Shedding More Light on Sunscreen Absorption

New research adds to our understanding of sunscreens.

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Even on cold, cloudy winter days, sunscreen safety remains a top priority at the U.S. Food and Drug Administration, as well it should since sunscreens are recommended for year-round use. Today, the FDA's newly-published research in the Journal of the American Medical Association (JAMA) provides much-needed additional information about the absorption of the active ingredients in sunscreens into the body's bloodstream after they are applied to the skin. It's an important follow-up study to prior research, published in JAMA in May 2019, that showed when certain sunscreens were used at their maximal recommended use (according to the product's label), their active ingredients were absorbed through the skin and into the body.

Important new information builds on last year's initial findings

Today's newly-published information adds to those key findings from last May. It describes the results of a clinical trial evaluating the absorption of a wider range of sunscreen active ingredients, six as opposed to four in the original study. This second study, in addition to studying application every 2 hours according to the product label (maximal use), also studied absorption after a single use. In the new study, we tested absorption of active ingredients contained in four commercially available sunscreen products (lotion, aerosol spray, nonaerosol spray and pump spray). While additional data are needed, results showed that all six active ingredients were absorbed into the body's bloodstream – even after a single use. An additional finding from this new study is that once absorbed, these active ingredients can remain in the body for extended periods of time. This study evaluated absorption of the active ingredients avobenzone, oxybenzone, octocrylene, homosalate, octisalate, and octinoxate. The prior study evaluated absorption of avobenzone, oxybenzone, octocrylene, and ecamsule.

The FDA is seeking more information on sunscreen ingredients

Importantly, both of these studies support an FDA proposed rule, issued in February of 2019, aimed at bringing over-the-counter (OTC) sunscreens up to date with the latest scientific

standards. It’s a high priority for the FDA and we continue to work toward establishing final marketing requirements for sunscreens. As part of this rule, the FDA has asked industry and other interested parties for additional safety data on 12 active sunscreen ingredients currently available in marketed products. While both of these studies make a great start, additional data are needed for each of these 12 active sunscreen ingredients in order to fully understand their absorption into the body as well as the long-term effects of absorption. Without further testing, the FDA does not know what levels of absorption can be considered safe.

Absorption does NOT equal risk — the FDA advises continued use of sunscreens

The findings in these studies do not mean that the FDA has concluded that any of the ingredients tested are unsafe for use in sunscreens, nor does the FDA seeking further information indicate such. The agency’s proposed rule requested additional safety studies to fill in the current data gaps for these ingredients. The rule also proposed that two active ingredients (zinc oxide and titanium dioxide) are generally recognized as safe and effective for use in sunscreens, and additional data was not requested for them.

Given the recognized public health benefits of sunscreen use, the FDA strongly advises all Americans to continue to use sunscreens in conjunction with other sun protective measures (such as protective clothing) as this important rulemaking effort moves forward. Broad Spectrum sunscreens with SPF values of at least 15 are only one element of a skin-cancer prevention strategy that should also include other sun protective behaviors such as wearing protective clothing that adequately covers the arms, torso, and legs; wearing sunglasses and a hat that provides adequate shade to the whole head; and seeking shade whenever possible during periods of peak sunlight. Other medical authorities, such as the Centers for Disease Control and Prevention, the American Academy of Dermatology, and other major physicians’ associations endorse similar recommendations. More about sun protection and sunscreens can be found on the FDA website.

The FDA’s research and studies, as well as our ongoing work to update the regulatory framework for sunscreens, reflected in the proposed rule on Sunscreen Drug Products for Over-the Counter Human Use, are two of many ways the agency is working to help ensure safe use of sunscreens for the American public.

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