May 23, 2011

The Honorable Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 1, Room 2217
Silver Spring, MD 20993

Re: Regulating Sunscreens

Dear Commissioner Hamburg:

I am writing on behalf of the Environmental Working Group to urge you to issue the U.S. Food and Drug Administration over-the-counter sunscreen regulations. As a defender of public health and the environment, EWG believes that nearly 33 years is an extraordinarily generous amount of time to take such action – particularly when you consider that the federal government completed projects like the Panama Canal in just a third of the time. EWG again calls on FDA to make good its promise to establish rules that adequately ensure the safety and effectiveness of U.S. sunscreens.[1]

In 1978, FDA announced its intention to develop regulations to "establish conditions for the safety, effectiveness and labeling" of OTC sunscreen products.[2] Yet FDA waited another 15 years before proposing a set of rules called the tentative final monograph.[3] The FDA has since amended the proposed regulations several times,[4] but they always seem to remain "just a few months" away from completion.

Why is this delay unacceptable?

[1] EWG has sent several letters to FDA advocating the completion of its sunscreen regulations. Letter from Kenneth A. Cook, EWG President, to CDR Diem-Kieu H. Ngo, Parhm.D., BCPS, Designated Fed. Official, Nonprescription Drugs Advisory Comm. (Oct. 6, 2010), http://www.ewg.org/files/FDA-NonRx-Drugs-Advisory-Committee-on-Sunscreen-TFM-October-2010.pdf; see also Letter from Kenneth A. Cook, EWG President, to Margaret Hamburg, M.D., FDA Comm'r (July 15, 2009), 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, Sunscreens 2011 (2011), http://www.ewg.org/sunscreen.

[2] Sunscreen Drug Products for Over-the-Counter Human Use, 43 Fed. Reg. 38,206 (Aug. 25, 1978).

[3] Sunscreen Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 28,194 (May 12, 1993). Note that this "delay . . . was nearly twice as long as the average eight year wait before the other OTC monographs." Patrick R. Jones, Protecting the Consumer from Getting Burned: The FDA, the Administrative Process, and the Tentative Final Monograph on Over-the-Counter Sunscreens, 20 Am. J.L. & Med. 317, 330 (1994).

[4] E.g., Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007).

FDA has a clear mandate from Congress to protect public health. Yet the longer it takes for FDA to finish its regulations the more time consumers will spend outdoors with false sense of security about the safety and effectiveness of their sunscreens. Who can blame them for this assumption when FDA implicitly sanctions overstated SPF claims and formulations that contain potentially hazardous ingredients such as oxybenzone and retinyl palmitate, a form of vitamin A.

As FDA waits for the U.S. Office of Management and Budget to approve a draft final rule,[5] I would like to direct you to EWG's latest sunscreen research. Today, EWG has released a report entitled *Sunscreens 2011*.[6] As documented in EWG's report, 60 percent of more than 500 sunscreens with high sunburn protection (SPF 30 or more) provide inadequate UVA protection (1 or 2 stars in FDA's proposed 4-star UVA rating system). Furthermore, many brands continue to use retinyl palmitate, despite research by the FDA and National Toxicology Program indicating that the chemical may be photocarcinogenic. While the FDA undertakes further research to resolve this important question, EWG recommends that consumers avoid sunscreens that contain retinyl palmitate.

Until FDA issues sunscreen regulations, unscrupulous manufacturers can profit from unsubstantiated claims – among them, that high-SPF sunscreens allow their users to remain in the sun for many hours without experiencing harm. The resulting confusion may contribute to greater incidence of skin cancer – because the burning truth is that there is no safe way to tan.[7] The EWG report points out that high-SPF products contain more chemicals than low-SPF sunscreens. Consumers who use high-SPF formulations may stay out in the sun too long, increasing their exposure to UVA and the resulting risks for skin damage, skin cancer and potential hormone disruption.

Scientists have learned a lot about sunscreen safety and effectiveness since FDA began working on sunscreen rules more than three decades ago. Little was known then about UVA radiation and the potential phototoxicity of vitamin A. We hope you will consider our findings and recommendations carefully as FDA moves closer to completing this critical rulemaking.

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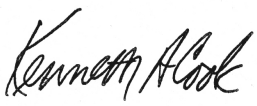
[5] Press Release, Dermagenics, FDA to Ban Misleading Sunscreen Labels; Dermagenics Predicts 90% of Sunscreen Products Will be Pulled Off Shelf Within One Year (Mar. 16, 2011), http://www.prweb.com/releases/2011/3/prweb8206908.htm.

[6] EWG, supra note 1.

[7] Am. Acad. Dermatology, Sunscreens, http://www.aad.org/media-resources/stats-and-facts/prevention-and-care/sunscreens (last visited May 17, 2011).

Skin cancer is the most common form of cancer in the United States, according to the federal Centers for Disease Control and Prevention (CDC).[8] It is time for FDA to do its part to protect Americans from this often preventable disease. The public interest demands it.

Sincerely,



Kenneth A. Cook
President
Environmental Working Group

[8] CDC, Skin Cancer Statistics, http://www.cdc.gov/cancer/skin/statistics/ (last visited May 16, 2011) (In 2007 . . . 58,094 people in the United States were diagnosed with melanomas of the skin . . . [and] 8,461 people . . . died from melanomas of the skin.").