



August 18, 2016

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Urgent need for greater oversight of SPF claims, including manufacturers' testing methodology and use of inactive sunscreen ingredients

Dear Commissioner Califf,

We respectfully submit this letter on behalf of the Environmental Working Group to express concerns about sunscreen ingredients that may enable manufacturers to advertise higher SPF values for their over-the-counter sunscreen products without offering users truly enhanced protection from UVA and UVB rays. We ask that the U.S. Food and Drug Administration investigate whether ingredients and other technologies are being used to boost SPF claims by masking the skin reddening that is the body's warning sign of sun damage. Such products may encourage people to remain in the sun, where, though they don't see or sense burning, they may in fact sustain subtle or profound damage to the skin, potentially leading to cancer.

Sunscreens are a valuable tool used to protect the public from damaging exposures to ultraviolet radiation. EWG appreciates FDA's continued efforts to establish a comprehensive set of regulations guiding the safety and efficacy of sunscreens. However, EWG is concerned that the agency's current rules have not kept pace with the formulation and marketing trends we have observed after a decade of assessing these products, to the potential detriment of public health.

Specifically, we believe that FDA should urgently investigate a critical question: whether sunscreens contain ingredients that boost SPF values without necessarily improving health benefits for consumers. Today, the majority of the sunscreen products listed in EWG's annual Guide to Sunscreens contain ingredients with anti-inflammatory or antioxidant properties. The current testing methodology prescribed by FDA does not address the increasing use of anti-inflammatories, antioxidants and other ingredients that may boost SPF readings and mask reddening, the body's early warning system that it is experiencing sun damage. Current testing requirements also have enabled the proliferation of high SPF claims that often cannot be verified.

Given this country's scourge of skin cancer, we call on FDA to take the following actions:



- 1. Investigate the use of anti-inflammatories, antioxidants and other ingredients in sunscreen products, which may increase SPF measurements without shielding the body from UV light; as well as the correlation, if any, between protection from skin reddening, immunosuppression, long-term skin damage and cancer.**
- 2. Finalize its proposed 2011 rule that would cap SPF values at 50+.**
- 3. Require companies to display the lower value obtained from measuring the sun protection factor *in vitro* and *in vivo* when determining the SPF of products.**

EWG is a national environmental health organization dedicated to empowering people to live healthier lives in a healthier environment. For more than two decades, the organization has used groundbreaking research, education and advocacy to drive consumer choice and civic action. For the past decade, EWG has published an annual sunscreen guide that aims to help consumers choose products that safely and effectively provide protection from the harmful effects of ultraviolet radiation.¹ Solar UV radiation is known to cause direct damage to DNA, as well as skin cancer, sunburn, free radical generation and photo-aging of skin.^{2,3}

Every year, more than 2 million Americans develop skin cancer.⁴ Over the past four decades, the incidence rate of melanoma, the deadliest form of skin cancer, has been increasing rapidly. When FDA initiated the sunscreen rulemaking process in 1978, the rate of new cases of melanoma was 8.9 per 100,000 people; yet by 2012, the rate had increased to 22.9 per 100,000 people – *more than a 250 percent increase*.⁵ Sunscreen is an important, if imperfect, tool in reducing the harm caused by UV radiation. The importance of proper sunscreen use and ensuring sunscreen efficacy, in conjunction with other habits – such as wearing sun-protective clothing and avoiding overexposure during peak hours – are paramount. Sunburn and inflammation are immediate and visible consequences of overexposure to UV radiation, but other long-term health effects, including cancer, may take years or decades to manifest. EWG urges FDA to conduct further research and regulate sunscreen products to better protect public health, as detailed below.

¹ EWG, EWG's 10th Annual Guide to Sunscreens. 2016. Available at www.ewg.org/sunscreen

² Jean Cadet, Thierry Douki and Jean-Luc Ravanat, Oxidatively Generated Damage to Cellular DNA by UVB and UVA Radiation. *Photochemistry and Photobiology*, 2015.

³ Jack Zhang and G. Tim Bowden, Activation of p38 MAP Kinase and JNK Pathways by UVA Irradiation. *Photochemical & Photobiological Sciences*, 2012.

⁴ American Cancer Society, Cancer Facts & Figures 2015. American Cancer Society, 2015. Available at www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf

⁵ Ibid.



1. Investigate the use of anti-inflammatories, antioxidants and other ingredients that increase SPF in sunscreen products without shielding UV light; as well as the correlation, or lack thereof, between protection from skin reddening, immunosuppression, long-term skin damage and cancer.

Current SPF values are based solely on reduction of erythema, commonly known as skin redness. Many sunscreens now contain anti-inflammatories, antioxidants and other ingredients that may not reduce exposure to UV radiation, but can block the biological pathways that lead to skin reddening, inflammation and sunburn. Topical treatment of human skin with antioxidants, including plant extracts rich with polyphenols, has been shown to reduce inflammation associated with UV overexposure.⁶ Although some common sunscreen chemical filters also possess anti-inflammatory and/or antioxidant characteristics, we are particularly concerned about the widespread use of ingredients such as butyloctyl salicylate, bisabolol, aloe, vitamin A, vitamin C and vitamin E, which may increase the SPF of a finished product without improving its UV radiation protection.^{7,8}

By inhibiting inflammation and reducing redness, such ingredients may result in inflated SPF values relative to the reduction in sun exposure. Products that protect skin from acute sunburn may not provide equivalent protection from UV-initiated skin cancer or photo-aging of skin. An SPF claim on a product label does not tell consumers whether it will protect them from UV-induced immunosuppression, which, along with DNA damage, plays an important role in processes that may lead to cancer.⁹ Ingredients that alleviate redness – such as antioxidants – may not reduce the risk of immunosuppression or skin cancer.¹⁰ It follows that anti-inflammatories, antioxidants, and other ingredients that block the biological pathways leading to sunburn while boosting SPF, may mislead consumers into believing they are receiving more protection than the sunscreen actually provides.¹¹

The anti-inflammatory/antioxidant effect of some sunscreen products can persist for more than six hours following application – even if the user does not reapply the product. As a result, the

⁶ Joi A. Nichols and Santosh K. Katiyar, Skin Photoprotection by Natural Polyphenols: Anti-Inflammatory, Antioxidant and DNA Repair Mechanisms. Archives of Dermatological Research, 2010.

⁷ C. Couteau et al., 2013. The Effect of Ultraviolet Radiation on the Anti-Inflammatory Effect of Filters. International Journal of Pharmaceutics, 2013.

⁸ Shao Yun et al., Practical Tools for Boosting Sunscreen Efficacy. Kobo Products, Inc. 2015.

⁹ Mary Norval and Gary M. Halliday, The Consequences of UV-Induced Immunosuppression for Human Health. Photochemistry and Photobiology, 2011.

¹⁰ Terence S. Poon, Ross Barnetson and Gary M. Halliday, Prevention of Immunosuppression by Sunscreens in Humans Is Unrelated to Protection from Redness and Dependent on Protection from Ultraviolet A in the Face of Constant Ultraviolet B Protection. Journal of Investigative Dermatology, 2003.

¹¹ See Couteau, supra note 7



user may not realize that skin damage is occurring.¹² Consumers may be lulled into a false sense of security and spend more time exposed to harmful UV radiation without reapplying a sun-filtering product, thus increasing their risk of developing skin cancer.

In 2011, FDA indicated that it did not expect the use of anti-inflammatory ingredients to influence SPF values, based on the length of time between exposure and evaluation of the erythema 18 to 24 hours after exposure.¹³ In our judgment, the agency's position is out of step with past scientific studies^{14,15,16} and some current product formulation recommendations to boost SPF using bioactive ingredients.¹⁷ Based on our analysis of the sunscreens in our most recent sunscreen guide, which reviewed more than 750 sunscreen products, those anti-inflammatory ingredients are in the majority of sunscreen products on the market.¹⁸

The implications for consumers extend beyond SPF values on product labels. The consequences extend to the degree of UVA protection offered by sunscreens. The testing methodology prescribed by FDA for "broad spectrum" protection relies entirely on the critical wavelength as measured *in vitro*. In contrast, the European Commission calls for evaluating balanced protection by comparing the amount of UVA protection measured *in vitro* with the labeled SPF measured *in vivo*.¹⁹ The European method, which we believe is more health-protective, takes into account the possible effects of SPF boosters, and aims to ensure that the product's UVA protection increases in parallel with the SPF advertised on its label.

Antioxidant ingredients may have benefits. However, a multitude of biochemical pathways are involved in the body's response to UV radiation. Scientists have much to learn about these pathways. The possible connections between antioxidants in sunscreen and cancer risks are not well understood. For that reason, FDA must evaluate the current state of scientific knowledge to understand how antioxidants fit into the complex biological reactions that may contribute to, or

¹² See Couteau, *supra* note 7

¹³ Food and Drug Administration, Sunscreen Drug Products for Over-the-Counter Human Use. 76 Fed. Reg. 35,672, June 17, 2011.

¹⁴ E. Law and A.J. Lewis, The Effect of Systemically and Topically Applied Drugs on Ultraviolet-Induced Erythema in the Rat. *British Journal of Pharmacology*, 1977.

¹⁵ Richard Smerbeck and Eugene Pittz, Synergistic Non-Steroidal Anti-Inflammatory Compounds and Compositions Thereof. United States Patent, 1984.

¹⁶ John Trevithick et al., Topical Tocopherol Acetate Reduces Post-UVB Sunburn-Associated Erythema, Edema, and Skin Sensitivity in Hairless Mice. *Archives of Biochemistry and Biophysics*, 1992.

¹⁷ See Yun, *supra* note 8

¹⁸ See EWG, *supra* note 1

¹⁹ European Union, Commission Recommendation of 22 September 2006 on the Efficacy of Sunscreen Products and the Claims Made Relating Thereto. *Official Journal of the European Union*. L 265/39, 2006.



reduce, cancer risks. If necessary, the use of antioxidant ingredients in sunscreen should be regulated in a manner that provides the public with a net benefit to long-term health.

2. Finalize FDA's proposed 2011 rule that would cap SPF value at 50+.

The most popular measure to compare sunscreen efficacy remains the “sun protection factor,” or SPF. Devised several decades ago, prior to modern understandings of the numerous harmful effects of ultraviolet exposure, SPF value is based on how well a product prevents UV-induced redness, better known as sunburn.²⁰ The FDA test for UVA effectiveness and broad-spectrum protection is based on an *in-vitro* test that does not need to match the SPF value. EWG is concerned that bioactive ingredients can be used to boost the SPF value over 50 without changing the amount of incident light that reaches the skin, as measured through *in-vitro* testing.²¹ As such, SPF values may be misleading for modern products, since exposure to UV light is associated not only with sunburn but also a host of other adverse health effects, including skin cancer, photo-aging and immunosuppression.²²

Over the years, Americans have been barraged with advertisements for personal care products with higher and higher SPF values. In a recent survey of American consumers, the top factor in deciding which sunscreen to buy was the SPF value.²³ In EWG's 2007 sunscreen guide and market survey, only 10 products claimed an SPF of 70 or greater. In contrast, this year, 61 products in our guide make claims of SPF 70 or higher.²⁴ However, as products' SPF values have increased, the chemical filters available to manufacturers to reduce UVA exposure have remained unchanged. Currently, nearly every non-mineral-based sunscreen product on the market with an SPF of 30 or greater has exactly the same UVA filter, avobenzene, at a concentration of 3 percent. Such products may use different UVB filters, or varying concentrations of active and inactive ingredients, such as anti-inflammatories and antioxidants, to achieve such high SPF values.

Accordingly, we are concerned that FDA requirements do not effectively evaluate whether UVA protection increases as SPF values rise. As described above, the market shift toward higher SPF

²⁰ Sergio Schalka et al., The Influence of the Amount of Sunscreen Applied and its Sun Protection Factor (SPF): Evaluation of Two Sunscreens Including The Same Ingredients at Different Concentrations. *Photodermatology, Photoimmunology & Photomedicine*, 2009.

²¹ See Yun, *supra* note 8

²² Steven Wang, Joseph Stanfield and Uli Osterwalder, In Vitro Assessments of UVA Protection by Popular Sunscreens Available in the United States. *Journal of the American Academy of Dermatology*, 2008.

²³ Betty Y. Kong et al., *JAMA Dermatology*. 2015.

²⁴ See EWG, *supra* note 1



products may be misleading for consumers. Using a high-SPF sunscreen may influence some people to spend more time in the sun, unaware that the product does not provide a corresponding increase in UVA protection. There is significant evidence that “intentional sun exposure tends to be of longer duration when a sunscreen is used or when SPF increases.”²⁵

FDA can readily address the problem by capping SPF claims, as regulatory authorities have already done in Europe, Australia, Canada and Japan.²⁶ The agency itself has stated that SPF values higher than 50 are “inherently misleading.”²⁷ FDA should limit sunscreen product SPF claims to “50+.”

3. Require companies to use the lower value obtained from measuring the sun protection factor *in vitro* and *in vivo* when determining the SPF of products.

EWG is concerned that store shelves are currently stocked with sunscreens advertising inflated SPF values that do not accurately convey the protection they provide from UV radiation. Testing data for more than 140 products, submitted to FDA by Procter & Gamble, provide substantial evidence of the widespread discrepancy between the labeled SPF and the SPF measured *in vitro*.²⁸ The calculated SPF values from the *in vitro* measurements were systematically lower than the SPF values on labels. For products with a SPF over 50, the average calculated SPF from *in vitro* measurements was just half the labeled SPF.

Product testing used by sunscreen formulators demonstrates that antioxidant/anti-inflammatory ingredients do not change the SPF measured *in vitro* in laboratories or in modeling. These ingredients also do not change the critical wavelength used by FDA to assess UVA protection.^{29,30} Additionally, seemingly small variations in testing conditions and sunscreen application thickness can lead to significant differences in SPF test values measured *in vivo*.³¹ For example, in recent independent testing by Consumer Reports, a significant percentage of products did not provide the labeled SPF when measured *in vivo*.³²

²⁵ Philippe Autier, Mathieu Boniol and Jean-François Doré, Sunscreen Use and Increased Duration of Intentional Sun Exposure: Still a Burning Issue. *International Journal of Cancer*, 2007.

²⁶ EWG, What’s Wrong with High SPF? 2016. Available at www.ewg.org/sunscreen/report/whats-wrong-with-high-spf

²⁷ U.S. Food and Drug Administration, Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule. Federal Register: U.S. Food and Drug Administration, 2007. Available at www.fda.gov/OHRMS/DOCKETS/98fr/07-4131.htm

²⁸ J.F. Nash, 2009 Market Analysis - Study Data – Report. FDA-1978-N-0018-0689, 2009.

²⁹ Bernd Herzog and Uli Osterwalder, Simulation of Sunscreen Performance. *Pure and Applied Chemistry*, 2015.

³⁰ See Yun, *supra* note 8

³¹ The Procter & Gamble Company, Comments on the Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use. Docket No. FDA-1978-N-0018, RIN 0910-AF43, 2011.

³² Consumer Reports, Get the Best Sun Protection. 2016.



Know your environment.
Protect your health.

Current FDA testing and evaluation methods required for sunscreen products inadequately inform and protect Americans. FDA should reevaluate the *in vivo* testing methodology used to substantiate a product's labeled SPF value. By using the minimum value obtained from *in vivo* and *in vitro* testing, FDA would provide consumers with a more accurate reflection of those products' effectiveness, ultimately increasing users' protection from the sun's harmful rays.

EWG has repeatedly urged FDA to institute comprehensive regulations that would provide an adequate threshold for the safety and effectiveness of sunscreens.³³ However, FDA's current rules do not address many of EWG's concerns regarding the inclusion of anti-inflammatory, antioxidant and other ingredients, inflated SPF ratings, and flawed efficacy testing methodologies. Because users rely upon sunscreen as an important means to help protect themselves from damaging UVA and UVB rays, it is critical that FDA ensure that SPF and broad spectrum protection claims are accurate. For all of these reasons, FDA must act swiftly to investigate and respond to the concerns detailed above, given the significant stakes for sun safety and public health.

Sincerely,

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Thomas Cluderay
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Dave Andrews
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³³ Letter from Kenneth A. Cook, EWG President, to Margaret Hamburg, M.D., FDA Commissioner. May 23, 2011. Available at 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 Federal Official, Nonprescription Drugs Advisory Commission. Oct. 6, 2010. Available at 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 Commissioner. July 15, 2009. Available at www.ewg.org/files/FDA-Hamburg%20sunscreen-letter-by-ken.pdf