



DEPARTMENT OF THE ARMY  
U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE  
5158 BLACKHAWK ROAD  
ABERDEEN PROVING GROUND, MARYLAND 21010-5403

48 100 SEP -5 110 36

REPLY TO  
ATTENTION OF

Laser/Optical Radiation Program

August 23, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
RE: Sunscreen Drug Products (FR Vol. 65, No. 111, June 8, 2000)

This letter is to respond to your request for comments related to Docket No 78N-0038 on the subject of Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph. As a medical physicist working in the field of public health and protection against optical radiation hazards, I thought it would be helpful to provide the following general comments. I serve as Director of Division 6 (Photobiology and Photochemistry) of the CIE and also on the International Commission on Non-Ionizing Radiation (ICNIRP), where the subject of sunscreens is frequently addressed.

Two technical committees of CIE Division 6, as well as other organizations have been grappling with the problem of recommending a reasonable test procedure for the latest generation of broad spectrum sunscreens to protect the skin against solar ultraviolet radiation. Several very interesting sessions dealt with this problem at least indirectly at the recent International Congress on Photobiology held in San Francisco (California, 1-6 July 2000). There appears to be a growing consensus that the typical level of application of sunscreens by the general public ranges from 0.5 to 0.8 mg/cm<sup>2</sup> regardless of public education programs which recommend "liberal application of the sunscreen." The test procedures for sunscreens were developed with an eye toward improving reliability and accuracy of the SPF measurement by requiring an application rate of 2 mg/cm<sup>2</sup>. A number of experts in the field of photodermatology and public health have remarked at the ICP and at other meetings that the actual protection afforded to the public by the application of current sunscreens is typically only about 1/4 of the SPF rating, and certainly no more than 1/2 of the rating on the bottle. This certainly is not meant to be a criticism of the industry, nor the government regulators, nor the public health community. It is simply recognizing current practice. When I spoke to some specialists who perform testing about this at the ICP, they re-emphasized that the 2 mg/cm<sup>2</sup> application level was developed at a time when

*Readiness thru Health*

78N-0038

C 570

the products in use at the time spread unevenly, and this method was thought to be required to attain reproducibility of testing. However, with today's products, some now feel that the application rate could be reduced at least to 1 mg/cm<sup>2</sup> if not to 0.5 mg/cm<sup>2</sup>. There are several reasons to at least consider amending the test method to require a lighter application.

From a public health standpoint, it certainly is not advisable that we continue the current situation where the *de facto* SPF, the actual SPF, of applied sunscreens is greatly less than what the given rating may be. In discussing this problem with a number of scientists and physicians at the ICP, there was a general (but not unanimous) agreement that the test method should be changed and that one of the benefits would be that the current difficulties of performing *in vivo* tests with high SPF's due to excessive thermal load on the skin, would be greatly reduced. A number of experts argued against changing the actual rating scheme with which the public has become familiar, even if the test methods are changed. Certainly if the public health community currently agrees that we do not wish individuals to prolong their exposure by the SPF factor, and we wish only a generic index, this would not be a problem. However, at the same time, I have been present at meetings where it has been argued that we do not need to recommend SPF's above a given value because a person would not receive more than X MED's in any one day. If we look at a typical sunscreen formulation of 15, and recognize that in a typical application, it is providing only an SPF of about 4, there is no question that an MED may result in many environments. One MED certainly exceeds current recommendations for chronic repeated exposure of workers in either an indoor or outdoor workplace. Indeed, it could be argued that if the seemingly high SPF's of 30 or 60 represent only SPF's of 7 – 15. These may not be fully protective for the shoulders and other surfaces exposed directly to the sun for outdoor workers.

As I see it the public health and occupational health communities are now faced with several very fundamental questions, which are somewhat dependent upon how sunscreens are tested and how SPF values are determined. These more fundamental questions need to be answered before we can be comfortable in providing future guidance to outdoor workers:

1. Should guidelines for clothing and sunscreens be quantitatively based on the assumption that the lowest achievable ultraviolet radiation exposure should be the goal? Neither I nor Dr. Jan van der Leun (Utrecht) and others feel that this approach is valid based upon the beneficial effects of low-level ultraviolet radiation. I did not hear any strong comments in favor of aiming at such a conservative approach at the ICP.

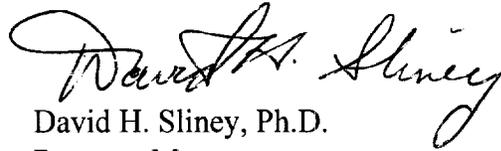
2. If there is an optimum range of UVR exposure, what level is this? The current ICNIRP and ACGIH guidance to limit exposure for workers is approximately .67 SED or about 1/3 MED and this has been argued to largely protect against inadequate DNA repair. Certainly I did not hear any suggestion that one minimal erythemal dose per day was acceptably low to preclude delayed effects.

Recognizing current attitudes of fashion in the western world, it is unlikely that any public health or occupational health program can achieve a very conservative exposure goal, however, it would certainly be useful to reconsider the SPF concept with an aim to provide the consumer with a more realistic and meaningful message. The impact of SPF numbering can have a significant public health impact and that perhaps the test method needs to be changed and

the numbering of SPF be reconsidered. Perhaps, light, moderate and heavy protection would provide more meaning. .

I would be happy to discuss this issue in greater detail with FDA staff persons deliberating on these issues. I can be contacted at (410) 436-3002.

Sincerely,

A handwritten signature in cursive script that reads "David H. Sliney". The signature is written in black ink and is positioned above the printed name and title.

David H. Sliney, Ph.D.  
Program Manager  
Laser/Optical Radiation Program  
USACHPPM  
Director, Division 6, CIE  
Chairman, Sub-Committee 4 on  
Optical Radiation, ICNIRP

4x4

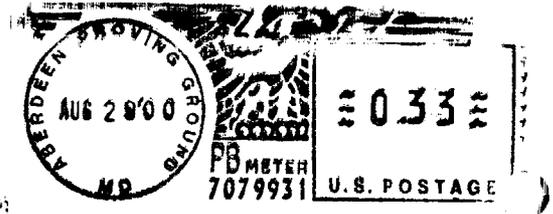
**DEPARTMENT OF THE ARMY**

COMMANDER  
USACHPPM  
ATTN MCHB-TS-OLO  
APG MD 21010-5403

ABERDEEN PROVING GROUND, MD ~~21010~~

OFFICIAL BUSINESS

AN EQUAL OPPORTUNITY EMPLOYER



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

**FIRST CLASS**

115

20852+0001

