A Petition to the FDA

The sun is a source of power and life but we are not powerless in the light of it. We can harness the power of the sun for energy. We can defend ourselves from its harmful effects. As we confront the sun, we know intuitively that one individual cannot possibly battle this life-giving and life-taking force alone. Collectively, we have the technology and the know-how to use the sun's energy to our best advantage and yet, standing alone, we get burned. But as the petition letter at right demonstrates, together we can get things done.

For the past six months, two of my colleagues and I have been discussing skin cancer, sunscreen developments, new UV filters and, above all, the pending regulations regarding UV Filters issued by the FDA. Dr. Steven Wang, Director of Dermatological Surgery at the Memorial Sloan-Kettering Cancer Center in NJ, Dr. Rebecca Sutton of the Environmental Working Group and I have been meeting and conference calling to address a number of pressing issues. It is our intention to create a better understanding and appreciation amongst the cosmetic industry, scientists, dermatologists, environmentalists, concerned citizens, and academicians as it relates to skin cancer, sunscreen developments, new UV filters and, above all, the pending regulations by the FDA.

That's why we decided to draft a letter to Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the U.S. FDA and also to Margaret Hamburg, the commissioner of Food and Drugs. This letter was sent also to some of our colleagues requesting that they join us in the petition.

April 15, 2010

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration WO51-2201
10903 New Hampshire Avenue
Silver Spring, MD 20993

cc: Margaret Hamburg, M.D., Commissioner of Food and Drugs

Re: Final Monograph – Sunscreen Drug Products for Over-the-Counter Human Use

Dear Dr. Woodcock:
As professionals engaged in dermatology, product development, manufacture of sun care cosmetics and ultraviolet filters, academia and public health advocacy, we urge the U.S. Food and Drug Administration (FDA) to move quickly to issue enforceable sunscreen standards that include meaningful protection from ultraviolet-A (UVA) radiation. As well, we believe the FDA should complete its health and safety reviews of new active ingredients awaiting approval.

The FDA first announced its intention to publish such standards (the sunscreen "monograph") in 1978 and has since refined its proposals. The most recent revision of the monograph, published Aug. 27, 2007, tackled for the first time the key question of UVA protection, specifying a uniform methodology for rating this property. Despite this promising advance, industry and consumers alike still await final standards to ensure that all sunscreens are as safe and effective as possible.

Sunscreens currently on the U.S. market have two major limitations. First, manufacturers do not have to substantiate claims of UVA protection. As a result, consumers may receive unexpectedly high UVA exposure when using products that actually provide low or no UVA protection. Damage associated with excessive UVA exposure is well known. In 2009, the International Agency for Research on Cancer (IARC) reaffirmed the carcinogenicity of solar radiation and noted that UVA radiation triggers the same mechanistic DNA damage as UVB radiation.

Second, U.S. sunscreen manufacturers cannot use a number of active ingredients believed to be safer and more effective, even though these ingredients are found in products sold in other countries. For instance, there are at least 29 ultraviolet filters approved for use in the European Union, compared to just 17 filters approved in the U.S. Newer active ingredients may offer manufacturers the capability to create safer products with superior UV protection.

More than 1 million Americans will be diagnosed with basal and squamous cell skin cancer this year, and another 60,000 will develop malignant melanoma. We commend the FDA for the many improvements to the sunscreen monograph outlined in 2007 and ask it to finalize enforceable standards in 2010. We further ask the agency to expedite review of new sunscreen active ingredients.

Thank you for your consideration.

Nadim Shaath
Alpha Research & Development Ltd

Dr. Nadim Shaath is the president of Alpha Research & Development Ltd., a consulting firm in White Plains, NY, specializing in sunscreen formulations and new product ideas in cosmetics, essential oils and ultraviolet filters. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase, the technical director at Felton, the president of Nickstadt-Moeller, Inc. and the CEO of Kato Worldwide. He can be reached at *alpharnd@aol.com*

Overwhelming Support

Not surprisingly, we received overwhelming support from our colleagues, with only a few who raised concerns. One prominent scientist objected to our statement about UV radiation causing melanoma, citing SEER database information that the rate of increase of melanoma has declined in the USA from 2000 to 2006. Well, this is a welcome development, if true, but it falls short of saying that the incidence of melanomas has been significantly reduced or eliminated. Perhaps our efforts to protect, educate and promote the use of sunscreens have already panned out. Unfortunately, melanoma is not the only dangerous consequence of overexposure to the harmful rays of the sun.

Another colleague of mine pointed to the many failures of the proposed Final Monograph as published in August of 2007. He insisted he would not support a Final Monograph as published. I wholeheartedly agree with him, but point to the disastrous consequences of not having any enforceable regulations in the land. This can only contribute to the chaos, instability, innuendos, rumors, and the general failures of our current products and regulations. We firmly believe that the FDA should allow the use of new and effective UVA filters, introduce a practical UVA standard, finalize SPF ratings, address issues of photostability and the use of nanoparticles, natural filters, boosters and quenchers. Above all, it should eliminate the uncertainty in regulations, issue enforceable standards with meaningful UVA protection, and complete the health and safety review of new UV active ingredients.

I have reported in previous editions of my column "The Sunscreen Filter" on the efforts of Senators, Congressmen and Attorney Generals in requiring the FDA to complete its review and issue Final regulations.[1] Please join us in a grassroots effort to assist the FDA in finalizing its long awaited Monograph. ●

NOTE: As we were going to press, a spokesperson announced that the FDA will issue the Final Regulations in May. In the interest of sun safety, we remain skeptical and focused. The FDA has made similar promises that were never fulfilled in the past. With over 100 signatures already gathered in support, we decided to go ahead with our petition.

References

1. The Sunscreen Filter, HAPPI, January 2009.

If you wish to support this petition, e-mail your name, affiliation and address to Dr. Nadim Shaath at alpharnd@aol.com.