

September 15, 2011

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: EWG Comments on Proposed SPF Value Labeling Cap and Safety of Spray Sunscreens

Docket No. FDA-1978-N-0018 (RIN Nos. 0910-AF43, 0910-ZA40)

The Environmental Working Group submits this letter in response to the U.S. Food and Drug Administration's request for comments on a proposal to cap the labeling of sunscreen protection factor (SPF) values at 50+ for over-the-counter sunscreens¹ and for information about the safety and effectiveness of spray sunscreens.² EWG is a non-partisan, non-profit organization dedicated to using the power of information to protect public health and the environment. As part of that endeavor, EWG routinely brings to light toxicity concerns associated with exposures to chemicals used in consumer products. EWG in turn uses its research to advocate health-protective laws addressing those concerns, particularly for vulnerable segments of the population such as children.

For the past five years, EWG has published an annual sunscreen report to help consumers determine which products provide safe and effective protection from the sun's harmful rays.³ 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.⁴ EWG has simultaneously urged FDA to establish a comprehensive set of laws to ensure that U.S. sunscreens meet an adequate threshold for safety and effectiveness.⁵

In 1978, FDA announced that it would be developing rules to achieve that aim.⁶ Yet FDA waited another 15 years before proposing a set of regulations, the tentative final monograph.⁷ Despite making subsequent updates,⁸ FDA made little progress toward finalizing the proposal, or aspects

¹ Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,672 (June 17, 2011).

² Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,669 (June 17, 2011).

³ E.g., EWG, Sunscreens 2011 (2011), <http://www.ewg.org/sunscreen> [hereinafter EWG, Sunscreens 2011].

⁴ Id.

⁵ 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, 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>.

⁶ Sunscreen Drug Products for Over-the-Counter Human Use, 43 Fed. Reg. 38,206 (Aug. 25, 1978).

⁷ Sunscreen Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 28,194 (May 12, 1993).

⁸ E.g., Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007).

of it, until this summer, nearly thirty-three years after beginning the rulemaking process.⁹ On June 17, 2011, FDA issued a much-anticipated final rule on sunscreen labeling and effectiveness standards.¹⁰ Because FDA left essential matters unresolved, it still has work to do before establishing a complete set of conditions for when sunscreens are generally recognized as safe and effective (GRASE).

FDA's final rule is a mixed bag from a public health perspective. On the one hand, the rule bars misleading terms from labels such as "waterproof," "sweatproof," and "sunblock," which for too long have given consumers a false sense of security about the level of protection their sunscreens afford.¹¹ On the other hand, FDA sets 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.¹² 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.¹³ In addition, FDA has done nothing to address new toxicity concerns related to active ingredients approved for use in OTC sunscreens. FDA has neither reviewed new combinations of approved active ingredients nor reviewed the safety of active ingredients that have been used in Europe, and elsewhere, for more than ten years.¹⁴ Despite these weaknesses, FDA's action at least signals a renewed willingness to work toward ensuring the safety and effectiveness of these products.

With regard to issues still under review – whether to cap SPF values on sunscreen labels and how to regulate spray sunscreens – EWG would like to submit the following comments:

1. EWG strongly endorses FDA's plan to cap the labeling of SPF values at 50+ for OTC sunscreens. In comparison to lower-SPF products, sunscreens with SPF values greater than 50 give consumers a false sense of security about their level of sun protection; have unproven clinical benefits, yet expose users to greater quantities of active ingredients; and offer proportionally lower UVA protection compared to UVB protection.

As detailed in EWG's latest sunscreen report,¹⁵ research shows that "users of high-SPF sunscreens have similar or even higher exposures to harmful [] UV rays than people relying

⁹ Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35,620 (June 17, 2011).

¹⁰ Id.

¹¹ Id. at 35,643.

¹² See J.F. Nash, Ph.D., Comments on Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007) (submitted Sept. 4, 2009), <http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0693>.

¹³ See EWG, U.S. Sunscreens Get Flunking Grade for UVA: UVA Protection Too Weak to Stop Subtle Harm (2010), <http://www.ewg.org/Sunscreens-Get-Flunking-Grade-for-UVA-Protection> [hereinafter EWG, Sunscreens Flunking Grade] (EWG "analysis of 446 beach and sport sunscreens with SPF ratings of 30+ found that nearly two-thirds of them provide inadequate UVA protection," and among those, "284 products are too weak for the European market, where manufacturers voluntarily comply with a European Union recommendation that all sunscreens provide meaningful UVA protection in relation to the . . . product's ability to shield against UVB rays").

¹⁴ Steven Q. Wang & Henry W. Lim, Current Status of the Sunscreen Regulation in the United States: 2011 Food and Drug Administration's Final Rule on Labeling and Effectiveness Testing, 65 J. Am. Acad. Dermatology 863 (2011).

¹⁵ EWG, Sunscreens 2011, *supra* note 3.

on lower SPF products.”¹⁶ According to published research, users of these products remain in the sun for longer periods of time without reapplying because they falsely believe that these products offer greater protection.¹⁷ FDA recently referenced two studies showing a significant association between sunscreen use by children and longer durations of sun exposure.¹⁸ Nevertheless, FDA has decided to allow companies to advertise that sunscreen products “reduce[] the risk of or prevent[] skin cancer” when used as part of a comprehensive strategy to reduce solar exposure.¹⁹ At a time when skin cancer is the most common form of cancer in the United States,²⁰ FDA should disallow products from the market that encourage longer exposures to the sun.

As required under FDA GRASE principles, the addition of active ingredients must provide a clinical benefit that outweighs the risk. High-SPF sunscreens simply cannot meet that standard. As SPF values “get higher and higher, [there’s] not really a practical difference,” according to Dr. David M. Pariser, president of the American Academy of Dermatology.²¹ High-SPF sunscreens contain greater amounts of sun-blocking chemicals compared to low-SPF products, yet offer only minimal increases in UV protection.²² Studies have shown that active ingredients in sunscreens are linked to hormone disruption, estrogenic effects, allergic reactions, and skin irritation.²³

Only two active ingredients, zinc and avobenzone, provide adequate broad-spectrum UVA protection. FDA currently limits the amount of avobenzone used in sunscreens to 3 percent.²⁴ However, avobenzone is the only broad-spectrum UVA filter used in the vast majority of high-SPF products.²⁵ Accordingly, high-SPF sunscreens may increase UVB protection, but cannot provide similar increases in UVA protection. EWG believes this is problematic because numerous studies raise health concerns about overexposure to UVA radiation.²⁶ EWG also is concerned that the in-vitro critical wavelength method used to measure UVA protection overestimates levels offered in high-SPF products due to underestimating the SPF. According to one study, these in-vitro measurements of SPF were on average as much as 50 percent lower than the value appearing on the labeling of U.S. sunscreens.²⁷

¹⁶ Id.; see also Philippe Autier, Sunscreen Abuse for Intentional Sun Exposure, 161 *Brit. J. Dermatology Supp.* 3, 40 (2009).

¹⁷ EWG, Sunscreens 2011, supra note 3.

¹⁸ Sunscreen Drug Products for Over-the-Counter Human Use, 76 *Fed. Reg.* 35,620, 35,632 (June 17, 2011).

¹⁹ Id.

²⁰ Ctrs. for Disease Control & Prevention, Skin Cancer, <http://www.cdc.gov/cancer/skin/> (last visited Sept. 14, 2011).

²¹ Catherine Saint Louis, Confused by SPF? Take a Number, *N.Y. Times*, May 13, 2009, <http://www.nytimes.com/2009/05/14/fashion/14SKIN.html?pagewanted=all>.

²² See EWG, Sunscreens 2011, supra note 3.

²³ Id.

²⁴ Sunscreen Drug Products for Over-the-Counter Human Use, 61 *Fed. Reg.* 48,645, 48,655 (Sept. 16, 1996).

²⁵ See Nash, supra note 12.

²⁶ Diane E. Godar et al., Increased UVA Exposures and Decreased Cutaneous Vitamin D(3) Levels May Be Responsible for the Increasing Incidence of Melanoma, 72 *Med. Hypotheses* 434-43 (2009).

²⁷ See Nash, supra note 12.

The protection consumers receive from sunscreen largely depends on the manner in which they apply it, making high-SPF claims inherently misleading. For example, test data submitted by Playtex indicates that users' levels of SPF protection heavily depend on the thickness of sunscreen applied to the skin.²⁸ Other studies indicate that consumers apply one half to one fifth the amount used in controlled laboratory tests.²⁹ Moreover, chemicals used in high-SPF sunscreens still break down over time, wash off, or rub off on users' clothes and/or towels.³⁰

Until FDA caps the labeling of SPF values, unscrupulous manufacturers will continue profiting from a marketing game that leads consumers to believe that greater SPF values are always superior to lower-SPF products. Consumers in turn increase their exposure to the sun and the resulting risks of skin damage and skin cancer. It is thus imperative that FDA finalizes its proposed SPF 50+ cap, which will go a long way toward protecting public health.

2. EWG backs FDA's plans to examine the safety of sunscreen sprays, which present unique health concerns compared to traditional lotion forms. Virtually no information is available to the public to assess the sun protection provided by sunscreen sprays or the potential toxicity of active and inactive ingredients used in these products, especially from inhalation of chemicals that can occur during and after spraying. Before approving them for OTC use, FDA must be able to ensure that sunscreen sprays provide adequate sun protection and do not pose unnecessary risks to public health.

When subject to in-vitro testing, sunscreen sprays appear to offer reasonable UV protection, but significant questions remain about whether these products perform well in the real world. Consumers may not apply sufficient levels to achieve adequate sun protection or to provide an even coat over the skin. The application thickness and extent of sun protection remain more uncertain for sunscreen sprays compared to lotions because many consumers do not use their hands to rub in the product. In one study, researchers reported that sunscreen sprays provided spotty skin coverage when they were not rubbed in, but acknowledged that it may be difficult to achieve this outcome with quick-drying formulations.³¹ One additional publication found that consumers preferred to use sunscreen sprays over lotions, but did not determine whether they used sufficient amounts or reapplied the product appropriately.³²

Before FDA can make a determination about the safety and effectiveness of sunscreen sprays, it must first assess the amount of spray that is inhaled under ordinary and worst-case-use scenarios. EWG's observations suggest that consumers often misuse sunscreen sprays –

²⁸ Playtex Products, Inc., Comments on Sunscreen Drug Products for Over-the-Counter Human Use, 72 Fed. Reg. 49,070 (Aug. 27, 2007) (submitted Dec. 26, 2007) (on file with EWG).

²⁹ EWG, *Sunscreens 2011*, *supra* note 3; Philippe Autier, *Quantity of Sunscreen Used by European Students*, 144 *Brit. J. Dermatology* 288-291 (2001); R.M. Azurdia et al., *Sunscreen Application by Photosensitive Patients is Inadequate for Protection*, 140 *Brit. J. Dermatology* 255-258 (1999).

³⁰ *See id.*

³¹ Jerome Barr, *Spray-On Sunscreens Need a Good Rub*, 52 *J. Am. Acad. Dermatology* 180-181 (2005).

³² Benjamin Solky et al., *Patient Preferences for Facial Sunscreens: A Split-Face, Randomized, Blinded Trial*, 57 *J. Am. Acad. Dermatology* 67-72 (2007).

either by applying them directly to the face, or in windy or crowded conditions, increasing the risk of bystander exposure. EWG urges FDA to study consumer exposures directly rather than rely on modeling estimates, ideal application scenarios, and/or estimates submitted by product manufacturers.

As far as potential toxicity concerns, EWG believes that inhaled sunscreen ingredients are more likely to penetrate the lungs than is lotion applied directly to the skin. Sunscreen sprays contain active ingredients³³ that have been found to cause immediate toxicity issues such as skin sensitization or more subtle effects such as hormone disruption.³⁴ A case report from 2008 describes an individual who experienced anaphylaxis that was attributed to exposure to oxybenzone in sunscreen.³⁵ Safety assessments for active ingredients in sunscreens have focused exclusively on doses received by application to skin, whereas inhaled ingredients could result in more significant intake.³⁶

Inactive ingredients used in sunscreen sprays may also pose safety concerns. EWG's review of ingredient labels shows that isobutene, an inactive ingredient used as an aerosol component, is listed on the labels of at least thirty-eight sunscreen sprays. The Cosmetic Ingredient Review has observed a variety of respiratory effects in animals exposed to isobutane in concentrations ranging from 5 to 90 percent, including pulmonary and cardiac effects in monkeys inhaling 5 to 10 percent isobutane for 5 minutes.³⁷

A significant amount of literature also documents the toxicity and penetration risks of nanoscale zinc oxide and titanium dioxide inhalation.³⁸ Although these ingredients do not appear to be used in aerosol sprays, a number of companies sell these ingredients in sunscreen powders,³⁹ which FDA correctly determined were not safe and effective.

Finally, sunscreen sprays do not currently provide consistent warnings and/or guidance about how to safely use them. EWG believes that if sold, sunscreen sprays must clearly indicate the

³³ Spray sunscreens may contain active ingredients that account for roughly 40 percent of the total formula. *E.g.*, Neutrogena, Ultimate Sport Sunblock Spray SPF 100+, <http://www.neutrogena.com/product/ultimate+sport+sunblock+spray+spf+100-.do?sortby=ourPicks> (last visited Sept. 14, 2011).

³⁴ Margaret Schlumpf et al., *Endocrine Activity and Developmental Toxicity of Cosmetic UV Filters—an Update*, 205 *Toxicology* 113 (2004); Margaret Schlumpf et al., *Endocrine Active UV Filters: Developmental Toxicity and Exposure Through Breast Milk*, 62 *Chimia* 345 (2008).

³⁵ GT Spijker et al., *Anaphylaxis Caused By Topical Application of a Sunscreen Containing Benzophenone-3*, 59 *Contact Dermatitis* 248 (2008).

³⁶ *See, e.g.*, SCCP/1201/08, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_159.pdf (European Union Scientific Committee on Consumer Products opinion on benzophenone-3 from Dec. 16, 2008).

³⁷ Cosmetic Ingredient Review, *Final Report of the Safety Assessment of Isobutane, Isopentane, n-Butane, and Propane*, 24 *Int'l J. Toxicology Supp.* 1, 52-55 (2005).

³⁸ Christie M. Sayes et al., *Assessing Toxicity of Fine and Nanoparticles: Comparing In Vitro Measurements to In Vivo Pulmonary Toxicity Profiles*, 97 *Toxicological Sci.* 163 (2007).

³⁹ *E.g.*, Colorescience Pro, Sunforgettable Mineral Powder Sun Protection SPF 50 Brush – Medium, <http://www.colorescience.com/ProductDetails.asp?ProductCode=1350> (last visited Sept. 14, 2011); Bare Escentuals, SPF 30 Natural Sunscreen, <http://www.bareescentuals.com/bareMinerals-SPF-30-Natural-Sunscreen---medium/MasterSunscreen,default,pd.html> (last visited Sept. 14, 2011); Peter Thomas Roth Clinical Skin Care, Uber-Dry Sunscreen SPF 30, <http://www.peterthomasroth.com/p-96-uber-dry-sunscreen-spf-30.aspx> (last visited Sept. 14, 2011).

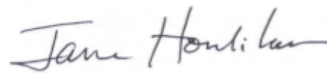
potential for inhalation toxicity and strict criteria for safe use. EWG's most recent sunscreen report⁴⁰ raises concerns about a number of spray products, particularly those marketed for babies and/or children, including one designed for use on a baby's scalp,⁴¹ as well as those advertised for use on "wet skin."⁴²

In light of the importance of these matters, EWG asks FDA to take its comments under careful consideration and to expeditiously wrap up its thirty-three year effort to establish comprehensive sunscreen regulations. EWG believes that ample evidence shows consumers are poorly served by sunscreens with SPF values greater than 50 and should be disallowed. Sunscreen sprays have not been adequately proven to protect skin and may result in significant inhalation of irritating and/or toxic ingredients. FDA must fully assess the worst-case scenarios for spray ingestion before labeling these products as GRASE. It is past time for FDA to do its part to help consumers. The public interest demands it.

Sincerely,



Thomas Cluderay
Assistant General Counsel



Jane Houlihan
Senior Vice President for Research



Dave Andrews
Senior Scientist



Sonya Lunder
Senior Analyst

⁴⁰ EWG, Sunscreens 2011, supra note 3.

⁴¹ Baby Blanket, Tender Scalps Spray SPF 45+, <http://www.babyblanketsuncare.com/view/1/11/> (last visited Sept. 14, 2011).

⁴² Neutrogena, Wet Skin Sunblock, <http://www.neutrogena.com/category/sun/wet+skin.do> (last visited Sept. 14, 2011).