Consumers Union
Nonprofit Publisher of Consumer Reports

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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
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Comments of Consumers Union of America
to the Food and Drug Administration
21 CFR Parts 347 and 352
"Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph"
Proposed Rule
Docket No. 1978N-0038
RIN 0910-AF43

Introduction

Consumers Union (CU), non-profit publisher of *Consumer Reports* and *Consumer Reports Online*, submits the following comments in response to the Food and Drug Administration's ("FDA" or "Agency") proposed rule, "Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph" (Proposed Rule).[1]

Summary

In general, CU supports the Proposed Rule, and the potential for many of the proposed changes to spur better-informed and safer use of sunscreens by consumers. We urge the FDA to act quickly to finalize the proposed changes, and we strongly urge the agency to take a proactive approach, and require labeling (*i.e.*, disclosure when products contain nano-sized particles) and testing of sunscreens that use nano-sized ingredients. Our specific comments and recommendations are detailed below:

[1] 72 Fed. Reg. 49070 (August 27, 2007).

Section II - Summary of Major Changes to the Final Monograph

B. UVB (SPF) Labeling

The FDA has proposed labeling that makes it clear that SPF refers to protection against UVB radiation and replacing the term "sun protection" with "sunburn protection." We agree that this would enhance consumer understanding of this parameter. CU also agrees with the proposal to increase the maximum allowable SPF claim from 30+ to 50+ and we concur with the addition of verbiage that allows consumers to compare products' relative effectiveness on a scale of low, medium, high and highest sunburn protection.

C. UVA Labeling

Current product label claims pertaining to UVA protection are too vague, and do not enable consumers to determine whether a given product provides a meaningful level of UVA protection. Furthermore, CU's own test results show that UVA protection can vary substantially among products. We, therefore, agree with the FDA's proposed requirement to include labeling that designates the level of UVA protection along with a descriptor (*i.e.*, low, medium, high or highest). The proposed four-star designation seems as if it will adequately convey to consumers the product's level of UVA protection. We also agree with the proposal to mandate that manufacturers inform consumers if their product fails to provide any UVA protection.

F. Directions

We are pleased with the proposed changes designed to address the under-application of sunscreen products by consumers – especially when compared to the amount of sunscreen used in laboratory efficacy tests worldwide. As the FDA has noted, it is well documented that consumers tend to apply much less than the 2 milligrams per square centimeter used in SPF and PPD testing. Reduced amounts in the neighborhood of 1/3 to 1/2 of the laboratory application rate have been reported. Consumers' use of these lower amounts significantly reduces actual protection in direct proportion to how much less sunscreen is actually applied. Accordingly, labeled SPF and future PFA labeling may give users a false sense of protection. Manufacturers need to provide consumers with directions that provide clear guidance on how much sunscreen to apply. In the alternative, labeling should be based on laboratory tests that are conducted using application rates that more closely resemble actual consumer behavior.

The FDA has proposed including directions to apply sunscreens "liberally" or "generously." CU does not consider these terms to be clear enough to ensure safe sunscreen use, because most consumers will not have a good sense of what these terms mean in practice. Unless or until a new validated protocol using reduced application rates is required, consumers should be informed, in the directions, that a typical adult should apply 2-3 tablespoons of sunscreen (one ounce) over their entire

body. Similarly, more descriptive directions should be included specifically for toddlers and young children. We realize that this could require a lot of text on a product's label, however, we believe this information is critical for consumers. This information also could effectively be expressed by listing the minimum dosage and total number of applications in the bottle, along with the phrase "sun protection depends on using a sufficient amount." Because of widespread consumer misunderstanding as to the need to apply sunscreen liberally to exposed areas, we ask that the FDA consider mounting an education campaign to inform consumers about the amount of sunscreen they should apply. In addition, if manufacturers would like to provide additional information, one possibility might be for the them to reference a web address that consumers could go to for more detailed information on product use.

We also are concerned about results from recent studies indicating that consumers may mistakenly extend the time they spend in the sun -- beyond what appropriate -- when using a higher SPF product. For example, some consumers who normally burn in ten minutes might use an SPF15 product, stay in the sun for 150 minutes, and then re-apply, thinking they can remain in the sun for another 150 minute period. We therefore encourage FDA to require the following language: "higher SPF products give more sun protection but, even with repeated application, are not intended to extend the time spent in the sun beyond what is indicated by the sun protection factor." Some of this language has been proposed as optional. (See p. 49087, third column).

H. UVA Testing

CU agrees with the proposal to require UVA testing and labeling. The proposed combination of in-vitro and in-vivo tests is very similar to what CU used for our July 2007 *Consumer Reports* sunscreen report (attached)[2]. We concur with the addition of pre-exposure to a sunlight simulator for the in-vitro test to measure possible photo-degradation of active ingredient effectiveness. We encourage the FDA to consider supporting the development of a similar photo-degradation test for the in-vivo UVA protection test. CU also agrees with the requirement of UVA testing after water immersion as is currently done for the SPF test.

Section III – FDA's Tentative Conclusions on the Comments

A. General Comments

We understand that manufacturers will need time to comply with the monograph once it is finalized. The FDA is proposing a deadline of 18-24 months. Manufacturers will have had a great deal of advance notice to prepare to meet the final monograph's requirements – provisions that will improve consumer understanding and safety. We believe that an 18-24 month time frame may be excessive. We suggest, instead, a shorter one-year implementation date as being in the best interest of the consumer.

[2] "Sunscreens, Some are short on protection," *Consumer Reports*, July 2007, p. 6.

G. Comments on Indications for Sunscreen Drug Products

We agree with the breakdown of the relative SPF values as listed (low = SPF 2 to <15, medium = SPF 15 to <30, high = SPF 30 to 50 and highest = SPF >50).

H. Comments on Directions for Sunscreen Drug Products

We agree that reapplication directions are needed and that people should be told to reapply every 2 hours or sooner depending on the actual water resistance claim (e.g. 40 or 80 minutes). Because, as recognized by most manufacturers, safe use requires reapplication after swimming and vigorous exercise, we recommend that labels be required to include this statement.

I. General Comments on SPF Testing Procedure

We agree that consumers can certainly use claimed SPF to compare relative sunscreen efficacy and we note that the FDA recognizes that SPF values do not reflect exact levels of sunburn protection. However, we urge the FDA to go a step further than merely inviting interested parties to submit data to support a lower application rate for sunscreen testing. We recommend that the FDA **actively** foster a coordinated effort between regulatory agencies in different countries around the world to develop a test protocol based on a lower application rate that is validated to an appropriate level of precision and reproducibility.

In addition, because of the large variability between test subjects, current SPF test methods require a large number of subjects. For manufacturers and, more importantly, for consumer organizations such as CU that test many products at one time, having a pass/fail (binomial) test to confirm SPF claims made by sunscreen products would be an enormous benefit from a cost and timing point of view. We, therefore, recommend that the FDA **actively** sponsor a forum and, if necessary, a test development effort to define such a method so that it can be incorporated into the revised monograph in a timely manner.

CU's Additional Concerns

Use of Nano-particles in Sunscreens

CU[3] and other consumer advocacy organizations recently have expressed major concerns about the lack of labeling and safety information pertaining to the use and effects of nano-particles (typically Zinc Oxide and Titanium Dioxide) in sunscreens. Studies show, and experts worldwide agree, that ingredients formulated at the nano-scale can have biological activity and availability that differs significantly from larger

[3] See "Nanotechnology Untold promise, unknown risk," *Consumer Reports*, July 2007, p. 40-45 (attached).

sized counterparts, with meaningful impacts on risks to exposed biological systems[4]. CU strongly urges the FDA to increase its oversight of the use of nano-size ingredients in sunscreen formulations and other consumer products. We are very concerned with the FDA's reliance on the results of toxicity assessments for larger sized ingredients as a means for assessing risks from nano-scale ingredients. In order enable consumers to exercise meaningful choice as to whether to use sunscreens with nano-sized ingredients, and to ensure the safety of the use of nano-scale ingredients, the FDA should require manufacturers to: (1) label any products formulated with nano-engineered ingredients and disclose when products contain nano-sized particles, and (2) submit results of safety tests performed with the nano-sized ingredients to the FDA to demonstrate that their products will not pose health risks.

Toxicity Testing for Additional Sunscreen Ingredients

The FDA also should require complete toxicity testing for other sunscreen ingredients such as menthyl anthranilate, homosalate, and octisalate, which continue to lack comprehensive toxicological profiles despite signs of potential harm in limited laboratory tests.

Effects of Sunscreen Ingredients on Other Personal Care Products

We are also concerned about the effects of sunscreen ingredients on the bioavailability of other ingredients in personal care products. We urge the FDA to promptly investigate recent findings that some sunscreen formulations can increase dermal absorption of insect repellant ingredients such as DEET, which often are used in combination with sunscreens.[5]

[4] Royal Society and the Royal Academy of Engineering, July 2004, Nanoscience and Nanotechnologies. ISBN 0 85403 604 0, Royal Society, London, at http://www.nanotec.org.uk/; Swiss Reinsurance Company, "Nanotechnology: Small Matter, Many Unknowns" (2004), http://www.swissre.com/.

[5] Brand, RM, L. McMahon, JL Jendrzejewski, AR Charron. 2007. Transdermal absorption of the herbicide 2.4-dichlorophenoxyacetic acid is enhanced by both ethanol consumption and sunscreen application. *Food Chem Toxicol* 45 (1):93-7; Gu,X, T Wang, DM Collins, S Kasichayanula, FJ Burczynski, 2005. In vitro evaluation of concurrent use of commercially available insect repellent and sunscreen preparations. *Br J Dermatol* 152(6):1263-7. Brand, RM., J Pike, RM Wilson, AR Charron. 2003. Sunscreens containing physical UV blockers can increase transdermal absorption of pesticides. *Toxicol In Health* 19(1):9-16.

Conclusion

We appreciate the FDA's proposal, and the potential for many of these changes to spur better informed and safer use of sunscreens by consumers. We urge the FDA to act quickly to implement the proposed changes, and we strongly urge the agency to take a proactive approach to requiring labeling (*i.e.*, disclosure when products contain nano-sized particles) and testing of sunscreens that use nano-sized ingredients.

Respectfully submitted,



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