August 13, 2003

1572 '03 AUG 14 A9:16

Dockets Management Branch(HFA-305)
Food and Drug Administration
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T A N N I N G
R E S E A R C H
LABORATORIES, INC.

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Re; Sunscreen Monograph, Docket No. 78N-0038

Dear Sir/Madam:

Attached is data indicating the photostability of several commercial sunscreen products and experimental Tanning Research Laboratories, Inc. (TRLI) products, as well as other comments. There are photostability comparisons of selected products in actual outdoor sun conditions and simulated spectra such as the COLIPA spectra for SPF testing and the JCIA spectra for in vivo testing.

Summarizing, the data show that unless a sunscreen product is photostable the tested and labeled SPF may be a miss-representation of the product's protective ability in actual sunlight. Likewise, the proposed in vivo and in vitro UVA tests may be overrated. The data indicates that in some cases the product's sunscreens have degraded and no longer absorb UV radiation. Clearly photolabile compounds do not satisfy the agencies "safety and efficacy" requirements for drug compounds.

Based on the attached photostability summary and previous comments made by TRLI and others, and reiterated herein, I am asking that the agency take the following monograph actions:

1) Require that all sunscreen products be photostable. Photostability must be tested in the sun or with spectra that mimics the sun. Neither the COLIPA SPF spectra nor the JCIA spectra are adequate. SPF can only be deemed accurate if the product is photostable.
SPF 30 products should be judged photostable if they maintain a minimum of 75% residual sunscreen as analyzed by HPLC, and if the critical wavelength as measured by in vitro monochromatic devices remains constant after exposure to 15 Minimum Erythemal Doses (MEDs) of natural sunlight. SPF's lower than 30 should be subject to the same acceptance criteria after exposure to the number of MEDs corresponding to approximately ½ of their labeled SPF. For example a SPF 15 should maintain its efficacy after exposure to 8 MEDs of natural sunlight.

78N-0038 C602

Ron Rice Beach Products

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2) Adopt the Pass/Fail test proposed in previous submissions. Additional data is supplied and referenced in this writing. The test is safer to test subjects, and provides a more conservative estimate of SPF based on true product protection rather than test failure as does the present SPF test. Since any reaction, erythema, tanning, or PPD, is considered a test failure it is a true indicator of "broad spectrum" protection.

3) Adopt the suggested changes to the SPF method that deal with UV Spectra as petitioned by Dr. Robert Sayre on November 7, 2001.

4) Allow unlimited SPFs. The two primary objections to SPFs higher than 30 were the relatively small increases in absorption as SPFs increased, and the concern of topical application of increasing amounts of chemical sunscreens to gain the higher numbers. Many US products may be over labeled due to the photostability issue discussed in item 1, and the fact that the high UVB solar simulator output produces SPFs higher than would be achieved in the actual sun.[1] However, even when these two factors are corrected based on this petition, the fact remains that consumers only use a fraction of the quantity utilized in the SPF test. SPF is an exponential function resulting in a rapid decrease in SPF when less than the tested quantity is used.[2,3,4] Also, with the use of photostable sunscreen combinations, less sunscreen actives are required to produce high SPFs. There is simply no practical reason to arbitrarily limit the amount of protection afforded to the public.

5) Do not require separate UVA testing and labeling. This is actually not needed if items 1 and 2 above are adopted, and if all products above SPF 15 are required to have a UVA sunscreen such as Avobenzone, but if a test is required and the product is photostable, a simple in vitro analysis and a 370 nm critical wavelength is adequate.

The changes proposed herein will require a great deal of industry expense and time. However, the changes suggested in this petition would produce less economic impact than the expected changes generated by the final sunscreen monograph scheduled in December of 2003, assuming it is like the 1999 Sunscreen Monograph with UVA testing and labeling added. Therefore previous FDA considerations under the Unfunded Mandates Reform Act and Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612) should be valid for actions per this petition. It is important that other scientists evaluate this petition and comment. A great deal of work needs to be done in the

area of photostability. However, we believe these issues are very important to consumer health, and think the agency should proceed with a monograph containing these recommendations in a reasonable time period. Previous comments by the petitioner have described the product development time needs.

Thank you in advance for considering this petition. Clearly protection from sun over exposure is extremely important. Consumers must be encouraged to do their part, apply and reapply sunscreen frequently, and we must do our part to make more efficacious and thus safer sunscreens. The health of all exposed to the sun is at stake.

Sincerely,

Dennis E Lott
VP Technical Affairs
Tanning Research Laboratories, Inc.

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