / Mean x 100		1.02	1.33		3.17	3.55
t Distribution		1.729	1.729		2.262	2.262
A = t x SD / √ # of subjects (95% Confidence Interval)		0.07	0.37		1.13	1.39
[SPF (95% CI)]		4.04	**15.80**		14.62	**15.86**

Intervals were: 0.69x /0.83x /0.91x /1.00x /1.09x /1.20x /1.44x (x = subject's MED)

Irradiation times for the Test Material, **Expected SPF 15**, were for the following SP Factors multiplied by the subject's MED:

1	2	3	4	5	6	7
10.35	12.45	13.65	15.00	16.35	18.00	21.60

1	2	3	4	5
9.60	12.00	15.00	18.75	23.43

Same Product Tested - Expected SPF of 20

	Final Monograph Method			International SPF Method		
	SUB #	CONTROL = 4.0	HRL PANEL 10-70098	SUB #	CONTROL = 15.0	HRL PANEL 10-70097
	01	4.00	23.00	01	15.00	20.00
	02	4.00	21.40	02	15.00	20.00
	03	4.00	21.40	03	18.75	25.00
	04	4.00	21.40	04	15.00	20.00
	05	4.40	21.40	05	18.75	20.00
	06	5.00	21.40	06	15.00	20.00
	07	4.00	20.00	07	18.75	20.00
	08	4.00	18.60	08	15.00	20.00
	09	4.00	23.00	09	15.00	25.00
	10	4.00	18.60	10	15.00	25.00
	11	4.00	21.40			
	12	4.40	21.40			
	13	4.00	21.40			
	14	4.00	20.00			
	15	4.00	20.00			
	16	4.00	20.00			
	17	4.00	21.40			
	18	4.00	21.40			
	19	4.00	21.40			
	20	4.00	21.40			
Protection Factor (Mean) = (ΣSPFi) / n		4.10	**21.00**		16.12	**21.50**
Standard Deviation (SD) = $\Sigma(SPFi^2) - ((\Sigma SPFi)^2 / (n-1))$		0.27	1.16		1.81	2.42
Standard Error = SD / √ # of subjects		0.06	0.26		0.57	0.76
Standard Error – Mean (%) SE / Mean x 100		1.45	1.23		3.55	3.55
t Distribution		1.729	1.729		2.262	2.262
A = t x SD / √ # of subjects (95% Confidence Interval)		0.10	0.45		1.29	1.73
[SPF (95% CI)]		4.00	**20.55**		14.83	**19.77**

Intervals were: 0.76x /0.87x /0.93x /1.00x /1.07x /1.15x /1.32x (x = subject's MED)

Irradiation times for the Test Material, **Expected SPF 20**, were for the following SP Factors multiplied by the subject's MED:

1	2	3	4	5	6	7
15.20	17.40	18.60	20.00	21.40	23.00	26.40

1	2	3	4	5
12.80	16.00	20.00	25.00	31.25

Same Product Tested - Expected SPF of 30

	Final Monograph Method			International SPF Method		
	SUB #	CONTROL = 4.0	HRL PANEL 10-70043	SUB #	CONTROL = 15.0	HRL PANEL 10-70094
	01	4.00	30.00	01	15.00	30.00
	02	4.40	34.50	02	18.75	33.60
	03	4.00	30.00	03	15.00	30.00
	04	4.40	30.00	04	15.00	33.60
	05	4.00	32.10	05	15.00	30.00
	06	4.00	32.10	06	15.00	33.60
	07	4.40	34.50	07	15.00	33.60
	08	4.00	34.50	08	18.75	33.60
	09	4.00	32.10	09	15.00	30.00
	10	4.00	27.90	10	15.00	30.00
	11	4.00	32.10			
	12	4.00	32.10			
	13	4.00	32.10			
	14	4.00	32.10			
	15	4.40	32.10			
	16	4.40	32.10			
	17	4.00	32.10			
	18	4.40	30.00			
	19	4.00	30.00			
	20	4.00	30.00			
Protection Factor (Mean) = (ΣSPFi) / n		4.12	**31.62**		15.75	**31.80**
Standard Deviation (SD) = $\Sigma(SPFi^2) - ((\Sigma SPFi)^2 / (n-1))$		0.19	1.73		1.58	1.90
Standard Error = SD / √ # of subjects		0.04	0.39		0.50	0.60
Standard Error – Mean (%) SE / Mean x 100		1.02	1.22		3.17	1.89
t Distribution		1.73	1.73		2.26	2.26
A = t x SD / √ # of subjects (95% Confidence Interval)		0.07	0.67		1.13	1.36
[SPF (95% CI)]		4.05	**30.95**		14.62	**30.44**

Intervals were: 0.76x /0.87x /0.93x /1.00x /1.07x /1.15x /1.32x (x = subject's MED)

Irradiation times for the Test Material, **Expected SPF 30**, were for the following SP Factors multiplied by the subject's MED:	1	2	3	4	5	6	7
	22.80	26.10	27.90	30.00	32.10	34.50	39.60

1	2	3	4	5
23.91	26.78	30.00	33.60	37.63

Test Article: 2011/03/23 SPF 18-25

	8% HMS Standard SPF 4.4	7.19S FDA 1999
1	4.4	23.5
2	4.4	22.0
3	5.0	25.3
4	4.4	23.5
5	4.4	25.3
6	4.4	25.3
7	5.0	25.3
8	4.4	25.3
9	4.4	25.3
10	4.4	29.1
11	4.4	25.3
12	5.0	25.3
13	4.0	29.0
14	6.3	25.3
15	5.0	25.3
16	4.0	23.5
17	5.0	25.3
18	4.4	25.3
19	4.4	25.3
20	5.0	25.3
Average SPF	4.64	**25.24**

	P3 Standard SPF 16.2	7.38S International
1	16.2	27.5
2	16.2	27.5
3	16.2	27.5
4	16.2	22.0
5	16.2	27.5
6	16.2	27.5
7	20.3	27.5
8	16.2	27.5
9	16.2	27.5
10	20.3	27.5
Average SPF	17.02	**26.95**

DETERMINING THE EFFICACY OF HIGHER SPF SUNSCREEN FORMULATIONS

A COMPARISON OF RESULTS FOR TWO HIGH SPF FORMULATIONS TESTED BY THE 1999 FINAL MONOGRAPH SUN PROTECTION FACTOR METHOD AT TWO LABORATORIES

Cosmetic, Toiletry, and Fragrances Association
September 2007

9/4/07

Introduction

The Sun Protection Factor (SPF) determined *in vivo* is now a universal indicator of the efficacy of sunscreen products against sunburn (1,2,3).

The ability of the current FDA SPF test methods to produce accurate and reproducible SPF values for sunscreen products with SPFs >30 was questioned by the Agency in its 1999 Final Rule (2). Data were provided to FDA in 2003 which demonstrated that the Sun Protection Factor methods described in the 1978, 1993 and 1999 sunscreen monographs were able to accurately and reproducibly achieve quality testing results for sunscreen formulations with SPFs as high as SPF 45 (4,5). That study not only concluded that currently existing SPF test methodologies could produce accurate and reproducible results for high SPF formulations, but also provided data to address the Agency's questions concerning the number of test subjects needed, the variability of the data, and the appropriate exposure increments for testing high SPF formulations.

In the time since 2003, the art of formulating sunscreens has evolved to a state where SPFs well in excess of those achievable in 1999 are now commonplace in the US market. The goal of presenting the new data in this report is to demonstrate that the current (1999) SPF method is able to accurately and reproducibly test formulations with SPFs up to SPF 50. Thus, there is no reason from an SPF methodology standpoint to increase the number of subjects required for formulations with SPFs of 30 to 50.

The purpose of these new data is to provide updated scientific data, and to enable the Agency to decide this issue with information that is directly relevant and essential for the Agency to consider in drafting its Final Monograph. We are asking the Agency to consider these data as providing new support for the ability of current SPF testing methods to accurately measure sunscreen protection provided by formulations with high SPFs. No additional subjects are needed based on these data.

Materials and Methods

Two experimental lotion formulations (each estimated at approximately SPF 50) were prepared and tested for Sun Protection Factor (SPF) at two laboratories[1] according to the 1999 final monograph SPF test method (2). The protocols for the test as conducted by each laboratory are provided in Appendix 1. A summary of the basic procedure is provided below.

In addition to the two experimental formulations, two reference control formulations (SPF 4 lotion and SPF 15 lotion) were also tested on each subject. The composition, manufacturing instructions and analytical methods for each of the two reference control formulas (SPF 4 and SPF 15) along with SPF data supporting these formulations has previously been submitted to the Agency (6).

The experimental high SPF formulations contained the active ingredients as listed below:

Formula 2859-21: active ingredients:	Octinoxate 7.50% Oxybenzone 6.00% Octisalate 5.00% Avobenzone 1.00% Octocrylene 0.80%
Formula 2833634: active ingredients:	Octinoxate 7.5% Octisalate 5% Octocrylene 7% Oxybenzone 6% Titanium dioxide 5.8%

The reference formulations (SPF 4: 8% Homosalate Lotion and SPF 15: 7% Padimate O, 3% Oxybenzone) are now also used worldwide as control formulations for SPF testing (1).

Laboratory A tested both of the high SPF formulations plus the two reference control formulations on 20 subjects within one test panel. Laboratory B tested each of the high SPF formulations on a separate panel of subjects, along with the two reference control formulations on each subject.[1]

The solar simulators used by each laboratory are described in detail in each protocol and in the data reports (Appendices 1 and 2).

[1] Laboratory A: Harrison Research Laboratories, Union NJ 07083
Laboratory B: Consumer Product Testing Co., Fairfield NJ 07004

An Overview of the SPF Testing Method Used by the Two Laboratories

Subjects

- Male/female with fair skin (Types I, II, and III)
- Good general health
- No medications known to produce abnormal sunlight responses
- No abnormal responses to sunlight, such as a phototoxic or photoallergic response
- No sunburn, suntan, scars, active dermal lesions or uneven skin tones on the areas of the back to be tested.
- Legally effective written informed consent
- Not more than 25 subjects, at least 20 subjects must produce valid data

Test sites

- Located on the back between the beltline and the shoulder blade and lateral to the midline
- A minimum of 50 square centimeters in area, outlined with ink, drawn with the subject in the test position

Application of test materials

- 2 milligrams per square centimeter
- Spread using a finger cot
- Applied in a blinded, randomized manner

Evaluation of skin responses

- The evaluator is not the same person who applied the test products or administered the doses of UV radiation.
- Erythemal responses are evaluated 22 to 24 hours after exposure using either a tungsten or warm white fluorescent light that provides a level of illumination at the test site within the range of 450 to 550 lux.
- Subjects are evaluated in the same position as when irradiated.

Minimal erythema dose [MED]

- The MED is the UV energy dose required to produce the first perceptible redness reaction with clearly defined borders on unprotected or protected skin.

Determination of the control (unprotected) MED

- The MED for unprotected skin is determined by administering a geometric series of 5 exposures represented by $(1.25)^n$
- A preliminary MED series is administered prior to the test; the result determines the doses administered to unprotected and sunscreen-protected skin used to calculate the SPF.

Determination of individual SPF values

- A series of 7 UV doses is administered to the sunscreen-protected sites. UV doses are determined by the preliminary MED and the expected SPF of the product.
- Immediate skin responses such as IPD, redness, are recorded.
- For products with an expected SPF less than 8, the exposures will be the MED of unprotected skin times 0.64X, 0.80X, 0.90X, 1.00X, 1.10X, 1.25X, and 1.56X, where X equals the expected SPF of the test product.
- For products with an expected SPF between 8 and 15, the exposures will be the MED of unprotected skin times 0.69X, 0.83X, 0.91X, 1.00X, 1.09X, 1.20X, and 1.44X, where X equals the expected SPF.
- For products with an expected SPF greater than 15, the exposures will be the MED of unprotected skin times 0.76X, 0.87X, 0.93X, 1.00X, 1.07X, 1.15X, and 1.32X, where X equals the expected SPF.
- The SPF value is then calculated as the ratio of the MED of sunscreen-protected skin to the MED of unprotected skin.

Determination of product SPF value

- SPF values from at least 20 subjects.
- Compute the mean SPF value, x, and the standard deviation, s.
- Find the upper 5-percent point from the t distribution, t.
- Calculate: A=ts/ sqrt n.
- The label SPF equals the largest whole number less than (x - A).

Solar simulator [1]

Continuous emission spectrum from 290 to 400 nanometers, similar to sunlight at sea level with the sun at a zenith angle of 10 degrees.

- Less than 1 percent total energy output from wavelengths shorter than 290 nanometers.
- Not more than 5 percent of total energy output from wavelengths longer than 400 nanometers.
- No significant time-related fluctuations in output.
- Beam uniformity within 10 percent.
- Output measured periodically with a calibrated spectroradiometer or equivalent.

Results

The test data for the subjects tested and test data summaries for the two experimental formulations are shown in Tables 1-4:

Table 1 contains the data from Laboratory A for Formula 2859-21. The mean SPF was 50.69 with a final calculated SPF of 49.1.
Table 2 contains the data from Laboratory B for Formula 2859-21. The mean SPF was 52.0 with a final calculated SPF of 50.83.
Table 3 contains the data from Laboratory A for Formula 2833634. The mean SPF was 52.71 with a final calculated SPF of 51.3.
Table 4 contains the data from Laboratory B for Formula 2833634. The mean SPF was 50.86 with a final calculated SPF of 49.86.

[1] The solar simulators used at both laboratories not only met current FDA requirements but also met the requirements of the International SPF Test Method (2006).

Results Summary

Sample	Mean SPF Lab A	Mean SPF Lab B	Final SPF Lab A	Final SPF Lab B
Formula 2859-21	50.69	52.0	49.1	50.83
Formula 2833634	52.71	50.86	51.3	49.86
SPF 4 Control	4.24	4.50 and 4.61	4.16	4.40 and 4.46
SPF 15 Control	17.08	16.17 and 16.34	16.34	15.78 and 15.91

The results for the SPF 4 and the SPF 15 control formulations are shown with each data set in Tables 1-4 and and are also shown in separate tables for each control formulation in Tables 5 and 6. These data were all within expected limits.

Discussion

The data shown in Tables 1 and 2 for Formula 2859-21 and in Tables 3-4 for Formula 2833634 illustrate that the current SPF methodology can be used to test sunscreen formulations with SPFs in the SPF 50 range. These data also demonstrate that the variability of the data is not outside what is expected in this type of test. The data fit within the desired statistical parameters for well formulated sunscreen products in the SPF 50 range. At each laboratory and for both SPF 50 formulations, the standard deviation within the data panels was less than five and the standard error was less than one. Using the calculation A=ts/ sqrt n, the values for A were 1.59 and 1.17 for Formula 2859-21, and 1.41 and 1.00 for Formula 2833634.

The data sets also can be used to support the appropriateness of "20-25" as the number of test subjects for a test panels up tot SPF 50. As one can see from the Tables, the number of subjects (20-25) are sufficient for the purpose of obtaining valid data for high SPF formulations as well as for the SPF 4 and SPF 15 reference control products, as the statistical variability is acceptable according to the analyses methods described in the sunscreen monograph.

Conclusions

The data illustrate that the Final Monograph SPF method can provide accurate and reproducible results for high SPF formulations. Further, these results can be achieved with panels of 20-25 subjects with an acceptable level of statistical variability for SPFs up to 50.

The data also show that either the SPF 4 or the SPF 15 reference control formulation can be tested with high SPF formulations as appropriate controls on laboratory methodology.

Based on the results shown in this study, the current methods for testing sunscreen formulations have been shown to be appropriate for testing formulations with SPFs in the SPF 50 range. The data do not support a need for adding subjects beyond the "20-25" used in the 1999 method for products with SPFs of 30 to 50.

The Final Monograph SPF test method can be used to determine valid product SPFs in the SPF 50 range.

References

1. COLIPA: International Sun Protection Factor Test Method, 2006
2. Federal Register: May 21, 1999 (Volume 64, Number 98), Final Rule, pp. 27666-27693.
3. Australia/New Zealand Standard: Sunscreen Products-Evaluation and Classification, AS/NZS 2604:1998.
4. Agin, Patricia A. and Edmonds, Susan. H. Testing high SPF sunscreens: a demonstration of the accuracy and reproducibility of the results of testing high SPF formulations by two methods and at different testing sites. Photodermatol Photoimmunol Photomed 2002; 18:169-174.
5. CTFA Submissions to FDA Docket 78N-0038, October 15, 1999, c000573_09 and c000557, January 14, 2000..
6. CTFA Submission to FDA Docket 78N-0038, March 6, 2000, SUP29, Attachment_C.

TABLE 1: Sunscreen Formula #2859-21

INDIVIDUAL SUBJECT DATA

LABORATORY A

SUB #	HRL ID #	SEX/ AGE	SKIN TYPE	MED*	8% HMS CONTROL	SPF 15 CONTROL	TEST MATERIAL #2859-21
01	26780	F61	I	12.5	4.40	15.00	50.00
02	11614	M41	I	12.5	4.40	18.75	53.50
03	02589	F59	I	12.5	4.40	18.75	53.50
04	29358	F49	III	12.5	4.00	15.00	57.50
05	29521	F48	I	10.0	4.00	18.75	57.50
06	29522	M26	I	10.0	4.40	15.00	53.50
07	25363	M46	I	10.0	4.40	15.00	46.50
08	20370	F64	II	12.5	4.00	15.00	50.00
09	28842	F58	I	12.5	4.00	15.00	50.00
10	23456	M46	I	12.5	4.40	18.75	46.50
11	03394	M48	II	12.5	4.00	18.75	46.50
12	03047	F61	I	15.6	4.40	18.75	46.50
13	19652	M51	I	12.5	4.00	15.00	50.00
14	28891	F52	I	12.5	4.00	15.00	50.00
15	27417	F46	I	12.5	4.40	18.75	43.50
16	00866	F48	I	12.5	4.40	18.75	57.50
17	12381	M68	II	10.0	4.40	18.75	50.00
18	27248	F66	II	10.0	4.40	18.75	50.00
19	09670	F60	II	12.5	4.00	15.00	50.00
20	28078	F69	I	12.5	4.00	15.00	46.50
Sun Protection Factor (Mean)			X		4.24	17.08	**50.69**
Standard Deviation			SD		0.20	1.92	4.12
Standard Error			SE		0.04	0.43	0.92
Standard Error - Mean (%)			SEM		1.06	2.51	1.82
t Distribution					1.729	1.729	1.729
A = t x SD / square root of # of subjects (95% Confidence Interval)					0.08	0.74	1.59
[SPF (95% CI)]					4.16	16.34	**49.10**

*MED = Minimal Erythema Dose (in seconds)

TABLE 2: Sunscreen Formula #2859-21

INDIVIDUAL SUBJECT DATA

LABORATORY B

Subject	CPTC#	Skin Type	Age/Sex		MED (in seconds)	8% HMS Control	SPF 15 Control	Sunscreen #2859-21
1 RS	51083	II	60	F	12	4.4	16.3	50.0
2 AA	29914	II	56	M	15	4.4	16.3	50.0
3 AS	52319	II	60	M	15	4.4	16.3	50.0
4 CM	18105	II	51	F	15	4.4	16.3	50.0
5 BR	21526	II	60	F	12	4.4	16.3	53.5
6 BK	7839	II	57	F	15*	4.0*	15.0*	<38.0*
7 KB	9040	III	55	M	15	5.0	16.3	53.5
8 EA	8026	III	56	F	15	4.4	16.3	50.0
9 JC	11205	II	63	M	15	4.4	15.0	50.0
10 AD	7918	II	55	F	15	4.4	16.3	53.5
11 DG	36842	III	37	F	19	4.0	15.0	53.5
12 MQ	34362	III	39	F	15	4.4	15.0	57.5
13 CQ	34412	III	40	M	15	4.4	15.0	53.5
14 CS	2162	II	48	F	15	4.4	15.0	50.0
15 AG	38891	II	44	F	15	5.0	18.0	46.5
16 BB	40368	II	64	F	15	5.0	18.0	50.0
17 AK	8778	III	62	F	15	4.4	15.0	50.0
18 JR	11693	III	51	M	15	4.4	16.3	57.5
19 ER	13680	II	63	F	15	4.4	16.3	53.5
20 EG	46049	II	50	F	12	4.4	16.3	50.0
21 ML	10848	II	57	F	15	5.0	18.0	57.5
Average SPF (n=20)						4.50	16.17	**52.00**
Standard Deviation						0.27	0.99	3.03
Standard Error						0.06	0.22	0.68
t (one-tail)						1.729	1.729	1.729
A						0.10	0.38	1.17
						4.40	15.78	**50.83**
SPF Label						4	15	50

*Data not included in calculations – Erythema in all subsites, Data rejected.

TABLE 3: Sunscreen Formula #2833634

INDIVIDUAL SUBJECT DATA

LABORATORY A

SUB #	HRL ID #	SEX/ AGE	SKIN TYPE	MED*	8% HMS CONTROL	SPF 15 CONTROL	TEST MATERIAL #283363 4
01	26780	F61	I	12.5	4.40	15.00	50.00
02	11614	M41	I	12.5	4.40	18.75	53.50
03	02589	F59	I	12.5	4.40	18.75	57.50
04	29358	F49	III	12.5	4.00	15.00	53.50
05	29521	F48	I	10.0	4.00	18.75	53.50
06	29522	M26	I	10.0	4.40	15.00	57.50
07	25363	M46	I	10.0	4.40	15.00	53.50
08	20370	F64	II	12.5	4.00	15.00	46.50
09	28842	F58	I	12.5	4.00	15.00	57.50
10	23456	M46	I	12.5	4.40	18.75	53.50
11	03394	M48	II	12.5	4.00	18.75	50.00
12	03047	F61	I	15.6	4.40	18.75	57.50
13	19652	M51	I	12.5	4.00	15.00	50.00
14	28891	F52	I	12.5	4.00	15.00	50.00
15	27417	F46	I	12.5	4.40	18.75	57.50
16	00866	F48	I	12.5	4.40	18.75	50.00
17	12381	M68	II	10.0	4.40	18.75	53.50
18	27248	F66	II	10.0	4.40	18.75	46.50
19	09670	F60	II	12.5	4.00	15.00	50.00
20	28078	F69	I	12.5	4.00	15.00	50.00
Sun Protection Factor (Mean)			X		4.24	17.08	**52.71**
Standard Deviation			SD		0.20	1.92	3.65
Standard Error			SE		0.04	0.43	0.82
Standard Error - Mean (%)			SEM		1.06	2.51	1.55
t Distribution					1.729	1.729	1.729
A = t x SD / square root of # of subjects (95% Confidence Interval)					0.08	0.74	1.41
[SPF (95% CI)]					4.16	16.34	**51.30**

*MED = Minimal Erythema Dose (in seconds)

TABLE 4: Sunscreen Formula #2833634

INDIVIDUAL SUBJECT DATA

LABORATORY B

Subject	CPTC#	Skin Type	Age/ Sex		MED (in seconds)	8% HMS Control	SPF 15 Control	Sunscreen Formula 2833634
1 JW	11951	III	48	F	19	4.0	17.2	50.0
2 SL	7587	II	60	F	15	4.4	16.3	50.0
3 DK	29665	III	64	M	15	4.4	16.3	50.0
4 CF	2089	III	53	M	15	4.4	18.0	50.0
5 MD	58	III	61	F	15	4.4	16.3	57.5
6 LD	48861	II	40	F	15	5.0	16.3	50.0
7 BR	34891	III	50	M	*	*	*	*
8 PF	49291	III	65	M	19	4.9	17.1	52.1
9 KT	31459	II	55	M	15	5.0	16.3	50.0
10 AM	33814	II	30	F	15	4.0	15.0	50.0
11 JM	33815	III	39	M	15	4.0	18.0	46.5
12 EP	35401	II	56	F	15	5.0	18.0	50.0
13 *	*	*	*	*	*	*	*	*
14 EA	8026	III	56	F	15	5.0	18.0	50.0
15 DS	20004	II	37	F	15	4.4	15.0	50.0
16 MZ	53408	II	24	M	15	4.4	15.0	53.5
17 BH	41325	III	60	M	15	4.4	16.3	50.0
18 CM	18105	II	51	F	15	5.0	15.0	50.0
19 MC	33146	II	20	F	15	4.4	16.3	50.0
20 AZ	25888	III	40	F	15	5.0	15.0	50.0
21 EP	41801	II	56	F	15	5.0	15.0	50.0
22 LC	42814	II	25	F	15	5.0	16.3	57.5
Average SPF (n=20)						4.61	16.34	**50.86**
Standard Deviation						0.38	1.10	2.58
Standard Error						0.09	0.25	0.58
t (one-tail)						1.729	1.729	1.729
A						0.15	0.43	1.00
						4.46	15.91	**49.86**
SPF Label						4	15	49

*Data was rejected since the subject was noncompliant.

TABLE 5: INDIVIDUAL SUBJECT DATA 8% HMS SPF 4 Control

SUB #	Lab A	Lab B Panel 1	Lab B Panel 2
01	4.4	4.4	4.0
02	4.4	4.4	4.4
03	4.4	4.4	4.4
04	4.0	4.4	4.4
05	4.0	4.4	4.4
06	4.4	4.0*	5.0
07	4.4	5.0	**
08	4.0	4.4	4.9
09	4.0	4.4	5.0
10	4.4	4.4	4.0
11	4.0	4.0	4.0
12	4.4	4.4	5.0
13	4.0	4.4	**
14	4.0	4.4	5.0
15	4.4	5.0	4.4
16	4.4	5.0	4.4
17	4.4	4.4	4.4
18	4.4	4.4	5.0
19	4.0	4.4	4.4
20	4.0	4.4	5.0
21	--	5.0	5.0
22	--	--	5.0
Sun Protection Factor (Mean)	**4.24**	**4.50**	**4.61**
Standard Deviation	0.20	0.27	0.38
Standard Error	0.04	0.06	0.09
t Distribution	1.729	1.729	1.729
A	0.20	0.10	0.15
SPF (95% CI)]	**4.16**	**4.40**	**4.46**

*Data not included in calculations – Erythema in all subsites, Data rejected.

**Data was rejected since the subject was noncompliant.

TABLE 6: INDIVIDUAL SUBJECT DATA SPF 15 Control

SUB #	Lab A	Lab B Panel 1	Lab B Panel 2
01	15.00	16.3	17.2
02	18.75	16.3	16.3
03	18.75	16.3	16.3
04	15.00	16.3	18.0
05	18.75	16.3	16.3
06	15.00	15.0*	16.3
07	15.00	16.3	**
08	15.00	16.3	17.1
09	15.00	15.0	16.3
10	18.75	16.3	15.0
11	18.75	15.0	18.0
12	18.75	15.0	18.0
13	15.00	15.0	**
14	15.00	15.0	18.0
15	18.75	18.0	15.0
16	18.75	18.0	15.0
17	18.75	15.0	16.3
18	18.75	16.3	15.0
19	15.00	16.3	16.3
20	15.00	16.3	15.0
21	--	18.0	15.0
22	--	--	16.3
Sun Protection Factor (Mean)	**17.08**	**16.17**	**16.34**
Standard Deviation	1.92	0.99	1.10
Standard Error	0.43	0.22	0.25
t Distribution	1.729	1.729	1.729
A	0.74	0.38	0.43
SPF (95% CI)]	**16.34**	**15.78**	**15.91**

*Data not included in calculations – Erythema in all subsites, Data rejected.

**Data was rejected since the subject was noncompliant.

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] Inc. UV-B Solar Simulator #NB1 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA: FDA existing and proposed standards for solar simulators

Europe: COLIPA standard for solar simulators

Japan: JCIA standard for solar simulators

Australia: Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] Inc. UV-B Solar Simulator #NB3 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION:	Proposed standard
USA:	FDA existing and proposed standards for solar simulators
Europe:	COLIPA standard for solar simulators
Japan:	JCIA standard for solar simulators
Australia:	Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] Inc. UV-B Solar Simulator #NB4 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA: FDA existing and proposed standards for solar simulators

Europe: COLIPA standard for solar simulators

Japan: JCIA standard for solar simulators

Australia: Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] UV-B Solar Simulator #NB5 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA: FDA existing and proposed standards for solar simulators

Europe: COLIPA standard for solar simulators

Japan: JCIA standard for solar simulators

Australia: Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] UV-B Solar Simulator #NB6 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

- **INTERNATIONAL HARMONIZATION:** Proposed standard

USA:	FDA existing and proposed standards for solar simulators
Europe:	COLIPA standard for solar simulators
Japan:	JCIA standard for solar simulators
Australia:	Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] UV-B Solar Simulator #NB7 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA: FDA existing and proposed standards for solar simulators

Europe: COLIPA standard for solar simulators

Japan: JCIA standard for solar simulators

Australia: Standards of Australia committee CS/42 standards for solar simulators

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] **UV-A Solar Simulator #NA1 was measured on this date and found to yield uniform and reproducible output.**

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA:	**FDA existing and proposed standards for solar simulators**
Europe:	**COLIPA standard for solar simulators**
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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] UV-A Solar Simulator #NA3 was measured on this date and found to yield uniform and reproducible output.

This Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA:	FDA existing and proposed standards for solar simulators
Europe:	COLIPA standard for solar simulators
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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] Solar Simulator #M1, Model XPS300, Serial No: 12713, was measured for UV-A on this date and found to yield uniform and reproducible output.

This Multiport Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION:	**Proposed standard**
USA:	**FDA existing and proposed standards for solar simulators**
Europe:	**COLIPA standard for solar simulators**
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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] **Solar Simulator #M1, Model XPS300, Serial No: 12713, was measured for UV-B on this date and found to yield uniform and reproducible output.**

This Multiport Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION: Proposed standard

USA: **FDA existing and proposed standards for solar simulators**

Europe: **COLIPA standard for solar simulators**

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CERTIFICATE OF SPECTRAL MEASUREMENT FOR SOLAR SIMULATOR COMPLIANCE

[redacted] Solar Simulator #M2, Model XPS300, Serial No: 12715, was measured for UV-A on this date and found to yield uniform and reproducible output.

This Multiport Solar Simulator meets all of the following applicable standards:

INTERNATIONAL HARMONIZATION:	**Proposed standard**
USA:	**FDA existing and proposed standards for solar simulators**
Europe:	**COLIPA standard for solar simulators**
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Spectral Standardization of Sources Used for Sunscreen Testing: 5 Years of Compliance

Robert M. Sayre and John C. Dowdy

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INTRODUCTION

In 1978, the US FDA published a report and monograph on sunscreen product testing and labeling (1). This monograph established that a solar simulator would be a source having a continuous emission spectrum from 290 to 400 nm and be filtered for a solar zenith angle of 10° and have less than 1% of its

energy contributed by wavelengths shorter than 290 nm. In addition, to avoid purported thermal problems, they also required that the solar simulator could not have more than 5% of its energy contributed by wavelengths longer than 400 nm. The beam uniformity is required to be within 10%. Specifically, latter monographs have recommended that a solar simulator requires periodic remeasurement with a calibrated spectroradiometer to insure the proper spectral distribution (2–4).

Efforts to refine the specifications of the solar simulator used for SPF testing have, over time, resulted in several additional proposed and adopted standards. In1990 Sayre et al. proposed a spectral standard for solar simulators recommending an upper- and lower-wavelength range appropriate for SPF testing (5). A similar, slightly less stringent, implementation of this approach was subsequently adopted in the Australian/New Zealand Standard for evaluation and classification of sunscreen products (6).

In 1994 COLIPA (The European Cosmetic, Toiletry, and Perfumery Association) published a method to test sunscreen products together with specifying a compliance standard for solar simulators (7). In 1999 the US Food and Drug Administration (FDA) was petitioned urging the adoption of the COLIPA Standard for Solar Simulators (8). The latest rendition of the Final Monograph did not formally adopt this recommendation, but as of this writing there is at least one petition to reopen the monograph pending (4).

The COLIPA standard requires that the spectrum of a solar simulator be measured throughout the ultraviolet (UV) from 250 to 400 nm. The spectrum measured is multiplied by the Commission Internationale de l'Éclairage (CIE) (McKinlay–Diffey) erythemal action spectrum to calculate the effective irradiance (9). The solar simulator is specified based on the percentage of erythemal effective radiation within a series of overlapping spectral ranges (Table 42.1), which is termed percent relative cumulative erythemal effectiveness (%RCEE).

An important point to consider about this standard is that unlike natural sunlight, it requires only 1% of the erythemally effective risk to be at UV-A wavelengths longer than 350 nm. The other point about this standard is that

Table 42.1 COLIPA (1994) Solar Simulator Specifications

Percent erythemal effective irradiance (%RCEE) (nm)	Acceptance limits (%)
<290	<1.0
290–310	46.0–67.0
290–320	80.0–91.0
290–330	86.5–95.0
290–340	90.5–97.0
290–350	93.5–99.0

there is no requirement that the source be absolutely continuous and a source with prominent spectral lines is acceptable as long as it meets the overall requirements. One finds that in addition to xenon arcs, mercury metal halide lamps and even fluorescent lamps can meet the standard. SPF testing labs in the USA and Canada, however, almost exclusively use filtered xenon arc Solar Light (Solar Light Co., Inc., Philadelphia, PA) solar simulators of the single port or multiport design.

Unlike Europe, where sunscreens are typically categorized as cosmetics not subject to regulatory mandate, the US FDA regulates sunscreen products as over-the-counter drugs (1–3). Consequently, SPF testing laboratories servicing the US market routinely monitor their solar simulators for compliance with all applicable standards as part of their respective quality assurance programs. This study, presented in part to the 2000 International Congress of Photobiology, presents a retrospective compilation of solar simulator compliance data from six participating North American SPF testing laboratories for the 5-year period from 1995 to 2000 (10).

METHODS

Measurement of a solar simulator requires three separate activities: calibration of the spectroradiometer, measurement of the source, and finally a recheck of the instrument response and recalibration of the system.

Instrumentation

The instrument used for these measurements is an OL-754 double grating spectroradiometer (Optronic Laboratories, Inc., Orlando, FL). For solar simulator spectral measurement the spectroradiometer was configured with an integrating sphere with a 6 mm entrance aperture to collect the radiation and 0.125/1.0/0.125 mm slits. This spectroradiometer comes with a device to check the photometric gain using a small tungsten–halogen source and check the wavelength accuracy using a small fluorescent source. Before each calibration and measurement the wavelength calibration and gain are checked or established.

Calibration Procedures

The OL 754 spectroradiometer was calibrated using a tungsten–halogen spectral irradiance standard lamp annually certified traceable to NIST. The calibration was transferred in 1 nm increments using procedures established by the manufacturer (Optronic Laboratories) of both the spectroradiometer and the NIST traceable tungsten standard source. The calibration spectrum used is the average of three spectral measurements of the standard.

Measurement Procedures

Spectral irradiance measurements were made at 1 nm intervals from 250 to 800 nm. Data were saved to magnetic media and identified using a portion of

the solar simulator site/serial number to establish the identity of the system measured. The center of the beam at the site for irradiating human volunteers was selected for spectroradiometric measurement and represents the highest intensity to which a human volunteer might be exposed. A special plug-in aperture was used to position the liquid waveguides of multiport solar simulators.

The final quality control check, conducted after solar simulator spectral irradiance measurements, consisted of repeating all checks performed prior to calibration. The result of this check and the subsequent recalibration of the system with the tungsten standard source indicate that the spectral radiometer functioned the same throughout this period of measurement.

Measurement Uncertainty

Our estimate is that the total possible uncertainty for measuring a solar simulator is less than 12% (Table 42.2). The major sources of uncertainty, potentially up to 10%, is that which may be attributed to reproducible positioning of the spectroradiometer relative to the source and to changing laboratory environments. The uncertainty from changing laboratory environments is due to different levels of electronic noise, temperature, and humidity between laboratories and the same laboratory from visit to visit.

RESULTS

A typical Solar Light single-port solar simulator, used for sunscreen SPF testing, consists of a 150 W ozone-free xenon arc which is filtered with a WG-320 filter

Table 42.2 Measurement Uncertainty Factors

Uncertainty factor	Uncertainty (%)	Uncertainty squared
1. Standard lamp uncertainty to NIST	2	0.0004000
2. Calibration transfer to spectroradiometer	3	0.0009000
3. Stray radiation	0.10	0.0000010
4. Nonlinearity of response throughout measurement range	1	0.0001000
5. Wavelength uncertainty	0.20	0.0000040
6. Wavelength repeatability	1	0.0001000
7. Noise in measurements	0.10	0.0000010
8. Reproducibility of measurements	1	0.0001000
9. Source positioning uncertainty	5	0.0025000
10. Laboratory environment	10	0.0100000
Sum quadrature uncertainties		0.0141060
Uncertainty		11.88%

of appropriate thickness and generally a UG-11 to remove excess visible. A set of representative spectral measurements collected on a typically configured single-port solar simulator (Fig. 42.1) show from year to year that there has not been much change in spectral distribution and only very slight variation in power level. Only one solar simulator using the less common configuration of a UG-5 filter in place of the usual UG-11 (Fig. 42.2) was monitored in this study. Over the years there appear to be some minor changes in the UV-B distribution; however, this variation is not progressing from year to year.

The other type of solar simulator commonly used for sunscreen SPF testing in North America is the Solar Light multiport. It has six complete sets of optics, configured with WG-320 and UG-11 filters, and six waveguides. The multiport's cooling fans force hot air over the waveguides, which consequently show thermal aging over time and periodically must be replaced. Compared to the single-port solar simulators, the multiport systems (Fig. 42.3) show a comparable magnitude of spectral variability per waveguide from year to year.

To compare solar simulators within the framework of COLIPA, we analyzed all data for each solar simulator, or multiport light guide, throughout the period of measurement and calculated the mean COLIPA results along with the standard deviation. This we have replotted (Fig. 42.4) within the %RCEE limits for all COLIPA ranges plus an additional non-COLIPA category for UV-A longer than 350 nm.

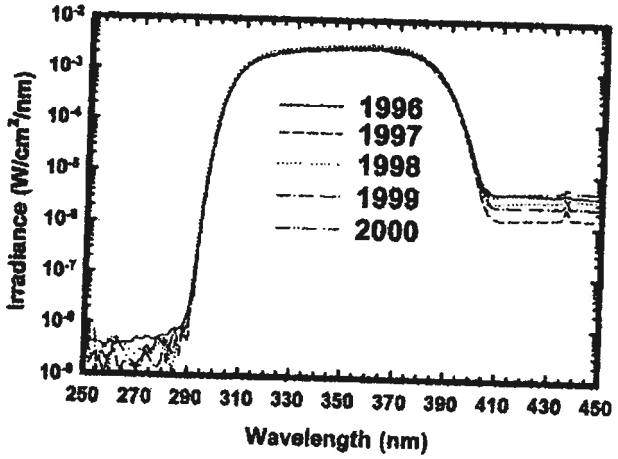

Figure 42.1 Spectral measurements collected on a typically configured Solar Light single-port solar simulator. For over 5 years, with regular maintenance, there was little detectable change in spectral cutoff or distribution over the 290–350 nm range and only slight variation in power level. Typical configuration consists of a 150 W ozone-free xenon arc combined with a WG-320 short-wavelength cutoff filter and a UG-11 UV band pass filter to limit visible emission.

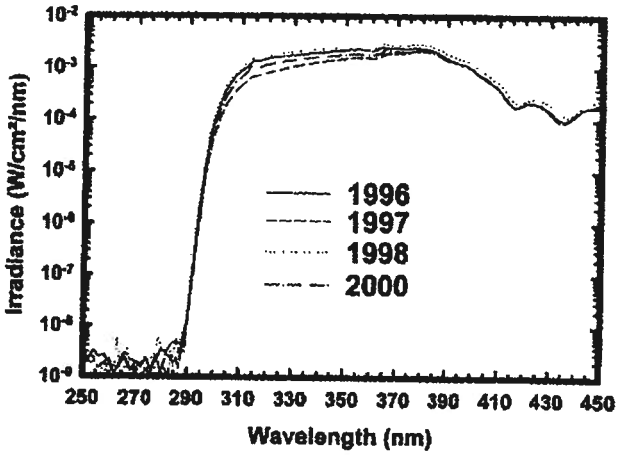

Figure 42.2 Spectral measurement series of a UG-5 single-port solar simulator. Over the measurement period reported, there is some variation in the 295–370 nm range, which does not appear to be a function of measurement interval. This configuration uses a UG-5 bandpass filter which does not limit visible emission to the same extent as the UG-11.

For the single-port solar simulators (Fig. 42.4A), stray radiation of <290 nm is in the lower half of the range allowed. In the 290–310 nm range, some diversity is observed. Over the next four ranges, the data for individual single-port systems are consistently in the upper acceptable range tending to push the limit. For the final non-COLIPA range of UV-A longer than 350 nm, all single-port solar simulators are at the bottom of the range allowed, that is, they have significantly less UV-A-1.

For the multiport solar simulator (Fig. 42.4B), stray radiation of <290 nm for all waveguides is also in the lower half of the range allowed. For the 290–310 nm range, there is some diversity, but unlike the single ports the waveguides all lie at the bottom of the limit range. In the 290–320 nm range, the waveguides lie just below midlimit range. Over the next three ranges, the data for individual waveguides are uniformly in the middle of the acceptable range. For the final non-COLIPA range of UV-A longer than 350 nm, all solar waveguides are at the middle of the range allowed, still there is significantly less UV-A-1.

DISCUSSION

The solar simulators presented in this study are all commercial units. All units are used daily and are well maintained. From the presentation of this set of representative solar simulators at six laboratories, it is clear that these devices not only are consistently compliant but also have changed very little even with extensive

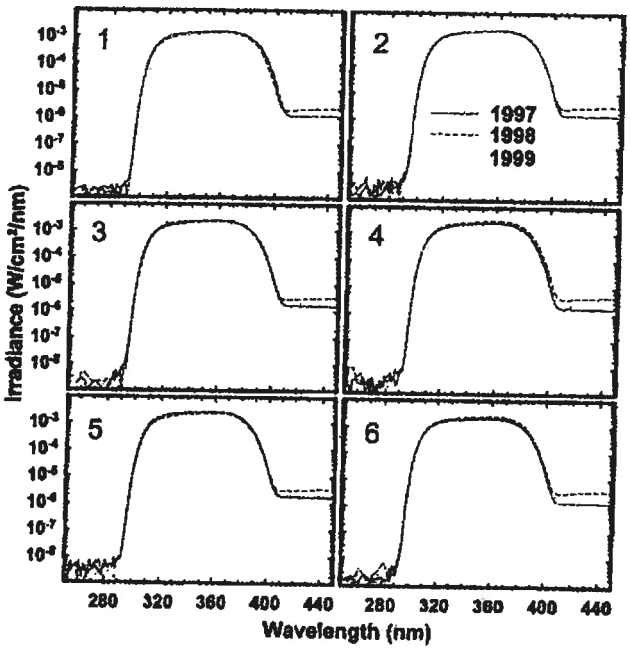

Figure 42.3 Characteristic multiport solar simulator spectral series. This model solar simulator is arrayed with six identical sets of optics (1–6) incorporating liquid light guides in addition to the usual WG-320 and UG-5 filter combination. Through several cycles of annual remeasurement, the multiport solar simulators showed spectral distribution and variability similar to comparably filtered single-port systems.

usage during the years reported. In spite of periodic lamp replacement, the long-term changes to individual solar simulators or between different solar simulators at various locations have all been minor. However, because many systems appear to push limits, it is critical that exacting standards of measurement are followed. It is equally important that the spectral radiometric equipment be rigorously maintained and precise checks performed in association with each measurement made.

It is unlikely that within this particular grouping of instruments, with the possible exception of the UG-5 system, any test might be different because of the particular solar simulator used. However, with only a single multiport solar simulator being included in this review, potentially the multiport type may be less stable from year to year because of the optical complexity of maintaining waveguides and in essence having six independent optical systems potentially aging at different rates.

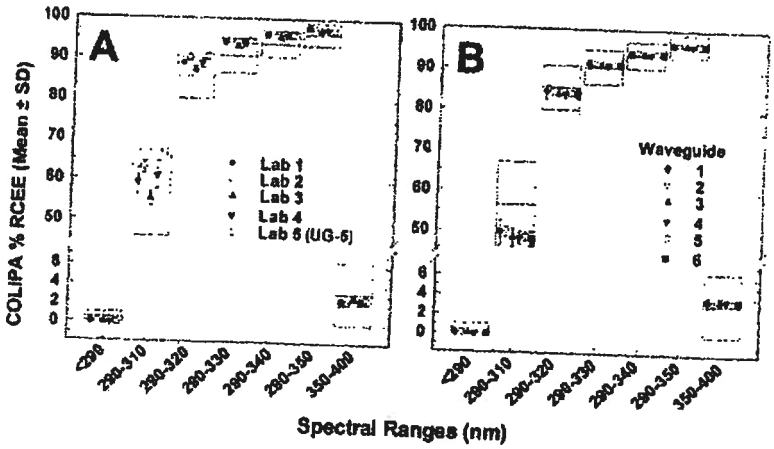

Figure 42.4 Comparison of single-port and multiport solar simulators. To compare solar simulators over time within the framework of COLIPA, we have analyzed all data throughout the period of measurement for each single-port solar simulator (A) or multiport waveguide (B). The mean COLIPA %RCEE results along with the standard deviation calculated are shown within the COLIPA limit range for all ranges. The single-port solar simulators all invariably push the maximum limits of the acceptable COLIPA ranges. An additional non-COLIPA >350 nm range shows that neither type of solar simulator appears to have abundant levels of UV-A-1 radiation.

In this review we have shown that a particular set of solar simulators have successfully been maintained to a rather tight and reproducible spectral profile over a period of years. However, the emission limits of the COLIPA specification have been suggested as being too broad (8). This was demonstrated by the failure of identical products to produce comparable SPFs when tested with solar simulators at opposite ends of the COLIPA acceptance limits (11). With proper maintenance, solar simulators should be able to meet a tighter revised standard in the future.

CONCLUSION

The spectral standardization of solar simulators used for sunscreen SPF testing is important because the resulting SPF of a sunscreen product should be independent of the solar simulator used for testing, the testing location, and the date tested. Spectral standards for solar simulators used for SPF testing are specified within the requirements of the 1978, and subsequent, US FDA sunscreen monographs and the 1994 COLIPA SPF test method. Most solar simulators employed in sunscreen testing by reputable US and Canadian laboratories have been routinely monitored for compliance with applicable standards for many years. This retrospective presents a compilation of solar simulator compliance data

from six participating North American SPF testing laboratories over a 5-year period from 1995 to 2000. During this period solar simulators, with proper laboratory maintenance have met the standard(s) and have continued to do so from year to year even when used daily.

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Spectral Standardization of Sources Used for Sunscreen Testing: 5 Years of Compliance

Robert M. Sayre and John C. Dowdy

Rapid Precision Testing Laboratories, Cordova, Tennessee and University of Tennessee Center for the Health Sciences, Memphis, Tennessee, USA

INTRODUCTION

In 1978, the US FDA published a report and monograph on sunscreen product testing and labeling (1). This monograph established that a solar simulator would be a source having a continuous emission spectrum from 290 to 400 nm and be filtered for a solar zenith angle of 10° and have less than 1% of its

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Spectral irradiance measurements were made at 1 nm intervals from 250 to 800 nm. Data were saved to magnetic media and identified using a portion of

the solar simulator site/serial number to establish the identity of the system measured. The center of the beam at the site for irradiating human volunteers was selected for spectroradiometric measurement and represents the highest intensity to which a human volunteer might be exposed. A special plug-in aperture was used to position the liquid waveguides of multiport solar simulators.

The final quality control check, conducted after solar simulator spectral irradiance measurements, consisted of repeating all checks performed prior to calibration. The result of this check and the subsequent recalibration of the system with the tungsten standard source indicate that the spectral radiometer functioned the same throughout this period of measurement.

Measurement Uncertainty

Our estimate is that the total possible uncertainty for measuring a solar simulator is less than 12% (Table 42.2). The major sources of uncertainty, potentially up to 10%, is that which may be attributed to reproducible positioning of the spectroradiometer relative to the source and to changing laboratory environments. The uncertainty from changing laboratory environments is due to different levels of electronic noise, temperature, and humidity between laboratories and the same laboratory from visit to visit.

RESULTS

A typical Solar Light single-port solar simulator, used for sunscreen SPF testing, consists of a 150 W ozone-free xenon arc which is filtered with a WG-320 filter

Table 42.2 Measurement Uncertainty Factors

Uncertainty factor	Uncertainty (%)	Uncertainty squared
1. Standard lamp uncertainty to NIST	2	0.0004000
2. Calibration transfer to spectroradiometer	3	0.0009000
3. Stray radiation	0.10	0.0000010
4. Nonlinearity of response throughout measurement range	1	0.0001000
5. Wavelength uncertainty	0.20	0.0000040
6. Wavelength repeatability	1	0.0001000
7. Noise in measurements	0.10	0.0000010
8. Reproducibility of measurements	1	0.0001000
9. Source positioning uncertainty	5	0.0025000
10. Laboratory environment	10	0.0100000
Sum quadrature uncertainties		0.0141060
Uncertainty		11.88%

of appropriate thickness and generally a UG-11 to remove excess visible. A set of representative spectral measurements collected on a typically configured single-port solar simulator (Fig. 42.1) show from year to year that there has not been much change in spectral distribution and only very slight variation in power level. Only one solar simulator using the less common configuration of a UG-5 filter in place of the usual UG-11 (Fig. 42.2) was monitored in this study. Over the years there appear to be some minor changes in the UV-B distribution; however, this variation is not progressing from year to year.

The other type of solar simulator commonly used for sunscreen SPF testing in North America is the Solar Light multiport. It has six complete sets of optics, configured with WG-320 and UG-11 filters, and six waveguides. The multiport's cooling fans force hot air over the waveguides, which consequently show thermal aging over time and periodically must be replaced. Compared to the single-port solar simulators, the multiport systems (Fig. 42.3) show a comparable magnitude of spectral variability per waveguide from year to year.

To compare solar simulators within the framework of COLIPA, we analyzed all data for each solar simulator, or multiport light guide, throughout the period of measurement and calculated the mean COLIPA results along with the standard deviation. This we have replotted (Fig. 42.4) within the %RCEE limits for all COLIPA ranges plus an additional non-COLIPA category for UV-A longer than 350 nm.

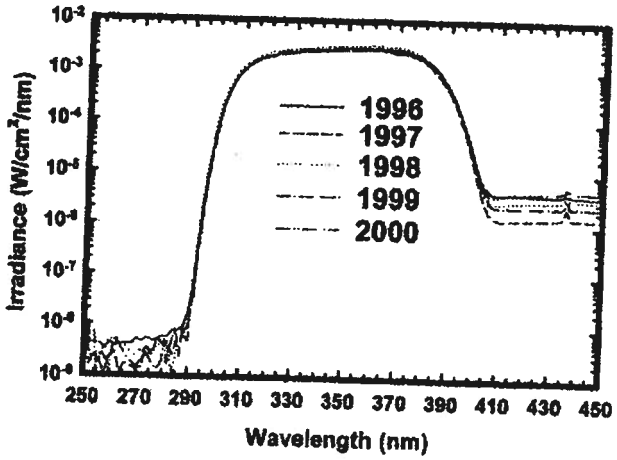

Figure 42.1 Spectral measurements collected on a typically configured Solar Light single-port solar simulator. For over 5 years, with regular maintenance, there was little detectable change in spectral cutoff or distribution over the 290–350 nm range and only slight variation in power level. Typical configuration consists of a 150 W ozone-free xenon arc combined with a WG-320 short-wavelength cutoff filter and a UG-11 UV band pass filter to limit visible emission.

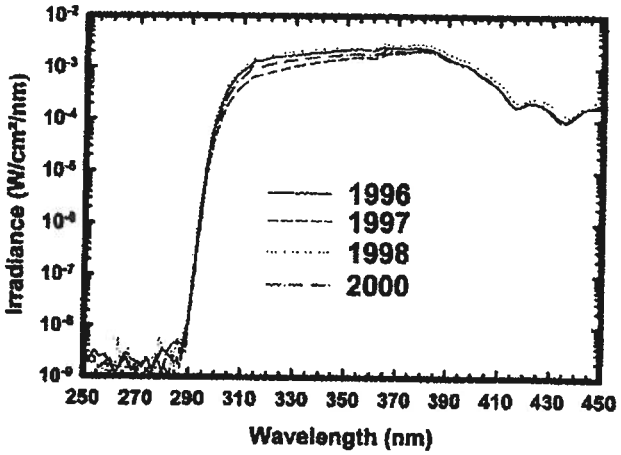

Figure 42.2 Spectral measurement series of a UG-5 single-port solar simulator. Over the measurement period reported, there is some variation in the 295–370 nm range, which does not appear to be a function of measurement interval. This configuration uses a UG-5 bandpass filter which does not limit visible emission to the same extent as the UG-11.

For the single-port solar simulators (Fig. 42.4A), stray radiation of <290 nm is in the lower half of the range allowed. In the 290–310 nm range, some diversity is observed. Over the next four ranges, the data for individual single-port systems are consistently in the upper acceptable range tending to push the limit. For the final non-COLIPA range of UV-A longer than 350 nm, all single-port solar simulators are at the bottom of the range allowed, that is, they have significantly less UV-A-1.

For the multiport solar simulator (Fig. 42.4B), stray radiation of <290 nm for all waveguides is also in the lower half of the range allowed. For the 290–310 nm range, there is some diversity, but unlike the single ports the waveguides all lie at the bottom of the limit range. In the 290–320 nm range, the waveguides lie just below midlimit range. Over the next three ranges, the data for individual waveguides are uniformly in the middle of the acceptable range. For the final non-COLIPA range of UV-A longer than 350 nm, all solar waveguides are at the middle of the range allowed, still there is significantly less UV-A-1.

DISCUSSION

The solar simulators presented in this study are all commercial units. All units are used daily and are well maintained. From the presentation of this set of representative solar simulators at six laboratories, it is clear that these devices not only are consistently compliant but also have changed very little even with extensive

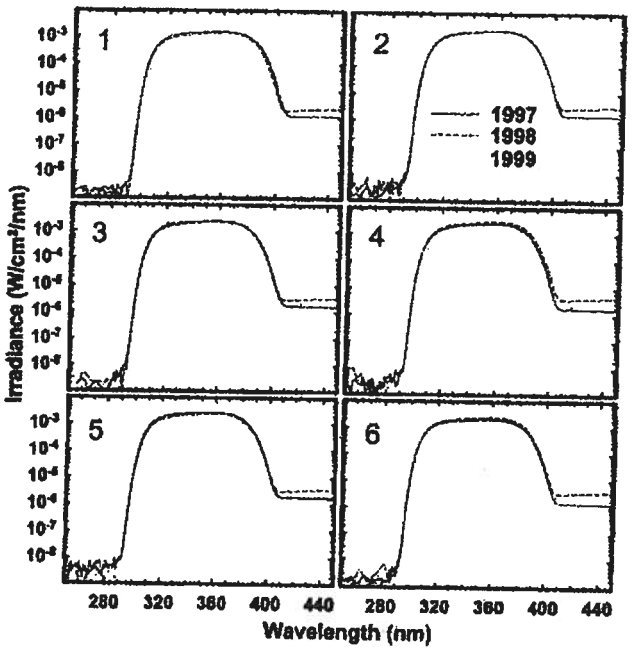

Figure 42.3 Characteristic multiport solar simulator spectral series. This model solar simulator is arrayed with six identical sets of optics (1–6) incorporating liquid light guides in addition to the usual WG-320 and UG-5 filter combination. Through several cycles of annual remeasurement, the multiport solar simulators showed spectral distribution and variability similar to comparably filtered single-port systems.

usage during the years reported. In spite of periodic lamp replacement, the long-term changes to individual solar simulators or between different solar simulators at various locations have all been minor. However, because many systems appear to push limits, it is critical that exacting standards of measurement are followed. It is equally important that the spectral radiometric equipment be rigorously maintained and precise checks performed in association with each measurement made.

It is unlikely that within this particular grouping of instruments, with the possible exception of the UG-5 system, any test might be different because of the particular solar simulator used. However, with only a single multiport solar simulator being included in this review, potentially the multiport type may be less stable from year to year because of the optical complexity of maintaining waveguides and in essence having six independent optical systems potentially aging at different rates.

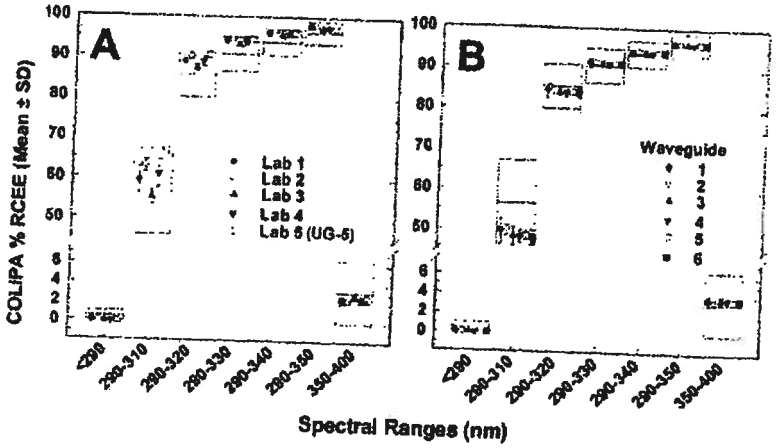

Figure 42.4 Comparison of single-port and multiport solar simulators. To compare solar simulators over time within the framework of COLIPA, we have analyzed all data throughout the period of measurement for each single-port solar simulator (A) or multiport waveguide (B). The mean COLIPA %RCEE results along with the standard deviation calculated are shown within the COLIPA limit range for all ranges. The single-port solar simulators all invariably push the maximum limits of the acceptable COLIPA ranges. An additional non-COLIPA >350 nm range shows that neither type of solar simulator appears to have abundant levels of UV-A-1 radiation.

In this review we have shown that a particular set of solar simulators have successfully been maintained to a rather tight and reproducible spectral profile over a period of years. However, the emission limits of the COLIPA specification have been suggested as being too broad (8). This was demonstrated by the failure of identical products to produce comparable SPFs when tested with solar simulators at opposite ends of the COLIPA acceptance limits (11). With proper maintenance, solar simulators should be able to meet a tighter revised standard in the future.

CONCLUSION

The spectral standardization of solar simulators used for sunscreen SPF testing is important because the resulting SPF of a sunscreen product should be independent of the solar simulator used for testing, the testing location, and the date tested. Spectral standards for solar simulators used for SPF testing are specified within the requirements of the 1978, and subsequent, US FDA sunscreen monographs and the 1994 COLIPA SPF test method. Most solar simulators employed in sunscreen testing by reputable US and Canadian laboratories have been routinely monitored for compliance with applicable standards for many years. This retrospective presents a compilation of solar simulator compliance data

from six participating North American SPF testing laboratories over a 5-year period from 1995 to 2000. During this period solar simulators, with proper laboratory maintenance have met the standard(s) and have continued to do so from year to year even when used daily.

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APPENDIX D: Spectrophotometer Bandwidth Analysis

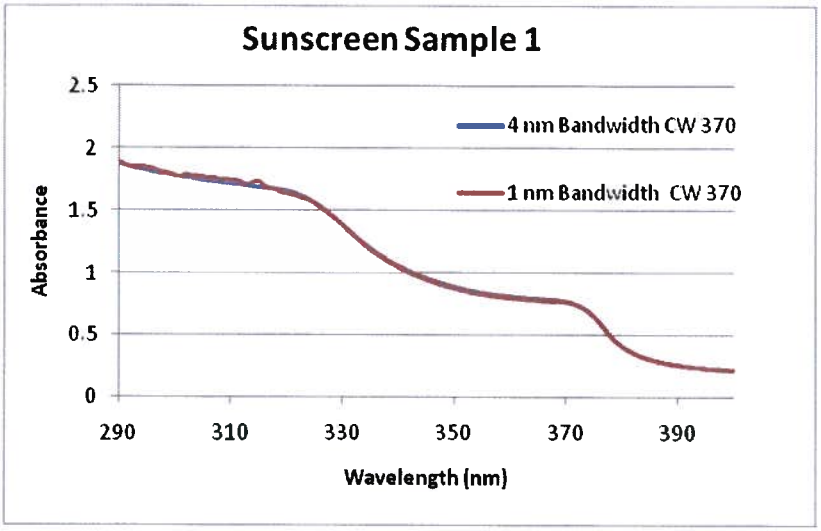
Spectrophotometer Bandwidth Analysis

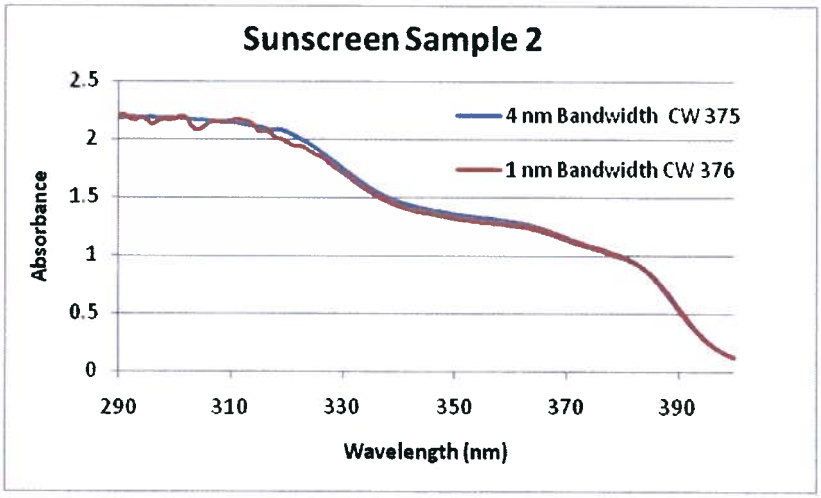
To demonstrate that reducing the instrument bandwidth below 4nm doesn't help with achieving more accurate results for critical wavelength 9 commercially available sunscreens were tested per the Agencies Federal Register Notice: "Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use" issued June 14, 2011, (using 6um surface roughness PMMA plates with 0.75mg/cm2 of sunscreen) on a Perkin Elmer Model Lambda 900 double monochromator spectrophotometer with slits set for 4 nm or 1 nm. Results show that the Critical wavelength value obtained with 4nm and 1nm bandwidths for all nine samples are virtually identical (within 1 nm of each other). Summary of measurement results and measurement set-up is provided below. It is noted in the samples with high absorbance values, the noise is noticeable in the curves with the reduced 1 nm bandwidth, seriously compromising with the overall dynamic range of the instrument and could lead to errors in the determination of the Critical Wavelength. These data are kindly provided by Labsphere , Inc., a manufacturer of spectrophotometric instrumentation used throughout the sunscreen industry for thin film *in vitro* sunscreen absorbance testing.

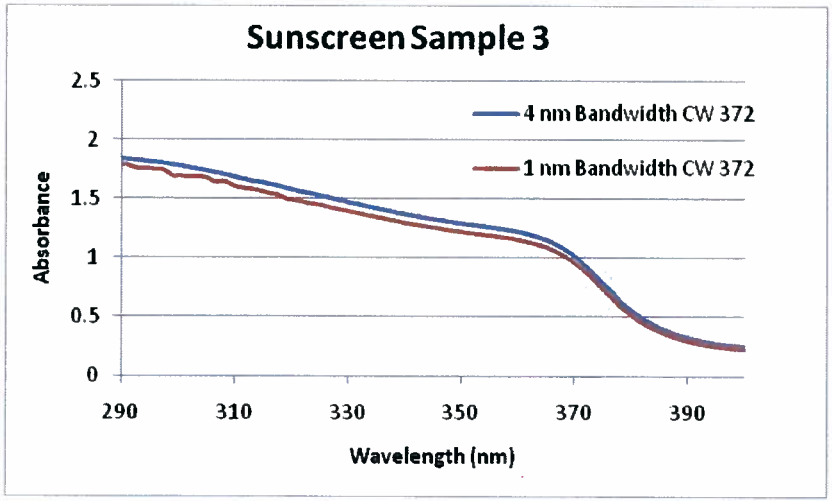
Absorbance data Interval: *1nm for all samples*

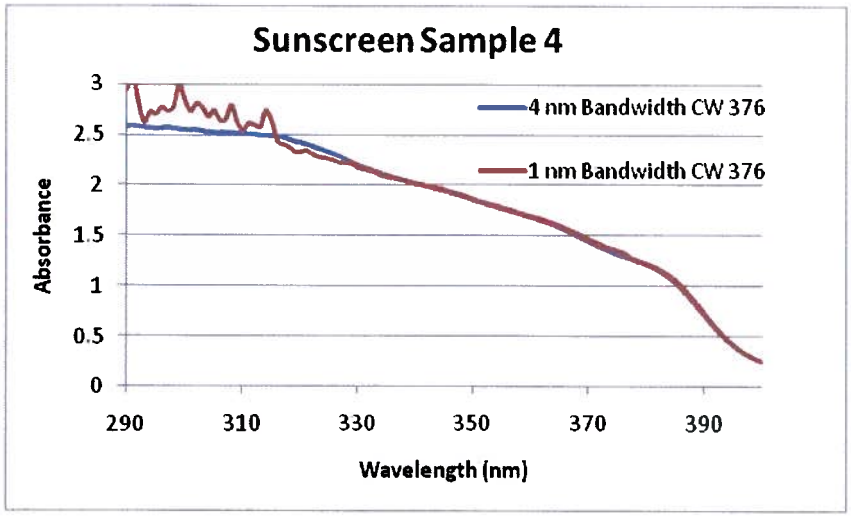
Critical Wavelength Results

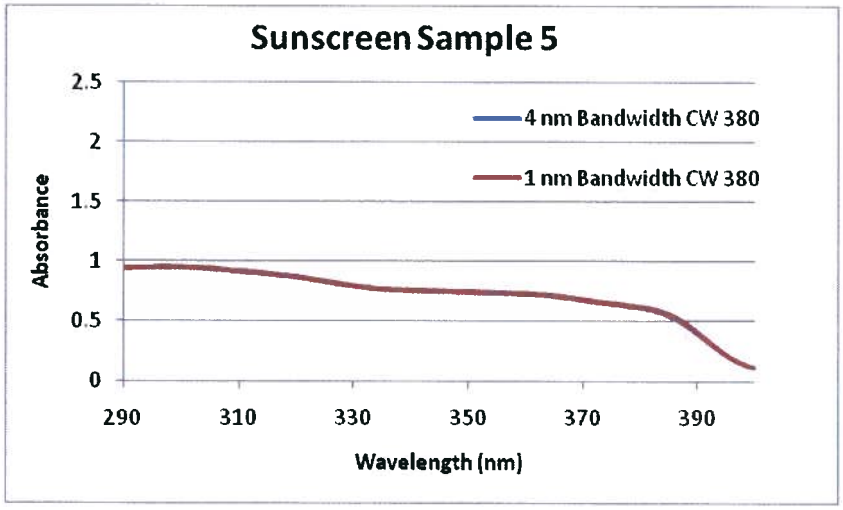
Sunscreen Sample #	Bandwidth (1 nm)	Bandwidth (4 nm)
1	370 nm	370 nm
2	376 nm	375 nm
3	372 nm	372 nm
4	376 nm	376 nm
5	380 nm	380 nm
6	361 nm	361 nm
7	380 nm	379 nm
8	363 nm	364 nm
9	374 nm	374 nm

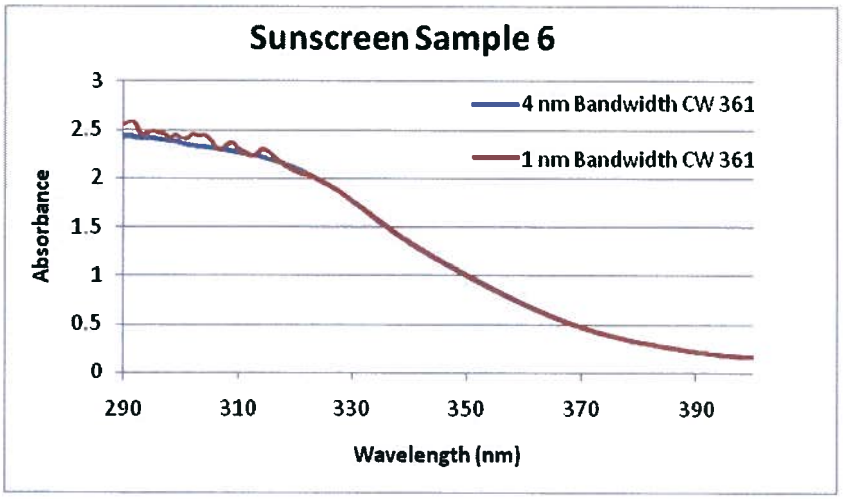

Sunscreen Sample 1
2.5
2
1.5
1
0.5
0
Absorbance
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 370
1 nm Bandwidth CW 370

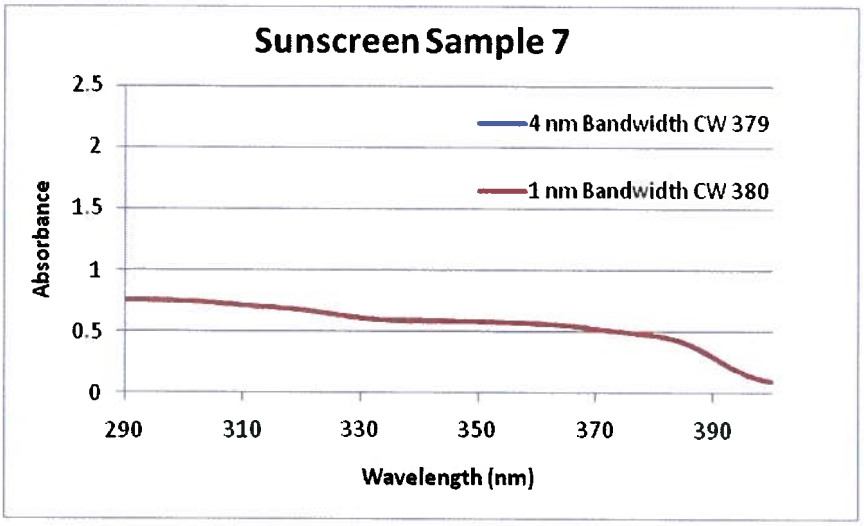

Sunscreen Sample 2
2.5
2
1.5
1
0.5
0
Absorbance
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 375
1 nm Bandwidth CW 376

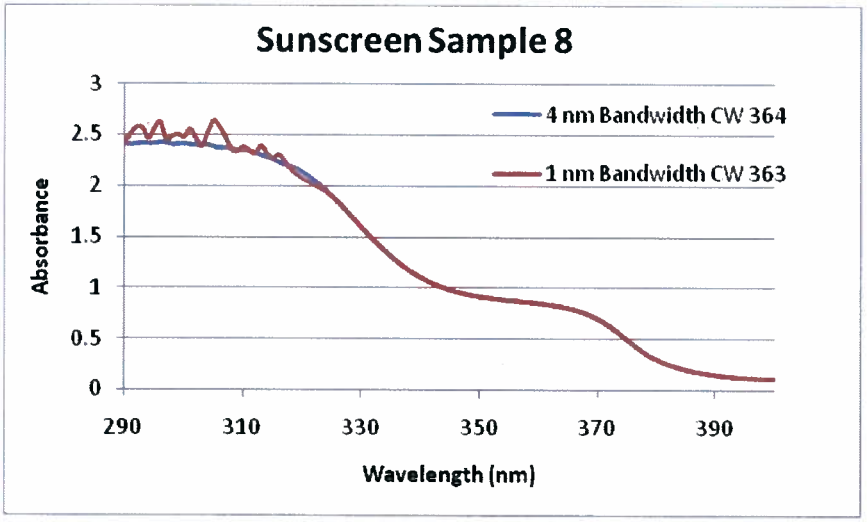

Sunscreen Sample 3
2.5
2
1.5
1
0.5
0
Absorbance
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 372
1 nm Bandwidth CW 372

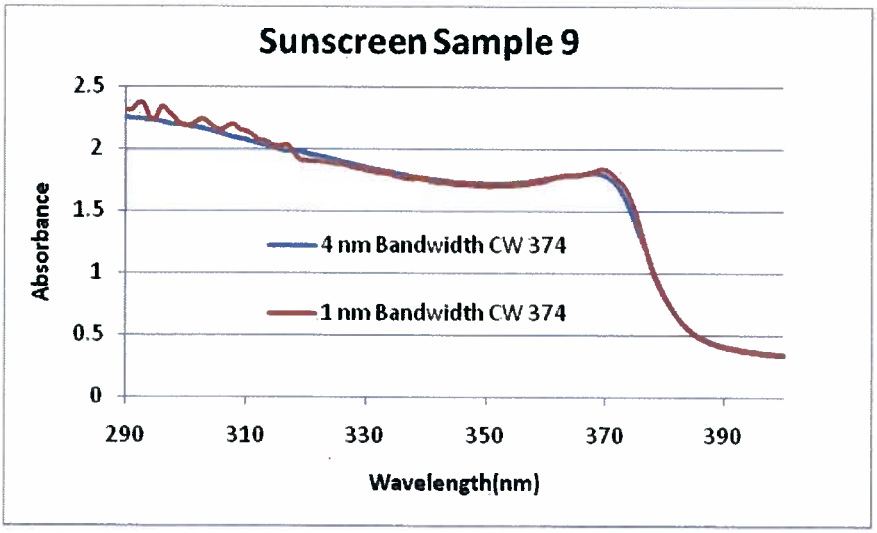

Sunscreen Sample 4
Absorbance
3
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 376
1 nm Bandwidth CW 376


Sunscreen Sample 5
Absorbance
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 380
1 nm Bandwidth CW 380


Sunscreen Sample 6
Absorbance
3
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 361
1 nm Bandwidth CW 361


Sunscreen Sample 7
Absorbance
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 379
1 nm Bandwidth CW 380


Sunscreen Sample 8
Absorbance
3
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength (nm)
4 nm Bandwidth CW 364
1 nm Bandwidth CW 363


Sunscreen Sample 9
Absorbance
2.5
2
1.5
1
0.5
0
290
310
330
350
370
390
Wavelength(nm)
4 nm Bandwidth CW 374
1 nm Bandwidth CW 374

APPENDIX E: Labeling samples for "regular size" products

BROAD SPECTRUM SUNSCREEN
WATER RESISTANT
UNCARTONED

DRUG FACT BOX FROM FDA
(USING STANDARD FORMAT)

DRUG FACT BOX RECOMMENDATION

SCALE 1:1

1 in

WILL MEASURE 1 in WHEN
PRINTED OR VIEWED AT 100%

BROAD SPECTRUM SUNSCREEN
WATER RESISTANT
UNCARTONED

DRUG FACT BOX FROM FDA
(USING STANDARD FORMAT)

DRUG FACT BOX RECOMMENDATION

SCALE 1:1

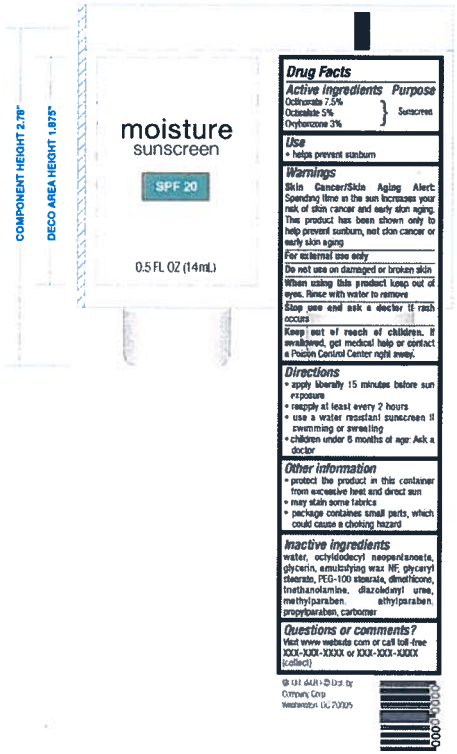
1 in

WILL MEASURE 1 in WHEN
PRINTED OR VIEWED AT 100%.

APPENDIX F: Labeling for small size tube without outer carton

SMALL SIZE OTC PRODUCT
NOT BROAD SPECTRUM, NOT WATER RESISTANT
UNCARTONED

DRUG FACT BOX FROM FDA
(USING STANDARD FORMAT)



DRUG FACT BOX RECOMMENDATION

SCALE 1:1

1 in

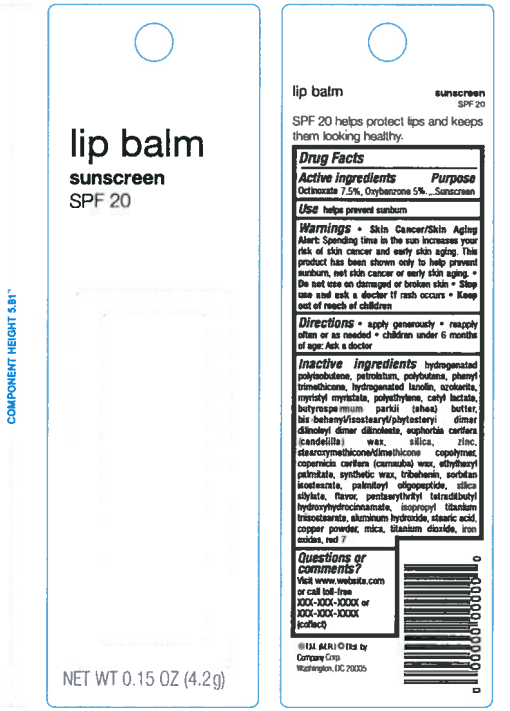
WILL MEASURE 1 in WHEN
PRINTED OR VIEWED AT 100%

APPENDIX G: Labeling for small size tube with and without outer carton

LIP PRODUCT WITH SUNSCREEN
SECONDARY COMPONENT (BLISTER CARD)

DRUG FACT BOX FROM FDA
(USING STANDARD FORMAT)

DRUG FACT BOX RECOMMENDATION



SCALE 1:1

1 in

WILL MEASURE 1 in WHEN
PRINTED OR VIEWED AT 100%

LIP PRODUCT WITH SUNSCREEN
UNCARTONED

DRUG FACT BOX FROM FDA
(USING STANDARD FORMAT)

COMPONENT 2.84"

DECO AREA 1.47"

DRUG FACT BOX RECOMMENDATION

COMPONENT 2.84"

DECO AREA 1.47"

SCALE 1:1

1 in

WILL MEASURE 1 in WHEN
PRINTED OR VIEWED AT 100%