

Rama I. Mani, Ph.D.
Department of Chemistry
Tennessee State University
Nashville, TN 37209-1561

AUG 22 1990

Dear Dr. Mani:

This is in response to your letter dated July 28, 1990, in which you requested clarification of an article published in BUSINESS WEEK (June 11, 1990) that mentioned my name in connection with the evaluation of the effectiveness of sunscreens in blocking UVA rays. After reading a letter written by Pat Pelot Sanders which was printed in your local newspaper, the TENNESSEAN, you wrote a letter to the editor based on information from the article mentioned above and stated that "So far, the only product to win FDA approval for its UV-A coverage is Photoplex, a product of Allergan Inc." You also stated that Ms. Sanders submitted another letter to the editor of the TENNESSEAN, refuting your statement about Photoplex being the only FDA-approved product for UVA coverage and stating that several pharmaceutical companies, including Med Derm Inc. in Kingsport, Tennessee via its product Aquaray, had products with sunscreens for blocking both UVA and UVB rays, which had FDA approval.

Your statement is basically correct. The only product that currently has official FDA approval for its UVA coverage is Photoplex, a product of Allergan, Inc.'s Herbert Laboratories located in Santa Ana, CA. However, at this time other products may also have UVA claims in their labeling provided they contain certain active ingredients included in the FDA's over-the-counter (OTC) drug review for sunscreen drug products and they meet the agency's enforcement policy which allows certain claims (previously available prior to the beginning of the OTC drug review) to appear in labeling until the rulemaking for that class of OTC drug products is completed. The rulemaking for OTC sunscreen drug products has not been completed to date. The agency hopes to publish a tentative final monograph for OTC sunscreen drug products in about 6 months. That proposal will further discuss UVA claims for OTC sunscreen drug products.

I hope this information will be helpful to you.

Sincerely yours,

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drug Evaluation and Research

cc: HFD-210:DDC-940.1/Deputy
HFD-213:(sunscreen TFM):Mason
R/D:SMason:8/8/90:#0239r
Init:AMustafa:8/9/90
Edited:GRachanow:WEGilbertson:8/13/90
Init:GRachanow:8/20/90
F/T:WEGilbertson:sam:8/20//90

~~WJG~~
GR

Dr. Rama I. Mani
Department of Chemistry
Tennessee State University
Nashville, Tenn. 37209-1561

July 28 1990

Dr. William E. Gilbertson,
Food and Drug Administration,
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Gilbertson,

Recently, I read an article in Business Week (June 11, 1990) where your name is mentioned in connection with the evaluation of the effectiveness of sunscreens in blocking UV-A rays. Based on what I read in the article, I wrote a letter to the editor of the Tennessean, the local newspaper, in which I stated, among other things, that so far the only product to win FDA approval for its UV-A coverage is Photoplex, a product of Allergan Inc., Santa Ana, California.

This statement of mine was questioned by Pat Pelot Sanders who, on July 25, wrote a letter to the Tennessean mentioning that Aquaray, a product of Med Derm Inc. has FDA approval for blocking both UV-A and UV-B rays and is about half the price of Photoplex.

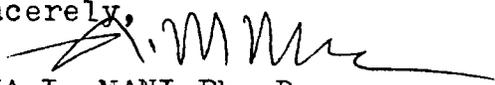
She also sent me a promotion material for Aquaray. Separately, she made a note on the envelope that the Med Derm Inc. may have information about carcinogens in some other sunscreens especially Photoplex.

For your convenience, I am enclosing copies of:

- a) the Business Week article, my source;
- b) my letter to the editor of the Tennessean (July 1);
- c) Pat Pelot Sanders's letters (June 9, July 25);
- d) promotion material for Aquaray.

I would very much appreciate a clarification from you. This would greatly facilitate my response to Ms. Sanders's letter ^{of July 25} in which the validity of my statement regarding Photoplex has been questioned.

Sincerely,


RAMA I. MANI Ph. D.
Professor of Chemistry

COSMETICS

SUN PROTECTION? THERE'S A RUB

The FDA is taking a hard look at claims for some products

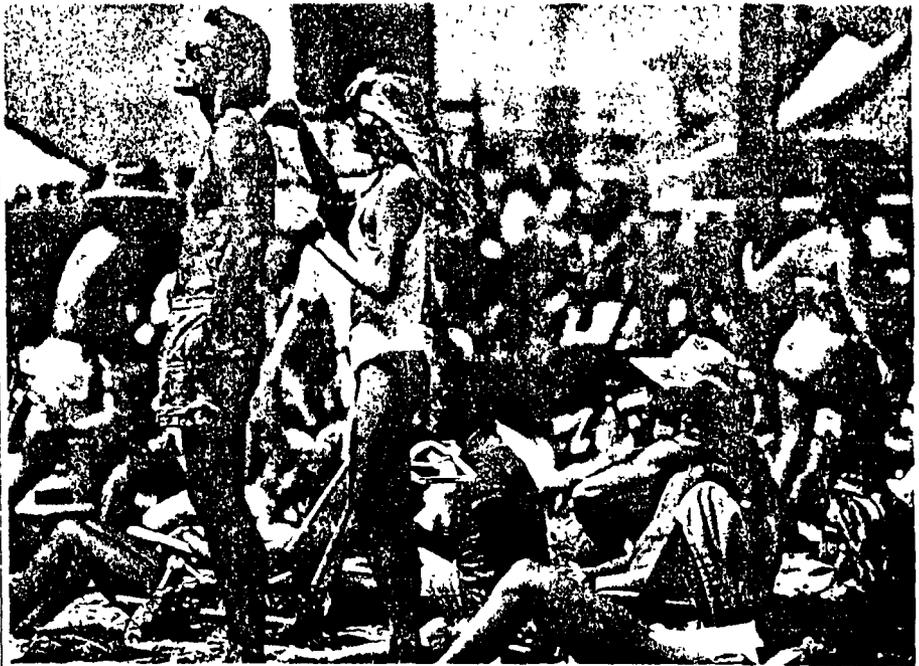
At the Beach 'n' Bikinis shop in Santa Cruz, Calif., rows of sun-care potions stand at attention ready to renew their annual war against the sun's rays. Here, as in stores across the country, it's no longer tanning oils and lotions leading the charge. Most consumers now reach for sunscreens such as Banana Boat's level 29 sunblock for babies, and Hair Guard, which helps keep dyed blondes from turning orange.

That's good news for consumers trying to stave off premature aging and even cancer. And it's good news for an industry that has enjoyed 20% annual sales growth since the mid-1980s. But some companies may get burned because of the claims they've been making.

WAVES OF CLAIMS. The Food & Drug Administration is increasingly concerned that some sun-care and cosmetic outfits are misleading the public about the ultraviolet radiation protection their products provide. Earlier this year, the agency sent "feedback" letters to Schering-Plough's Memphis-based HealthCare Products division, Westwood Pharmaceuticals in Buffalo, and Mary Kay Cosmetics in Dallas. While not regulatory

actions, the letters sternly reminded the companies that claims they and other manufacturers make of blocking so-called UV-A rays are "unsubstantiated."

Most sunscreens block UV-B rays, shorter-wavelength radiation that causes sunburn and some skin cancers. The longer UV-A rays were once thought to be safe but growing evidence shows they "contribute to aging, cancer, and cataracts," notes Brian L. Ripperre, an



IN THE DARK: THE FDA HASN'T SET A STANDARD FOR ULTRAVIOLET-A BLOCKERS

That makes Herbert Labs President

A. Thomas Bender furious. "We paid our dues," he fumes, including a three-year review process that added \$1 million to development costs. He vows to press the FDA to crack down on his less-panstaking rivals. "These companies," he says, "just changed their marketing."

Indeed, most companies admit they haven't added new ingredients. They've simply added the claim based on their own measures of UV-A protection. Many of those claims could be "misleading and confusing," notes William E. Gilbertson, director of the FDA's division of over-the-counter drug evaluation, in his letter to Schering-Plough Corp. He singles out Schering-Plough's Shade brand, which could "lead consumers to believe that they are obtaining a greater degree of UV-A protection than they actually are." Schering-Plough says only that its UV-A

But scientists now worry that people may buy very high-SPF products that block only UV-B rays, and then stay in the sun far too long. "You lull the consumer into a false sense of security, and they stay out all day long and fry with UV-As," says Sergio Nacht, research and development vice-president at Advanced Polymer Systems Inc., which is conducting research into a new high-tech sunscreen (box). That has the FDA worried, too, admits Ripperre.

MURKY RULES. Even the FDA admits its 12-year-old guidelines on sunscreens are inadequate today, and it's working on new ones. The once-simple suntan lotion business has become a \$500 million industry. And as the sun has been linked to premature aging, lipsticks and moisturizers have picked up SPF's. "Two years ago, sunscreen was a marketing advantage. Now it's the price of entry"

MY LETTER
To Editor

Sunscreens don't give complete protection

To the Editor: *TENNESSEAN*
July 1 1990

In a *Letter to the Editor* (June 9), Pat Pelot Sanders mentioned that skin cancer is preventable "simply" by applying sunscreen and wearing protective clothing and hats.

However, this is an oversimplification, and there is a snag.

Most sunscreens block ultraviolet B rays, shorter wavelength radiation that causes sunburn and some skin cancers. But they do not protect against the longer UV-A rays which are known to contribute to aging, cancer and cataracts. So far, the only product to win FDA approval for its UV-A coverage is Photoplex, a product of Allergan Inc., Santa Ana, California. The Food and Drug Administration is increasingly concerned that sun care and cosmetic outfits are misleading the public about ultra-violet radiation protection, which their products provide.

The sun protection factors (SPF's) on most sunscreens range from 2 to 50. A SPF of 15 offers sufficient protection for a day of sunning. But people buy very-high SPF products that block only UV-B rays and stay in the sun all day long and fry with the "aging" UV-A rays.

Concern over the sun's dangers has sparked new research into ways to fight sun damage. One intriguing pursuit is marshaling the body's defenses, such as melanin.

Melanin is nature's best sunscreen; several companies are experimenting with the so-called melanin-based sunblocks. But these products face years of testing. In the meanwhile, we have to be content with the product of an Arizona

based company, Frog-skins. It sells a long-sleeve shirt, which, it claims has an SPF of 36.

Rama I. Mani
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Warnings about skin cancer are timely

To the Editor: *THE TENNESSEAN*
JUNE 9

Many people don't realize the most common cancer is skin cancer and that it is essentially preventable, simply by applying sunscreen on the skin and wearing protective clothing and hats.

Malignant melanoma, the most deadly skin cancer, exceeds the incidence of Hodgkins Disease.

People who need sun protection the most can't ask for it and or don't know to ask for it, namely infants and young children.

It was wonderful to see *The Tennessean's* coverage of Martha Goldner by Sylvia Slaughter on April 8: "A mother with a mission — campaign warns kids about the sun" and Darrel L. Ellis, M.D.'s April 10 *Health Message*. "Sun, moles major links to melanoma."

For the welfare of all Tennesseans, this important health issue should be repeatedly emphasized by the media, especially as we are into the sun season.

Because of the Arthur Lee Goldner, M.D., Fund of the Skin Cancer Foundation, recently established in memory of Dr. Goldner, 60,000 schools nationwide have received a poster for fourth, fifth and sixth grades, warning children of the dangers of too much sun.

It is hoped that this campaign can be expanded to reach all the youth of this country.

P.O. Box 1275
Pat Pelot Sanders Murfreesboro
37133

Area company carries approved sun block

To the Editor: *THE TENNESSEAN*
July 25, 1990

Rami I. Mani (July 1) is wrong about Photoplex being the only FDA approved sunscreen to block ultraviolet A (UV-A) rays.

There are several pharmaceutical companies providing sunscreens with FDA approval to block UV-A and UV-B rays. One company right here in Tennessee, Med Derm Inc., is located in Kingsport (1-800-334-4286). Their product, Aquaray, has a SPF+20, is water-resistant, contain no paba, padimate-O, lanolin, parabens or fragrance. It is FDA approved for blocking UV-A and UV-B rays and is almost half the price of Photoplex.

Pat Pelot Sanders
P.O. Box 1275
Murfreesboro 37133

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