



November, 12, 2002

Beiersdorf AG, Postal Address D-20245 Hamburg

Street Address:
Unnastrasse 48, D-20253 Hamburg

US Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville MD 20852

Telephone +49-40-49 09-0
Telefax +49-40-49 09 34 34

Your Ref./Your Letter **RE: Docket 78N-0038: Sunscreen Drug Products for Over the Counter**
Human use: Final Monograph; Partial Stay; Final Rule

The Food and Drug Administration (FDA) has extended the effective date for the final monograph for over-the-counter (OTC) sunscreen drug products and requested for comments on key technical and labeling issues related to sunscreen products. These issues were outlined by FDA in the December 31, 2001 Federal Register. The agency has requested interested parties to provide specific types of data and information which would allow identification and adoption of a standard UVA testing procedure, along with a clear way to present UVA protection information in labeling to consumers.

Herewith we propose a new in vitro method to determine the potency of UVA protection in sunscreens. Validity and relevance of the method are shown with the example of the correlation to in vivo PPD data. The reproducibility was demonstrated in a Round Robin study with five marketed sunscreens which were measured in seven laboratories. The key steps in the proposed method are the simple transmission measurement through a sunscreen layer and secondly the inclusion of the labeled SPF into the calculation.

The resulting UVA INDEX represents both the broadness of UV protection i.e. the relation between UVA and UVB protection and also the amplitude of the UVA protection. The method covers several aspects required by authorities and experts and which is in agreement with former submissions: The sun protection factor (SPF) remains the main information about the effectiveness of the sunscreen. Consumers should select the appropriate sunscreen according to it. It should be guaranteed that the UVA protection is increasing with increasing UVB protection. A comprehensive and clear labeling can be derived from the UVA INDEX.

As an in vitro method the proposal avoids any damaging or changes in the skin of human volunteers. The determination of the UVA INDEX does not require any invasive step neither the invasive sampling to determine an physiological endpoint nor the invasion of high intensive UVA light to induce the endpoint. The proposal is a relevant alternative test procedure to in vivo assays.

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With this submission we want to contribute to the debate on UVA protection measurement and labeling and we hope that this information will assist your completion of a final

monograph. Should the Agency have any questions or comments on the information and data contained herein, please direct them to the undersigned.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Kenton". The signature is fluid and cursive, with a large loop at the end.

Jim Kenton.
- President -
Beiersdorf Inc.

Desk copies: Dr. Ganley
Dr. Wilkin