

FDA's Deemed Final Order Issued for Sunscreens

I am writing this column two weeks before the September 27 deadline imposed by the CARES Act of 2020 for the US Food and Drug Administration to publish its Final Administrative Order on sunscreens. Last year, as part of the CARES Act, the Sunscreen Innovation Act of 2014 was suspended. So, what is pending in the Administrative Order of September 27, 2021? The FDA submitted Proposed Regulations on February 21, 2019. It was followed by the CARES Act on March 27, 2020, which would presumably reform and modernize the US Regulatory Framework for OTC Drug Review. It specifically introduced:

- The Administrative Order (AO) Process replacing the original “Notice and Comment” Rulemaking Process.
- Expanded FDA resources via a User Fee Program authorized for five years (OMU-FA and OMOR fees).
- Suspension of the Sunscreen Innovation Act (SIA) of Nov 26, 2014.
- A mandate that the status of existing OTC Monograph and Ingredients be finalized by September 27, 2021.

The issue of finalizing the status of the 16 UV filters approved in the US as Category I ingredients is of paramount importance to the Sunscreen Industry and for ensuring that consumers are protected from the ravaging rays of the sun. Those solar rays presumably are responsible for the skin cancer epidemic that we are experiencing today in the US and around the world. After the publication of the MU_sT studies in

the Journal of the American Medical Association (JAMA) by the FDA scientists, the proposed regulations determined that only two UV filters (zinc oxide and titanium dioxide) are Generally Regarded As Safe and Effective (GRASE). Two filters (triethanolamine salicylate and PABA) were banned, and the remaining 12 Category I filters were given a Category III designation calling into question their safety. Despite the FDA's repeated assertions that these 12 filters could still be used for solar protection, consumers were left confused and bewildered and having to make their own decisions on their use.

A multi-billion-dollar industry relying on only two filters, zinc oxide and titanium dioxide, is impractical and would be a total nightmare. Sunscreen products on the US market today

with these two ingredients represent, at best, 15% of the total sunscreens in use. While these two ingredients are excellent UV blockers, they have serious limitations in filling the gap of the 85%, or more, of sunscreen products that currently use the 12 organic absorbing UV filters that are under the scrutiny of the FDA today. When you couple the potential banning of some, or all, of the remaining 12 organic filters by the FDA along with the news that some UV filters affect coral reefs, and the reluctance of the FDA to allow the European filters to be approved in the US under the Time and Extent Application (TEA) process, we are looking at an economic disaster in the sunscreen industry and a potential public health calamity due to a lack of adequate solar protection. I have stopped predicting what the FDA will decide on the major issues concerning sunscreen regulations, but I know that if it bans all or some of the 12 filters in question on September 27, we will see a major upheaval in the industry and a potential rise of skin cancer.

SEPTEMBER 27 UPDATE

A few days prior to the publication of this column, the FDA released its announcement on “Amending Over-the-Counter Monograph.” My editor allowed me to add the following literally one day before the column was set for printing. Here is what the FDA released:

“FDA is issuing this proposed order to amend and revise the Deemed Final Order established by the enactment of the CARES Act (March 27, 2020). This proposed order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be GRASE under section 201(p)(1) of the FD&C Act.”

Allow me to comment:

1. Apparently the CARES Act has enacted a “Deemed Final Order” not a “Final Order” that would have required the FDA to act by the imposed deadline of September 27?!
2. Note the statement: “This proposed order, if finalized,....” Implying that it may not be finalized soon!
3. The FDA kept the status quo exactly as it has been in its 2019 Proposed Rule. This Rule had set ZnO and TiO₂ as the only two GRASE approved UV filters, banned two filters (PABA and Trolamine Salicylate) and deferred the remaining 12 filters to a Category III status requiring additional testing to prove their safety as UV filters.

The bottom line is that the status quo will continue for at least one more year past the 45 day comment period specified. Still, the uncertainty regarding the safety of UV filters continues in the minds of consumers. ■



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