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

Comments on "Sunscreen Drug Products for Over-the-Counter Human Use"
Docket No. FDA-1978-N-0018

We, the undersigned organizations, strongly support the current efforts of the U.S. Food and Drug Administration (FDA) to update the regulations governing sunscreen products sold in the U.S., improving the safety and efficacy of these important products.

Millions of Americans use sunscreens daily and rely on the FDA to ensure that these products adequately protect them from damaging UV rays without themselves causing harm. To date, the FDA has failed to ensure that common sunscreen ingredients have been adequately tested for safety. It is imperative that the FDA's proposed updates to sunscreen regulations be finalized as these changes should ensure that the health benefits of using sunscreens outweigh any potential risk.

Sunscreens are no longer just stand-alone products saved only for special occasions, like hiking trips, or pool and beach outings. Sunscreen products are now used frequently and by every demographic, including children. The American Academy of Dermatology recommends that sunscreens should be worn every day if you go outside. And Americans are turning to sunscreens not just to prevent sunburn but to protect from long term skin damage and cancer. In response to the demand, manufacturers now add sunscreen ingredients, and a sun protection factor, or SPF, to daily-use personal care products like makeup, moisturizers, lotions, and lip products as well as BB and CC creams. Given the frequency of use, FDA's proposal to adequately test sunscreen ingredients to understand how much of these chemicals get into our bodies and any potential long-term health consequences that may result from their use is extremely important and long overdue.

Despite the increased use of sunscreens and other SPF products, the rate of melanoma has steadily increased since the mid 1970's, more than tripling in this time period. Improved sun protection products are urgently needed to address this public health crisis.

The FDA should finalize the proposed changes to the sunscreen monograph and require:

- Biomonitoring testing to determine how much of each sunscreen ingredient absorbs into the body.

Recent testing by the FDA found that four commonly used sunscreen ingredients readily absorb into the body at levels that should require additional safety testing. Yet, the FDA

has acknowledged that they have never required testing of these and other active ingredients currently on the market and they do not have adequate health and safety data to determine if they are safe. At a minimum, all sunscreen active ingredients should be tested to measure how much gets into the body. We support the FDA's proposal to ensure that manufacturers conduct absorbance testing on sunscreen active ingredients. We also urge the agency to ensure that absorbance testing consider all different product formulations, including those with ingredients that may increase absorbance.

- Comprehensive safety testing of ingredients that do absorb.

Active ingredients that are absorbed above the FDA threshold have the potential to cause longer term health harm, especially if these products are used regularly for years or decades or used by vulnerable populations like children and pregnant women. We support the FDA proposal to require additional safety studies, including tests of carcinogenicity, systemic toxicity, and reproductive and developmental toxicity including an assessment of how these ingredients may impact hormone levels.

The FDA proposed that oxybenzone as well as 11 other active ingredients be classified as Category III, indicating that the agency has insufficient data to determine if these ingredients are Generally Recognized as Safe and Effective. The proposed Category III classification for oxybenzone is unique given that it is one of the most common ingredients and also the active ingredient with the most documented health concerns. The FDA noted that oxybenzone is absorbed into the body in large amounts, and has been detected in breast milk, amniotic fluid, urine and blood. The agency cited studies showing that oxybenzone caused allergic reactions and endocrine disruption. Additionally, the FDA highlighted concerns that children could be more susceptible from harm to oxybenzone.

Despite the concerns, oxybenzone remains one of the most frequently used sunscreen active ingredients. According to a public interest nonprofit based in the U.S., more than half of the 80 sunscreens they tested, including all of their recommended products, contain oxybenzone. Another organization reported that oxybenzone was used in two thirds of non-mineral sunscreens the group assessed in its 2019 Guide to Sunscreens. Overall half of the nearly 1300 products assessed in the Guide contain ingredients without adequate testing data according to FDA.

The FDA determined that zinc oxide and titanium dioxide do not absorb into the body yet we proposed that these ingredients be periodically assessed for absorbance and toxicity due to their nanomaterial form and the evolving science on the toxicity of these new materials.

- Adequate evaluation of sunscreen safety for children and vulnerable populations.

According to the FDA, children may be more vulnerable to harm from oxybenzone than adults "because of the potential for higher absorption and bioaccumulation." Because of the expected long latency between sun exposure or UV damage and cancer development sunscreen use is critical during childhood. All sunscreens should be evaluated with consideration of early life exposure.

- Limits on the maximum SPF number.

We support the FDA proposal to limit allowable SPF claims to values that provide additional clinical benefits without providing the user a false sense of security. A survey conducted by researchers at Northwestern University reported that the most important factor for consumers when choosing which sunscreen to buy was a high SPF. This is troubling because according to the FDA proposal, high SPF sunscreens currently on the market may allow users to be exposed to excessively large doses of UVA rays, which have been associated with skin damage and skin cancer. In a 2007 sunscreen guide, 38 products adverted an SPF over 50+ and in 2019 that number grew to 84 products, representing more than 10 percent of the beach and sport sunscreens assessed. The FDA originally proposed to limit high SPF claims in 2007 but their efforts were thwarted by industry pressure. Given the continued rise in skin cancer rates in the U.S., it's important that the agency no longer delay action.

- Testing to ensure that sprayed and powdered sunscreens do not pose an inhalation risk to consumers.

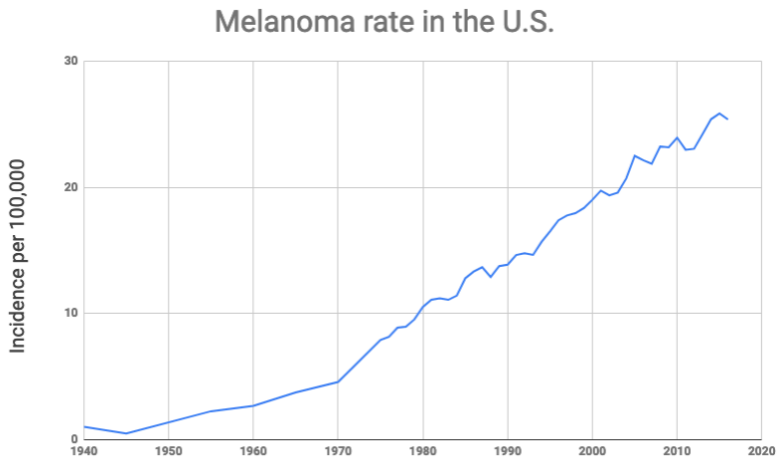
Particles in sprayed and powdered sunscreen products could potential pose an inhalation risk to consumers, particularly if the particle sizes of the emitted products are small enough to be inhaled into the deep recesses of the lungs where they may cause irrevocable and serious damage. The FDA has proposed that these product types must be tested to verify that the emitted particles are large enough not to cause damage if inhaled. Many spray sunscreens are advertised for use on children. Even for users who forgo using these products, exposure is nearly impossible to avoid because of common use in public spaces like pools and beaches.

- Improved standards for UVA protection.

Broad spectrum UVA protection is critical in sunscreen products, especially due to the scientific understanding linking UVA light to melanoma development. Tanning beds, which primarily emit UVA light, have been classified by the World Health Organization as a known human carcinogen due to increased melanoma rates in women. Highlighting the importance of UVA protection, a top researcher for BASF showed how a sunbather using a product with poor UVA protection would receive a similar overall exposure to a person using a tanning bed. We support the efforts FDA is making to improve the UVA protection offered by sunscreens sold in the U.S. and ensuring that the UVA protection increases with increasing SPF.

- Enable market entry and use of time and extent application, or TEA, sunscreen ingredients that provide improved UVA protection if they have improved safety profiles compared to other ingredients.

FDA emphasized the importance of strong UVA protection in reducing the risk of long-term skin damage and cancer. These concerns are not new and extend to studies of increased melanoma rates in differentially UVA exposed testing over two decades ago. Melanoma rates continue to climb as they have for decades.



Source: https://seer.cancer.gov/statfacts/html/melan.html &
https://www.ncbi.nlm.nih.gov/pubmed/22007306

Over the past decade the US sunscreen market has had the weakest collection of UVA filters in the world. This situation is untenable from a public health perspective. Based on the current scientific evidence sunscreen products should be formulated with UVA protection that is equivalent to the UVB protection. Balanced UVA protection is not possible in nearly all U.S. sunscreen products based on the lack of strong UVA filters. Any of the TEA sunscreen applicants that have comparable or improved safety values over the monographed ingredients should be usable as sufficient data is developed.

Conclusions

The FDA should finalize the proposed rules and not weaken the safety or efficacy standards at the bequest of industry. All sunscreen ingredients should be thoroughly tested for safety and effectiveness. We support the FDA's efforts to improve the sunscreen products available for sale in the U.S. and, as such, protect public health.

Enclosure

April 4, 2019

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Dear Chairman Alexander, Ranking Member Murray, Chairman Pallone, and Ranking Member Walden:

Our organizations strongly support efforts by the U.S. Food and Drug Administration to ensure the public is protected from hazardous or poorly-tested substances in products the agency regulates, including its recent steps to address the safety and effectiveness of sunscreen ingredients. We ask that you join us in supporting these recent actions by FDA.

As FDA noted in the agency's proposed sunscreen rule, sunscreen use has increased dramatically but many ingredients lack safety testing and have not been reevaluated based on the latest science. Some of the chemicals used in sunscreens are thought to be absorbed through the skin and the agency has expressed concern for potential endocrine disruption as well as the potential for reproductive, developmental and carcinogenic effects.

We strongly support FDA's request that chemical manufacturers conduct studies to assess the extent to which substances such as sunscreen chemicals are absorbed into the body, and the likelihood that these chemicals may cause serious health problems. Like FDA, we are especially concerned about the impacts of sunscreen chemicals and other substances on the developing bodies of children.

We strongly support FDA's efforts to assess the safety and effectiveness of sunscreens. Melanoma rates continue to climb and every year, thousands of Americans die from skin cancer. Safer and more effective sunscreens should help. But, as FDA documented in the proposed rule, many sunscreens do not provide adequate protection from the sun and make misleading and confusing claims.

We strongly support FDA's efforts to ensure the safety and effectiveness of sunscreen ingredients, and we urge you to support FDA's proposed sunscreen rule.