May 15, 2012

Attn: FDA FOIA Officer
U.S. Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Re: **Freedom of Information Act Request**

Dear Sir or Madam:

Under the provisions of the federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, and corresponding Food and Drug Administration (FDA) regulations, 21 C.F.R. Part 1401, the Environmental Working Group (EWG) hereby requests copies of the following records[1] located within the FDA:

(1) All correspondence and communications since June 17, 2011, among FDA staff, the Personal Care Products Council, the Consumer Healthcare Products Association, and/or their representatives, regarding the alleged feasibility of complying with the FDA's final rule "Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use," 76 Fed. Reg. 35,620 (June 17, 2011), by the original effective date, June 18, 2012;

(2) All correspondence and communications since January 2011, among FDA staff, the Personal Care Products Council, the Consumer Healthcare Products Association, and/or their representatives, regarding the development of the FDA's final rule "Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use," 76 Fed. Reg. 35,620 (June 17, 2011); and

(3) All correspondence and communications since January 2011, among FDA staff, the Personal Care Products Council, the Consumer Healthcare Products Association, and/or their representatives, regarding the development of the FDA's draft guidance document "Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application," published on June 17, 2011.

[1] For purposes of this FOIA request, "records" means information of any kind, including writings; memoranda; e-mails, including subject lines, the names of recipients, their e-mail addresses, and any attachments; text messages; letters; notes; meeting requests; calendar entries, including the names of invitees, their e-mail addresses, and any attachments; meeting minutes; documents; drawings; graphs; charts; photographs; electronic and magnetic meeting recordings; records of telephone conversations, including cell-phone records; and any other compilation of data from which information can be obtained.

EWG respectfully requests that the FDA make every reasonable effort to provide the requested records within the 20-day limit required by FDA regulations, 21 C.F.R. § 1401.7. Copies should be mailed within 20 days of receipt of this request to:

Thomas Cluderay
Assistant General Counsel
Environmental Working Group
1436 U Street NW, Suite 100
Washington, DC 20009

Should you determine that portions of the requested records are exempt from disclosure under the FOIA, please segregate those portions and mail the remaining records within the statutory time limit. For any records or portions of records that you determine to be exempt, please provide a specific description of the record or portion of the record exempted along with a particularized description of the exemption. EWG will accept the requested records with all Privacy Act-protected information redacted.

EWG is a non-profit public interest organization dedicated to using the power of information to protect public health and the environment. As part of that endeavor, EWG publishes an annual sunscreen report to help consumers determine which over-the-counter (OTC) sunscreen products provide safe and effective protection from the sun's harmful rays.[2] Invisible solar radiation reaches the earth in two forms: ultraviolet (UV) B radiation, which causes sunburn, direct damage to DNA, and skin cancer; and more-penetrating UVA radiation, which also causes cancer, free-radical generation, and skin aging.[3] EWG simultaneously has urged the FDA to establish a comprehensive set of laws to ensure that U.S. sunscreens meet an adequate threshold for safety and effectiveness.[4]

In 1978, the FDA announced that it would be developing rules to achieve that aim.[5] Yet the FDA waited another 15 years before proposing a set of regulations, the tentative final

[2] E.g., EWG, Sunscreens 2012 (2012), http://breakingnews.ewg.org/2012sunscreen/ [hereinafter EWG Sunscreens 2012].
[3] Id.
[4] E.g., EWG, Comments on Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,669, 35,672 (June 17, 2011) (submitted Sept. 15, 2011), http://static.ewg.org/pdf/EWG-Comments-to-FDA-SPF- Cap-Spray-Sunscreens-September-15-2011.pdf [hereinafter EWG 2011 Sunscreen Comments]; Letter from Kenneth A. Cook, EWG President, to Margaret Hamburg, M.D., FDA Comm'r (May 23, 2011), http://static.ewg.org/reports/2011/sunscreen/pdf/fda-sunscreen-letter-may-23-2011.pdf; Letter from Kenneth A. Cook, EWG President, to CDR Diem-Kieu H. Ngo, Pharm.D., BCPS, Designated Fed. Official, FDA Nonprescription Drugs Advisory Comm. (Oct. 6, 2010), http://www.ewg.org/files/FDA-NonRx-Drugs-Advisory-Committee-on- Sunscreen-TFM-October-2010.pdf; Letter from Kenneth A. Cook, EWG President, to Margaret Hamburg, M.D., FDA Comm'r (July 15, 2009), http://www.ewg.org/files/FDA-Hamburg%20sunscreen-letter-by-ken.pdf.
[5] Sunscreen Drug Products for Over-the-Counter Human Use, 43 Fed. Reg. 38,206 (Aug. 25, 1978).

monograph.[6] Despite making subsequent updates,[7] the FDA made little progress toward finalizing the proposal, or aspects of it, until last summer, nearly thirty-three years after beginning the rulemaking process. On June 17, 2011, the FDA issued a much-anticipated final rule on sunscreen labeling and effectiveness standards (the final rule).[8] Although the FDA left critical parts of the monograph unresolved,[9] EWG applauded it for banning misleading labeling terms such as "waterproof," "sweatproof," and "sunblock,"[10] which for too long have given consumers a false sense of security about the level of protection their OTC sunscreens afford. On the other hand, EWG took issue with how low it set the bar for products to qualify as "broad-spectrum" sunscreens.[11] However, on the whole, the FDA's actions at least signaled a renewed willingness to work toward ensuring the safety and efficacy of OTC sunscreens.

Developments over the past week have brought that willingness into serious question. On May 11, 2012, EWG learned that the FDA has decided to delay for six months the implementation of the final rule — just weeks before it was scheduled to go into effect on June 18.[12] Perhaps more troubling is the fact that the FDA's decision appears to be in response to pressure exerted by the Personal Care Products Council (PCPC) and the Consumer Healthcare Products Association (CHPA), industry trade groups representing a number of U.S. sunscreen manufacturers.[13] The new effective date for the final rule is Dec. 17, 2012. However, if history is any testament,[14] the FDA could very well end up postponing the final rule again. All the while, consumers will continue to be misled by overstated sunscreen claims, tempted to stay out in the sun for longer periods of time. As the FDA is well aware, skin cancer is "the most common form of cancer in the United States,"[15] again due in part to overexposure to the sun's harmful rays.

In light of these events, which cast doubt on the FDA's ability to adequately protect public health, EWG seeks records consistent with the purposes of the FOIA, namely "the citizens' right to be informed about 'what their government is up to.'" U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press, 489 U.S. 749, 773 (1989). EWG also seeks a fee waiver for this request because "disclosure . . . is likely to contribute significantly to public understanding of the

---

[6] Sunscreen Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 28,194 (May 12, 1993).
[7] E.g., Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007).
[8] Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,620 (June 17, 2011).
[9] For example, the FDA still is considering whether to cap the labeling of SPF values at 50+ for OTC sunscreens. It has yet to address new toxicity concerns related to active ingredients approved for use in such products (e.g., oxybenzone, which studies show can penetrate the skin and cause potential hormone disruption).
[10] Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. at 35,643.
[11] Id. at 35,659; EWG 2011 Sunscreen Comments, supra note 4, at 2.
[12] Press Release, EWG, FDA Bows to Industry Pressure, Delays Sunscreen Rules (May 11, 2012), http://ewg.org/release/fda-bows-industry-pressure-delays-sunscreen-rules. EWG acknowledges that the FDA has given the public six business days to comment on its decision to delay the final rule. 77 Fed. Reg. 27, 591 (May 11, 2012). As a practical matter, however, the comment window is so small that it prevents the public from offering any meaningful input to counter what appears to be a foregone conclusion by the FDA.
[13] Id.; see also, PCPC & CHPA, Comments on Draft Guidance for Industry on Enforcement Policy for Over-the-Counter-Sunscreen Drug Products Marketed Without an Approved Application (June 17, 2011) (submitted Aug. 16, 2011) (on file with EWG).
[14] See, e.g., Sunscreen Drug Products for Over-the-Counter Human Use, 66 Fed. Reg. 67,485 (Dec. 31, 2001) ("This rule . . . is stayed until further notice.").
[15] CDC, Skin Cancer Statistics, http://www.cdc.gov/cancer/skin/statistics/ (last visited May 14, 2012).

operations or activities of the government and disclosure is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); see also 21 C.F.R. § 1401.13. This request fits squarely into the factors outlined in the U.S. Department of Justice's (DOJ) FOIA guide to determine whether fee waivers are appropriate. See U.S. Dep't of Justice, Freedom of Information Act Guide (May 2004), http://www.usdoj.gov/oip/fees.htm#waiver.

The subject matter of the requested records sheds light on whether the FDA accepted at face value claims by the PCPC and the CHPA that sunscreen manufacturers could not comply with the final rule by June 2012, or whether it critically examined their arguments — or better yet, pushed back on them given the stakes for public health. The subject matter also reveals whether the FDA caved to industry pressure even before publishing the final rule last summer, when it was being finalized. For example, FDA set such a weak standard for products to qualify as broad-spectrum sunscreens that a large majority of those on the market already meet this requirement.[16] For comparative purposes, only about a third of the high-SPF sunscreens sold in the United States would meet more robust guidelines followed in Europe.[17] After waiting more than three decades for the FDA to develop rules guiding the safety and efficacy of OTC sunscreens, the public needs to know whether the FDA is looking out for its welfare, or simply beholden to the industry.

In particular, EWG seeks these records for their informative value to evaluate: (1) how the FDA developed its final rule, including the extent to which it incorporated the views of the PCPC, the CHPA, and/or its representatives; (2) whether the FDA pushed back on requests from industry groups, or merely gave them the rubber stamp; (3) how the FDA received complaints by industry regarding the alleged feasibility of complying with the final rule by June 2012; and finally, (4) whether the FDA accounted for the fact that postponing the final rule by six months means consumers will spend another summer in the sun, relying on misleading sunscreen claims. Accordingly, the subject matter of the requested records clearly concerns "identifiable 'operations or activities of the government.'" Id. (DOJ fee waiver factor No. 1).

The requested records are "likely to contribute" to an understanding of how the FDA developed the final rule and how it reached the decision to postpone its effective date by six months to December 2012. Moreover, complete records of communications and meetings among FDA staff, the PCPC, the CHPA, and/or their representatives generally are not accessible through means other than a FOIA request. The requested documents are "meaningfully informative" with regard to understanding the actions of the FDA as it develops a monograph establishing the safety and efficacy of OTC sunscreen products. To the extent that industry's lobbying efforts have compromised that rulemaking process, the public has a right to know. Id. (DOJ fee waiver factor No. 2).

[16] EWG 2011 Sunscreen Comments, supra note 4, at 2.
[17] Id.

Disclosure of the requested documents will unquestionably contribute to the understanding of the "public at large," as opposed to that of a narrow segment of the population. EWG routinely disseminates the information it receives through the FOIA regarding government operations and activities through comprehensive analyses and media releases, as well as by direct distribution through mailings, posting on EWG's website, and e-mailing the organization's million-strong supporters and other like-minded parties throughout the country.[18] EWG also disseminates information to the public through Congressional testimony, comments to federal agencies, and, where necessary, through the judicial system. As for EWG's capacity to disseminate the information, we unquestionably have the "specialized knowledge," "ability and intention" to share the requested information in the broad manner outlined above and do so in a way that contributes to the understanding of the public at large.[19] Consequently, EWG has undoubtedly demonstrated that the information sought in this request will contribute to the understanding of the public at large. Id. (DOJ fee waiver factor No. 3).

Disclosure of the requested records will contribute "significantly" to the public's understanding of how the FDA developed the final rule and why the FDA decided to delay its effective date by six months. EWG hopes the records specifically identified by this request will answer the questions already identified herein, which are of great concern to consumers nationwide. If the public is to trust the FDA to make decisions affecting its health and safety, then it has a right to know whether sunscreen manufacturers, via their trade groups, have co-opted the OTC sunscreen rulemaking process. Id. (DOJ fee waiver factor No. 4).

Finally, the disclosure of this information is purely noncommercial. EWG has no intention of using this information in a manner that "furthers a commercial, trade, or profit interest as those terms are commonly understood." See id. Any publication of any analysis of the requested information would be for the sole purpose of dissemination to the public to educate how the FDA is working with stakeholders to review the safety and efficacy of OTC sunscreens and how to regulate them accordingly. Id. (DOJ commercial interest factor).

For all of these reasons, EWG asks the FDA to waive search or review fees related to this request in accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 1401.13. If the FDA cannot grant a fee waiver, EWG is willing pay up to $100 so that the FDA may conduct the requested search in a timely fashion. In any event, EWG's request for a fee waiver should not be construed an extension of time in which to reply to this request.

[18] E.g., EWG, Flat-Out Risky: Hair Straightener Makers and Salons Cover Up Dangers (2011), http://www.ewg.org/hair-straighteners/our-report/executive-summary/ ("Over the past two years, the [FDA] has received 47 complaints of adverse reactions and injuries from salon workers and clients who used Brazilian-style straightening treatments, according to FDA records obtained by the [EWG] through a [FOIA] request.").
[19] E.g., EWG Sunscreens 2012, supra note 2; EWG 2011 Sunscreen Comments, supra note 4.

EWG looks forward to your reply to this request within 20 business days, as provided under 5 U.S.C. § 552(a)(6)(A)(i) and 21 C.F.R. § 1401.7. If you require further clarification about this request or anticipate any problems with releasing the requested documents, please contact me at (202) 667-6982.

Sincerely,

Thomas Cluderay
Assistant General Counsel
Environmental Working Group