



March 22, 2016

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

**Comments of members of the Patient, Consumer, and Public Health Coalition
on the FDA Draft Guidance entitled "Over-the-Counter Sunscreens: Safety and
Effectiveness Data"**

Docket No. FDA-2015-D-4021

As members of the Patient, Consumer, and Public Health Coalition, we appreciate the opportunity to comment on the draft guidance entitled "Over-the-Counter Sunscreens: Safety and Effectiveness Data." **As members of the coalition, we strongly support the safety and effectiveness clinical and nonclinical testing requirements to obtain generally recognized as safe and effective (GRASE) status, as they are articulated in the draft guidance.**

Americans are using sunscreens more frequently and on a more long-term basis than ever before. Our safety and efficacy standards must reflect that Americans of all ages rely on these products to protect them from skin cancer.

We need clear evidence that sunscreen products are safe and effective for long-term use, particularly for infants, children, and pregnant women. Although current sunscreens are marketed for skin cancer prevention, we have very little evidence that they are effective for this purpose. In fact, major public health authorities, including the FDA, National Cancer Institute, and the International Agency for Research on Cancer, have concluded that the available data do not support the assertion that sunscreens alone reduce the rate of skin cancer.^{1,2,3} The safety and effectiveness testing requirements proposed in the draft guidance will provide the level of evidence that we need to be able to trust our sunscreen products to protect us and not harm us.

We strongly support the FDA's proposal to require that active ingredients be tested for carcinogenicity and developmental and reproductive toxicity prior to marketing. These studies must be carefully designed to mimic the conditions of real-life sun exposure, including temperature and humidity.⁴ Additionally, the National Institute of Environmental Health Services has concluded that endocrine-disrupting agents often have greater risks at low doses so dose-response testing is not appropriate for these studies.⁵ Without well-designed studies, children and other vulnerable groups could be harmed by hormone-altering ingredients.

Infants and children are more vulnerable to unsafe chemicals, because they use sunscreen more often and are more susceptible to the risks of chemicals in sunscreen. Although children are at disproportionate risk of harm from unsafe sunscreen products, we have very little data on the safety of these products in this young population. **For those reasons, we strongly urge the FDA to stipulate that clinical studies must provide demographic subgroup analyses of these and other susceptible populations before the products are allowed to be marketed for widespread use.**

Sunscreens are not “just cosmetics” and should not be regulated as such. Sunscreen chemicals may lose their effectiveness when exposed to light, or, worse yet, may actually cause cancer rather than prevent it.⁶ It is important that manufacturers provide clear scientific evidence proving the product remains active when exposed to sunlight for a reasonable length of time.

There is also evidence that certain active ingredients demonstrate potentially carcinogenic activity when exposed to UV light, such as generating free radicals that damage DNA and cause harmful mutations.⁷ Testing for carcinogenic activity should be done under conditions that reflect real-world use as closely as possible, e.g., during UV light exposure. Without such information, products intended to help prevent cancer may do just the opposite.

Several sunscreen ingredients currently on the market have endocrine-disrupting or carcinogenic activity.⁸ For example, oxybenzone is a widely used sunscreen ingredient and, with up to 10% absorption through the skin, it is found in the blood of nearly every American as well as in breast milk.⁹ Research has shown it acts like an estrogen in the body, is associated with endometriosis in women, and alters sperm production in animals.¹⁰ This ingredient should be banned from sunscreen and FDA must not let this mistake be repeated by allowing new sunscreen ingredients to be marketed without sufficient safety testing.

Finally, we strongly agree with the proposal to require testing of the active sunscreen ingredient with each vehicle (e.g. cream, spray, etc.) in which it will be delivered. Different product formulations that are more water or lipid soluble may change the properties or absorption of active ingredients in ways that could affect safety or efficacy of the final product. For example, alcohol-based formulations appear to increase sunscreen absorption and some sunscreen chemicals may enhance the skin absorption of other sunscreens when applied in combination.¹¹

In conclusion, the safety and effectiveness testing requirements for new sunscreen chemicals proposed in the draft guidance will assure our country's most vulnerable that the products will protect them from skin cancer and not cause unintended harm. We understand the desire for innovative new sunscreen products but this must not come at the expense of safety or effectiveness. We urge you to finalize this draft guidance without delay.

Sincerely,

Advocating Safety in Healthcare E-Sisters (ASHES)
Annie Appleseed Project
Breast Cancer Action
Cancer Prevention and Treatment Fund
Iowa Breast Cancer Edu-Action (IBCE)
Medication-Induced Suicide Prevention and Education Foundation (MISSD)
MedShadow Foundation
National Organization for Women
National Physicians Alliance
National Women's Health Network
Our Bodies Ourselves
Washington Advocates for Patient Safety
Woodymatters

The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The Coalition can be reached through Tracy Rupp at (202) 223-4000 or at tr@center4research.org.

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

² IARC (International Agency for Research on Cancer). IARC Summary Recommendations for Public Health Action, 2001. Available at: <http://www.who.int/uv/resources/recommendations/en/IARCSum.pdf>. Accessed 03/16/2016.

³ National Cancer Institute: PDQ Skin Cancer Prevention. Bethesda, MD: National Cancer Institute. Date last modified 02/05/2016. Available at: <http://www.cancer.gov/types/skin/hp/skin-prevention-pdq>. Accessed 03/16/2016.

⁴ Klimová Z, Hojerová J, Beránková M. Skin absorption and human exposure estimation of three widely discussed UV filters in sunscreens--In vitro study mimicking real-life consumer habits. *Food Chem Toxicol*. 2015;83:237-50.

⁵ Schug TT, Janesick A, Blumberg B, Heindel JJ. Endocrine disrupting chemicals and disease susceptibility. *Journal of Steroid Biochemistry & Molecular Biology*. 2011;127: 204– 215.

⁶ Gonzalez, H et al. Photostability of commercial sunscreens upon sun exposure and irradiation by ultraviolet lamps. *BMC Dermatology*. 2007; 7:1.

⁷ Hsiao IL, Huang YJ. Effects of serum on cytotoxicity of nano- and micro-sized ZnO particles. *J Nanopart Res*. 2013;15:1829.

⁸ Schlumpf M et al. In vitro and in vivo estrogenicity of UV screens. *Environ Health Perspect*. 2001 Mar;109(3):239-44.

⁹ Janjua NR, Kongshoj B, Andersson AM, Wulf HC. Sunscreens in human plasma and urine after repeated whole-body topical application. *J Eur Acad Dermatol Venereol*. 2008. 22(4): 456-61.

¹⁰ Krause M, Klit A, Blomberg JM, et al. Sunscreens: are they beneficial for health? An overview of endocrine disrupting properties of UV-filters. *International Journal of Andrology*. 2012. 35: 424–436.

¹¹ Benson HA. Assessment and clinical implications of absorption of sunscreens across skin. *Am J Clin Dermatol*. 2000;1(4):217-24.