CITIZEN PETITION

The undersigned, on behalf of SolRx Global, Inc. submits this petition under the Federal Food, Drug, and Cosmetic Act ("the FDC Act") and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs amend the water resistance testing procedures in new 21 C.F.R. § 201.327(i)(7) to allow for continuation of the water exposure regimen beyond the 80 minute total and to allow that the "water resistance" claims be expanded beyond 80 minutes for products meeting such testing requirements.

This amendment is especially necessary where, as here, the OTC Sunscreen products meeting such expanded testing requirements have been conceived, formulated and marketed to offer superior water resistance (i.e., "superior" to the 80 minute FDA allowed "water resistance" claim) for "Active" sunscreen products in order to meet the SPF protection needs of water and endurance athletes.

A. Action Requested

This petition requests that FDA amend its regulation on the OTC sunscreen testing procedure for "Water Resistance", 21 C.F.R. § 201.327(i)(7), to allow for continuation of the water exposure regimen beyond the 80 minute total and to allow expanded water resistance claims beyond 80 minutes for "active" sunscreen products meeting such testing requirements under the extended testing regimen. See Attachment A for current and proposed format.

Currently, FDA has set an 80 minute upper exposure limit for water resistance claims on OTC sunscreen product labeling. This petition requests no change to the FDA’s water resistance procedure’s controlled conditions or testing parameters, i.e. the 20-minute water immersion periods. The petition merely requests that 21 C.F.R. § 201.327(i)(7) be amended to allow for a continued water exposure regimen beyond the current 80 minute upper exposure limit (consisting of four, 20-minute immersion periods). Extending the water exposure regimen would allow testing protocols (and claims based upon meeting parameters) such as AMA Laboratories, Inc.’s
“Evaluation of Sun Protection By SPF Determination – 480 Minute Water Resistant” protocol. The requested amendment will make it easier for “active” consumers seeking products with superior water resistance. The proposed extended testing protocols and label claims will help active water, endurance and other athlete-consumers have a more accurate and informed understanding of water resistance as a part of their purchase decision.

The relevant portions of supporting References (listed in footnotes) have been attached per the instructions listed in 21 C.F.R. § 10.20(c) (1), and are included in Attachment B.

B. Statement of Grounds

1. Introduction

SolRx Global, Inc. is an Own Label Distributor of high performance “active” OTC sunscreen products. The firm’s entire manufacturing process is performed by Contracted Facilities, subject to current Good Manufacturing Practices (cGMPs).

2. Regulatory Background

Per Federal Register of June 17, 2011 (76 Fed. Reg. 35620), the Agency published its Final Rule which included new testing and labeling requirements for Over-the-Counter (OTC) sunscreen drug products. The Final Rule states, in part, that:

[i]n this document, [FDA is] specifically identifying [certain] claims as not allowed on any OTC sunscreen product...[c]laims for “all-day” protection or extended wear claims citing a specific number of hours of protection that are inconsistent with the directions for application in 21 C.F.R. § 201.327.

76 Fed. Reg. 35643 (June 17, 2011)

FDA regulations currently state an upper exposure limit for testing the “water resistance” of OTC sunscreen drug products at “Water Resistant (80 minutes)”. Specifically the Agency states that:

[f]or products that provide 80 minutes of water resistance according to the test in [21 C.F.R. § 201.327(i)(7)(ii)]. The [Principal Display Panel of product] labeling states “Water Resistant (80 minutes).”

21 C.F.R. § 201.327(a)(2)(ii)
The labeling of the product should contain the following statements, as appropriate, under the heading “Directions.” More detailed directions applicable to a particular product formulation may also be included. For products satisfying the water resistant testing in FDA’s new regulations [“Water Resistant (80 minutes)”] in 21 C.F.R. § 201.327(i)(7)(ii), the product labeling should state the following:

- Reapply:
  - After [80 minutes] of swimming or sweating
  - Immediately after towel drying
  - At least every 2 hours

21 C.F.R. § 201.327(e)(3)

FDA has reaffirmed the critical importance of water resistance testing to sunscreen consumers and has laid out the newly modified testing procedures in new 21 C.F.R. § 201.327. According to 76 Fed. Reg. 35628 (June 17, 2011), the Agency has well-founded reasoning for its affirmation of water resistance testing:

The water resistance test indicates that a sunscreen’s product’s labeled SPF protection is retained for a certain period of time after immersion in the water. This is useful information to consumers. Therefore [FDA concluded] that a water resistance statement based

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In 64 Fed. Reg. 27666 (May 21, 1999), FDA allowed comments to the proposed Final Rule governing (at the time) Water Resistant Labeling and Testing for Sunscreen Drug Products. Comment 34 was discussed by the Agency, as there was data presented which supported the expansion of the water exposure regimen beyond an 80-minute total and suggested that the [now stated, “Water Resistant (80 minutes)”] claim be expanded beyond 80 minutes for products meeting such testing requirements. See, 64 Fed. Reg. 27676 (May 21, 1999) (stating that the Agency did not concur with the expansion of water resistance claims beyond the 80-minute total,
"[a]lthough data submitted by the comment (Ref. 24) show that under testing conditions products may retain their SPF values for up to 270 minutes of water exposure, no usage data were presented to refute the Panel's determination of an 80 minute upper exposure limit."

3. **Consumer behaviors dictate that extended water resistance testing and claims will help protect during long periods of swimming and sun exposure.**

Consumer behaviors in reapplying sunscreens are lacking, in spite of well-established knowledge and consumer health education. Sunscreen labeling since 1978 has always included the need for sunscreen reapplication. Dermatologists and the AAD along with sunscreen manufacturers have stressed the importance of reapplication for over 30 years. Despite these facts, a majority of adults and adolescents do not reapply sunscreen. The results of a nation-wide telephone survey of adults showed that 35% do not reapply sunscreen, even when they have been exposed to the sun for an entire day. Similarly, of the 67% of teenagers who apply sunscreens at least a quarter of the time they go out in the sun, 38% never or rarely reapplied sunscreen after swimming. Sunscreen products formulated and verified by testing to have superior water resistance (i.e., 270-minute or 480-minute water resistance) can help to better protect consumers who do not reapply and can help compensate for consumer under-application.

4. **Athletes and Water Sportsmen are at increased risk for UV penetration and sunburn due to longer periods in water, longer sun exposure periods and lack of consistent reapplication.**

Athletes, water sportsmen and other consumers who consistently engage in physical activity and sweating are at increased risk of UV ray exposure, UV ray penetration and sunburn due to longer periods in the water, longer sun exposure periods and lack of consistent reapplication. Endurance athletes such as cyclists and triathlon athletes are particularly at risk—at the collegiate, professional or lower competitive levels. A survey of 186 NCAA college

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athletes revealed that none reapplied sunscreen during practice or training sessions \(^5\), and a survey of 64 professional cyclists showed that only 8% reapplied sunscreen during a 3-5 hour ride.\(^6\)

The combination of high temperatures and long periods in the sun makes sunburn a common problem in triathlons, Ironman and other endurance events. Ironman entrants in the 1999 World Championships in Hawaii were exposed during the course of the day to eight times the dose of UV light that is thought sufficient to cause sunburn on normal white skin.\(^7\) Endurance athletes spend significantly more time in the sun vis-à-vis other consumers and even other high-intensity athletes. In 2011, the men’s world record time for completing the fastest Ironman triathlon race was 7 hours, 45 minutes, 58 seconds, and in the same race the women’s championship time was 8 hours, 43 minutes, 34 seconds.\(^8\)

In addition to sunburn and increased UV exposure, these types of activities and rigorous lifestyle demands of high-intensity athletes may increase UV penetration into the skin. It has been demonstrated that swimming, physical activity and sweating may increase UV penetration and facilitate the erythemal reaction, resulting in up to a 40% reduction in ultraviolet energy required to produce one MED.\(^9\) FDA water-resistance testing protocols allowing for continuation of water exposure regimen beyond 80-minute total would affirm the sunscreen products formulated for superior water resistance and allowing water resistance claims beyond 80-minutes would identify these products to consumers.

Current SolRx® sunscreen products, along with certain other products on the market, have been conceived and formulated for superior water resistance to meet the lifestyle demands of high-intensity athletes, water sportsmen and other consumers engaged in active outdoor endeavors. The attached proposed testing protocols have shown consistently that SolRx® sunscreen products are water resistant for a 480-minute water immersion period. The protocol, established by AMA Laboratories, has consistently verified that these sunscreens will perform at

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virtually full SPF-rating throughout the 480-minute testing period, and during a re-SPF test performed after completion of the 480 minutes. See Attachment A.

5. Conclusion

Consumer behaviors in reapplying sunscreens are lacking, and data shows this to be true even after consumers have been swimming and exposed to the sun all day. Athletes are particularly lacking reapplication of sunscreen during activities, as has been shown by studies of collegiate athletes, professional cyclists and triathlon competitors. Data shows that physical activity, swimming and sweating may even increase UV penetration. Furthermore, high-intensity athletes at all levels of competition engaged in physical activity and sweating are at increased risk for UV exposure and sunburn due to longer exposure periods and lack of reapplication. Allowing sunscreen manufacturers to extend water resistance testing protocols beyond the 80-minute limit and to label the products passing these extended protocols with superior water resistance claims will help protect consumers and help active consumers make more informed purchase decisions regarding water resistance and SPF protection of the sunscreens they intend to use during physical activity, in or out of the water.

Consumers, especially athletes or those engaging in physical activity need to be able to select and purchase sunscreen products with superior water resistance to achieve maximum sun protection from sun exposure. The U.S. Skin Cancer Foundation recognizes this need for distinction between “daily-use” and “active” sunscreen products. The Foundation’s “Seal of Recommendation Program” requires more stringent protection standards for “active products” than for “daily use products”—i.e., active products are designed to protect consumers from extended sun exposure or during recreational activities. As such these products require proof of water resistance, a key parameter of sun protection. This petition merely posits that FDA should allow extended water resistance testing protocols and label claims to similarly distinguish high performance, water resistant sunscreens (beyond the 80-minute limit) from sunscreens at 80-minutes or below. This petition offers testing protocols from a well-established SPF laboratory with years of industry experience in extended water resistance testing. The lab has taken FDA’s water resistance testing protocol (see Federal Register, June 17, 2011) and continued the water exposure regimen beyond 80-minutes to 480-minutes of immersion. The protocol has consistently verified that SolRx® sunscreen products tested will perform at virtually full SPF-rating throughout the 480-minute testing period and during a re-SPF test following completion of the 480-minute testing period.

Sunscreen manufacturers should continue to educate consumers about a comprehensive sun protection strategy, including that water resistant sunscreens are only part of that strategy, in

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addition to covering up with clothing and hats, and where possible avoiding mid-day sun, seeking shade, and avoiding unnecessary sun exposure. At the same time, the consumer should be offered sunscreen products with labeled and tested water resistance beyond 80-minutes, in order that they can make an informed purchase decision based upon their individual needs and intended usage (i.e., they should be given the opportunity to distinguish between “daily use” and “active products,” in that active products would possess superior water resistance to meet the demanding lifestyle of high intensity athletes and water sportsmen).

Appropriately tested and labeled sunscreen products with extended (beyond 80-minutes) water resistance should be available to consumers who need or desire a higher level of protection, particularly athletes or others who engage in lengthy periods of swimming, physical activity and sweating—i.e., those who are at increased risk of UV ray exposure, penetration and sunburn due to water immersion, longer sun exposure periods, and / or lack of consistent reapplication. By capping the water resistance testing and claims at 80-minutes, many consumers will be left without the ability to purchase sunscreen products suitable to their more active, rigorous lifestyles – resulting in less than sufficient sun protection levels.

C. Environmental Impact

According to 21 C.F.R. § 25.30(k), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

D. Economic Impact

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Tim Ewing
President / Owner
SolRx Global, Inc.

Attachments

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