

October 6, 2010

CDR Diem-Kieu H. Ngo, Pharm.D., BCPS  
Designated Federal Official  
Nonprescription Drugs Advisory Committee  
Division of Advisory Committee and Consultant Management  
Office of Executive Programs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

cc: Margaret Hamburg, M.D., FDA Commissioner

Re: Requesting Final Action on Tentative Final Monograph for Sunscreen Drug Products

Dear Ms. Ngo:

I am writing on behalf of the Environmental Working Group (EWG) to urge the Food and Drug Administration (FDA) to finalize its regulations for over-the-counter (OTC) sunscreen products. As an organization committed to fighting for public health and the environment, EWG believes that three decades is more than enough time to implement rules that carry the force of law to ensure that Americans have access to safe, effective sunscreens. For that reason, EWG calls on the Nonprescription Drugs Advisory Committee to recommend that the FDA at long last take final action on sunscreen rules.<sup>1</sup>

In 1978, the FDA announced its intention to write rules to “establish conditions for the safety, effectiveness and labeling” of over-the-counter sunscreen products.<sup>2</sup> Yet the FDA waited another 15 years before proposing a set of regulations, called the tentative final monograph (TFM).<sup>3</sup> The FDA has since amended those proposed regulations several times,<sup>4</sup> but they continue to languish in the doldrums of the regulatory process.

And the result?

Consumers are still in the dark about the safety and effectiveness of their sunscreen products – not only duped by exaggerated SPF claims but also exposed to potentially hazardous ingredients.

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<sup>1</sup> EWG wrote the Hon. Margaret Hamburg, M.D., on this matter a little over a year ago. Letter from Kenneth A. Cook, EWG President, to Margaret Hamburg, M.D., FDA Comm’r (July 15, 2009), *available at* [www.ewg.org/files/FDA-Hamburg%20sunscreen-letter-by-ken.pdf](http://www.ewg.org/files/FDA-Hamburg%20sunscreen-letter-by-ken.pdf). EWG has renewed its request in light of its latest report on sunscreens and UVA rays. EWG, U.S. SUNSCREENS GET FLUNKING GRADE FOR UVA: UVA PROTECTION TOO WEAK TO STOP SUBTLE HARM (2010), <http://www.ewg.org/node/28635>.

<sup>2</sup> Sunscreen Drug Products for Over-the-Counter Human Use, 43 Fed. Reg. 38,206 (Aug. 25, 1978).

<sup>3</sup> Sunscreen Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 28,194 (May 12, 1993).

<sup>4</sup> *E.g.*, Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007).

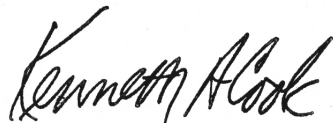
As the FDA considers next steps for finalizing its regulations for sunscreens, we at EWG would like to direct the committee's attention to our ongoing sunscreen research. Last week, for example, EWG released a report entitled "U.S. Sunscreens Get Flunking Grade for UVA: UVA Protection Too Weak to Stop Subtle Harm."<sup>5</sup> The report highlights the need for legally enforceable rules on "broad spectrum" sun protection. EWG has determined that "only one-third of high-SPF products provide strong protection against both UVA and UVB rays," yet manufacturers give consumers a false sense of security about their products by claiming that they provide all-day, waterproof protection.

The longer the FDA leaves sunscreen products in a state of regulatory limbo, the longer unscrupulous manufacturers will be able to profit from those who believe their unsubstantiated claims. Moreover, consumers who buy high-SPF sunscreens believe, erroneously, that they can remain in the sun for many hours without experiencing harm. Yet, as our report showed, a product's SPF is no a shield from more prevalent, more penetrating UVA radiation. The resulting confusion will inevitably contribute to greater incidence of skin cancer in the years to come. Moreover, the EWG report points out that high-SPF products contain more sun-blocking chemicals than low-SPF sunscreens, which means consumers who use them may experience higher risks of skin damage, skin cancer and potential hormone disruption.

Scientists have learned a lot more about sunscreen safety and effectiveness since the FDA first began working on sunscreen rules in 1978. By highlighting its latest research, EWG hopes to convince the committee to recommend final FDA action on sunscreen regulations. Skin cancer is the most common form of cancer in this country, according to the Centers for Disease Control and Prevention. Much of its toll can be prevented. It is past time for the FDA to do its part to help Americans make informed decisions to protect themselves and their families from the damage caused by UV radiation.

Thank you very much for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Kenneth A. Cook". The signature is written in a cursive, flowing style.

Kenneth A. Cook  
President  
Environmental Working Group

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<sup>5</sup> EWG, *supra* note 1.