FDA's Greenlight of Old Chemical Offers Chance to Restore Faith in Sunscreen

Sunscreen ingredient bemotrizinol (BEMT) has been used safely around the globe for decades. Its FDA approval may boost competition and consumer confidence.

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Officials, environmental health advocates, and skin care industry groups are expressing hope that the Food and Drug Administration's approval of a sunscreen ingredient on June 9 — after consideration for two decades, and global use for nearly as long — will help restore Americans' wavering faith in sunscreen.

"Bemotrizinol has been used safely in Europe for decades," Health and Human Services Secretary Robert F. Kennedy Jr. said in the announcement about the approval. "FDA's action will increase competition and consumer confidence in sunscreen products."

Nonprofits that advocate for health, such as the Environmental Working Group, and the skin care industry alike had lobbied for approval of the ingredient, which makes sunscreens sheerer and lighter on the skin than many available American options while blocking a wider spectrum of ultraviolet rays that can cause premature aging and skin cancer.

The newly approved sunscreen filter will allow companies to reformulate sunscreens to address consumers' concerns, said Carl D'Ruiz, a senior manager at DSM-Firmenich, a Swiss maker of sunscreen chemicals that applied for the FDA approval. In addition to allowing companies to offer what the FDA calls safe and effective formulations, he said, the approval will allow sunscreens that are more like sought-after South Korean brands to be sold in the U.S. by autumn.

Confidence in U.S. sunscreen has faltered on two fronts: among those concerned about what's in the sunscreens they use and those who believe sun exposure is healthy. But will the new ingredient win the trust of Make America Healthy Again skeptics and Gen Zers intentionally tanning? RFK Jr., strikingly bronzed, has helped stoke this confusion by pledging in 2024 to fight what he called the FDA's "war on public health" and "aggressive suppression" of sunshine. Under his leadership, the FDA backed away from a plan in March to ban people under 18 from using tanning beds.

All this matters because 1 in 5 people will develop skin cancer by age 70 in the United States. It is the most common cancer in the nation, where about 3.3 million people are diagnosed each year with basal and squamous cell carcinomas.

D'Ruiz said he thinks bemotrizinol, also known as BEMT, will change the dynamic. "People will talk more positively about sunscreens," he said.

In the U.S., new sunscreen chemicals are regulated as over-the-counter drugs like aspirin or cough syrup rather than as cosmetics, as in Japan and the European Union. That means they face more elaborate testing and safety protocols, such as animal testing that runs afoul of EU laws, which is why the approval process for bemotrizinol took nearly two decades, D'Ruiz said.

What's "generally recognized as safe and effective," otherwise known as "GRASE" in FDA-speak, is at the center of the American sunscreen debate. Bemotrizinol joins zinc oxide and titanium dioxide on the FDA's GRASE list.

That could help rebuild trust, said Alexa Friedman, an environmental epidemiologist at the Environmental Working Group, a nonprofit that researches the ingredients in consumer products.

"It has strong safety data," Friedman said. "The documents submitted to the FDA to achieve 'generally recognized as safe and effective' include tests of irritation, sensitization to allergies, two-year animal studies for carcinogenicity, and reproductive health."

The approval will also give consumers access to sunscreens that don't leave as much of a white cast, she said, which makes some people hesitant to use mineral sunscreens such as zinc oxide and titanium dioxide.

Bemotrizinol's approval won't change the possibility of several chemicals with unclear safety profiles being added to sunscreens.

In 2019, the FDA said there was insufficient data to support a positive "generally recognized as safe and effective" determination for 12 commonly used sunscreen chemicals.

The concerns emerged after the FDA published a study that said some sunscreen ingredients had been found in humans' bloodstreams. Though the industry has since phased out several of those chemicals lacking GRASE status, four are still widely used: avobenzone, homosalate, octisalate, and octinoxate.

"The European Union had recently concluded that homosalate was not safe at concentrations that they were using and recommended a very low percentage — which was effectively a ban," Friedman said. "The U.K. also issued a safety evaluation."

Octisalate and octinoxate have been associated with disruption of the endocrine system, and octinoxate was banned for sale in Hawai'i due to concerns that it harms marine life and bleaches coral reefs.

Avobenzone breaks down when exposed to light, making it less effective, Friedman said, and has been associated with allergic reactions.

Mark Mitchnick, a pediatrician who invented transparent zinc oxide, which is known under the brand Z-Cote, said bemotrizinol will give chemists a new tool to make sunscreens that people will want to wear.

“It’s a good UVA block,” he said. “It gives us good flexibility. In my mind, it allows you to make really good products without using avobenzone, which I think has a lot of baggage.”

Most of the UV rays people are exposed to are UVA rays that can penetrate the middle layer of the skin and cause up to 90% of skin aging, along with a smaller amount of UVB rays, which are responsible for sunburns. Ultraviolet radiation falls on the electromagnetic spectrum between X-rays and visible light.

Mitchnick said major companies have used chemical filters because they work better on a per-pound basis compared with mineral sunscreens made with zinc oxide and titanium dioxide. “That’s why hybrids are great — you get the best of both worlds.” He said he expects companies, including his own, to release hybrid products containing bemotrizinol and zinc oxide later this year.

He worries the industry has contributed to the trust gap by adding unapproved UV filters, called boosters, to mineral sunscreens, to raise sun protection factor ratings, or SPF. This leads consumers to wonder what’s in the products they’re buying.

Still, in Australia, where bemotrizinol has been used in sunscreens for years, a recall scandal over ineffective products shows that even when regulators allow lauded UV filters, bad actors can taint a whole industry.

“People are not shunning sunscreen because they have stopped believing UV is dangerous,” said Joseph Mizikovsky, a director of the Australian Sunscreen Council. “They are shunning it because they have lost trust in what is in the bottle.”

He applauds the FDA’s transparency with American consumers about the lack of safety data for filters without GRASE status, and FDA’s insistence on mandatory microbial testing of products.

But he said the FDA could do more to rebuild trust in sunscreens.

“My view is the FDA should move faster to ban filters that are missing safety data, and the public should focus on physical protection — shade, clothing, hats, sunglasses — with sunscreen as the last layer, not the first.”

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