July 22, 2013

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: Requesting Final Action on Tentative Final Monograph for OTC Sunscreen Products

Dear Commissioner Hamburg:

The Environmental Working Group submits this letter to urge the U.S. Food and Drug Administration to issue a comprehensive set of regulations for over-the-counter sunscreen products. Although the FDA issued several final rules for sunscreens in 2011,[1] the agency left a number of critical questions on the table. Addressing them is vital to ensuring the safety and efficacy of sunscreen products. The FDA has been working on sunscreen rules for more than three decades — and yet consumers still can't be sure that their sunscreen offers adequate protection.

With a dedicated interest in consumer protection, EWG has long reported on the risks of exposure to the sun's harmful rays and the extent to which sunscreens offer a meaningful option for protection.[2] When the FDA issued its rules in 2011, EWG applauded the agency for barring the use of certain deceptive sunscreen labeling claims such as "waterproof," but criticized it for issuing a weak standard for "broad spectrum" products. Virtually any sunscreen on the U.S. market passes the "broad spectrum" test — and shouldn't.

EWG criticized the FDA for failing to complete other key aspects of sunscreen regulation, among them:

> (1) The lack of an enforceable cap on SPF values above 50, even though the FDA acknowledges that they don't work and give sunscreen users a false sense of security;
> (2) The FDA's failure to respond to petitions to allow new, modern sunscreen filters to be added to products for sale in the U.S.;
> (3) The agency's failure to regulate common sunscreen ingredients linked to health problems, including oxybenzone, associated with endocrine disruption,[3] and the Vitamin A-derivative retinyl palmitate; and
> (4) The lack of rules for spray sunscreens, even though the FDA acknowledges they can be inhaled and may not work.

---

[1] Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,620 (June 17, 2011) (addressing deceptive labeling claims and establishing efficacy standard for "broad spectrum" products).
[2] EWG, Sunscreen 2013 (2013), http://www.ewg.org/2013sunscreen/.
[3] Id.

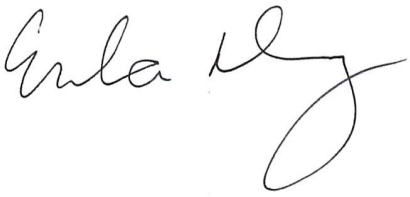
After two years, the FDA still has not moved forward to issue rules covering these gaps.

Meanwhile, every year, more people are being diagnosed with skin cancer than any other form of cancer.[4] Over the past three decades, as the FDA has pondered sunscreen rules, more people have had skin cancer than all other cancers combined.[5] Sunscreen regulations should be a top priority for the FDA, especially since some studies suggest that people use sunscreen to extend their time in the sun, unaware that these products won't thoroughly protect them.[6]

EWG respectfully submits this letter to reiterate the need for legally enforceable sunscreen rules that truly protect people in search of safe and effective sun protection.

Thank you for your attention.[7]

Sincerely,



Erika Duthely
Stabile Law Fellow

[4] Am. Cancer Soc'y, Skin Cancer Facts, http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts (last updated Mar. 25, 2013).
[5] Skin Cancer Found., Skin Cancer Facts, http://www.skincancer.org/skin-cancer-information/skin-cancer-facts (last updated Feb. 12, 2013).
[6] EWG, Sunscreen 2013 (2013), http://www.ewg.org/2013sunscreen/.
[7] This letter was drafted with the invaluable assistance of Maggie Joyce, University of Tennessee College of Law.