

KNOW YOUR ALPHABET: OMUFA, OMOR AND AO

THE OTC Reform Act legislation was discretely introduced in the coronavirus stimulus bill, entitled The CARES Act, on March 27, 2020. This sunscreen bill has legislated several crucial elements that will shape and influence sunscreen regulations for many years to come. Its key provisions are:

1. It replaced the current "Notice and Comment" process with an "Administrative Order" (AO) system.
2. It repealed the February 2019 Tentative Final Monograph (TFM) and authorized the FDA to issue new proposed AO or Final AOs under the CARES Act.
3. It authorized a 5-year User Fee Program.
4. It sunsetted the Sunscreen Innovation Act (SIA) by September 2022.

Let me briefly discuss the ramifications of each of these four provisions:

- **The introduction of the Administrative Order:** Basically, this provision entitles the FDA to arbitrarily decide on all issues

without any appeals being allowed. The current "Notice and Comment" rulemaking process was permanently replaced giving the FDA the veto power to regulate potentially without discussion or consultation. It did, however, stipulate that either the industry or the FDA can initiate the AO in an expedited process.

- **The repeal of the 2019 TFM:** The "Proposed Rules" issued on February 26, 2019 had called for, among other provisions, the removal of two filters, namely (trolamine salicylate) and PABA, that were designated Category III status. It also called for the GRASE Category I status of only two filters, namely zinc oxide and titanium dioxide, and classified all the remaining filters, previously classified as approved for use as Category I filters, to a Category II status. This would mean that they would be disallowed in sun care formulations unless additional extensive testing (including the previously described MUsT, DART, and other tests) were performed. These ingredients are avobenzene, homosalate, octinoxate, octisalate, octocrylene, oxybenzone, ensulizole and meradimate.

Realizing this ban would have a far-reaching impact on the sunscreen industry, the FDA has allowed their temporary use in current formulations until they issue final approvals or rejections of those UV filters. Meanwhile, the FDA published two crucial studies in the prestigious Journal of American Medical Association (JAMA) in late 2019 and early 2020 basically revealing that seven of those currently designated as Category I failed the MUsT test, (penetrating skin at unsafe levels) and would not qualify as approved filters. Those seven UV filters are avobenzene, oxybenzone, octocrylene, ecamsule, homosalate, octisalate and octinoxate. The Personal Care Product Council has pleaded with the FDA to allow another round of MUsT tests for these eight filters to be

conducted hoping for an act of God or an unforeseen miracle that they would pass the unrealistic threshold of 0.5 ng/ml detection levels in the blood of volunteers. Not sure that will happen!

- **The 5-Year User Fee:** The Act expands FDA resources to issue the Final Monograph via a five-year user fee program entitled "OTC Monograph User Fee Application (OMUFA)." It establishes that a drug is "misbranded" if made in a facility that did not pay user fees. This provision alone will make it extremely difficult for the hundreds of small to mid-sized "contract manufacturers" to continue their current business. It allows for an "OTC Monograph Order Request (OMOR)" fees of:

- a. Tier 1 @ \$500,000 for new ingredients or changes in protocols requiring human testing.
- b. Tier 2 @ \$100,000 for any minor modifications or labeling in the monograph.

Those fees are a recipe for potential barriers to small or medium size sunscreen companies doing business in the US. The OMOR fees, however, offer an 18-month exclusivity to companies that have paid those fees, under certain circumstances, and sets timelines for their reviews.

- **The Sunsetting of the SIA:** By September 20, 2022, the SIA will no longer be valid. This means that the five-year edict in the SIA, stipulating the issuance of the Final Monograph (which expired November 26, 2019), is no longer in effect. Also, the status of the eight European TEA has been suspended pending the issuance of an AO. Any new filters awaiting approval must abide by all the current provisions of the CARES Act including the OMUFA and OMOR requirements and subject to the Administrative Order (AO) provisions.



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New Impediments

The impact of the above new provisions and requirements is the suspension of issuing the Sunscreen Final Monograph to a date that is quite distant in the future! In the meantime, all the issues that are confronting the sunscreen industry today are there with many new impediments added. These issues are:

1. Safety of the UV Filters: With the recent JAMA studies revealing that seven of the most important UV filters (used in 90% of the current sunscreen formulations) penetrating the bloodstream at unsafe levels, the only filters now designated as GRASE Category I are ZnO and TiO₂ (used in 10% of the current sunscreen formulations).
2. The new impediments set for approving the European TEA ingredients.
3. The SPF maximum levels and the race for higher and higher SPF products.
4. Safety of spray sunscreens.

5. Combinations allowed with avobenzene. This condition would not be important if avobenzene itself was banned due to its unsafe bloodstream absorption.
6. Quenchers and photostabilizers that are unapproved UV filters.
7. Nanoparticles in sunscreen products.
8. Dosage forms of sunscreens products.
9. Environmental concerns and their impact in banning potentially approved UV filters.
10. The impact of the current AO and OMOR user fees on the marketing and viability of current sunscreen products.

The Chaos Continues

It is clear that technological advances in producing new effective UV filters that are safe, minimally absorbed into the bloodstream and at the same time effective in preventing skin cancer from the harmful solar radiation, are either lacking or stymied by stringent and inconsistent

FDA regulations. It is true, however, that consumer habits in their over reliance on sunscreens for solar radiation protection has totally changed since the inception of regulations in 1978, thereby warranting careful deliberations in issuing a Final Monograph for sunscreen use.

Nevertheless, the fact that no clear and final regulations have been issued by the FDA has contributed to the chaos that confronts sunscreen use today. Publications by the FDA revealing that seven of the most popular UV filters penetrate the skin and are detected in the bloodstream of volunteers at unsafe levels—without offering the consumer clear alternatives—is disheartening and discouraging.

Hawaii and Florida have attempted to ban Category I UV filters unilaterally due to environmental concerns and have even required medical prescriptions for their use without deferring to the FDA, the organization authorized to legislate such action. Not only are these actions baffling to those the industry, but consumers are confused. It is incumbent on both the FDA and sunscreen manufacturers to allay their fears and to immediately address all those issues dealing with the safety and efficacy of sunscreen products for solar protection in the US.

In other developments, Alex Azar, secretary of Health and Human Services (HHS), barred FDA and other health agencies from signing any new rules regarding the nation's food, medicines, medical devices and other products, including vaccines. Obviously, this is a power grab by this administration to ensure that the FDA does not make any decisions on the upcoming vaccine. Usurping the power to issue Final Regulations from the FDA will also impact the issuance of Sunscreen Regulations. Interestingly, HHS is considering the approval of a vaccine that has been developed in Oxford, UK. For political expediency, the administration, including the FDA, will apparently accept foreign data for drugs and vaccines to be used in the US. Ironically, for years the FDA has denied the approval of the Sunscreen TEA filters on the basis that the data has been generated in Europe and not the US! ●