

WILL THE US ELECTION IMPACT SUNSCREEN REGULATIONS?

I NEVER THOUGHT that I would ever comment on political issues as they relate to sunscreens, but the situation is highly charged and future decisions are bound to matter with any changes in the administration and the political landscape.

As I am writing this column, Vice-President Joe Biden has won the US Presidential Election. President Donald Trump, however, has not acknowledged his defeat in the election and has vowed to contest that decision. The Senate is also being contested and the two run-off elections in the state of Georgia deciding the majority status will be held in early January. A split Congress, with the majority in the House and Senate belonging to the opposing parties, will have significant implications on future regulations.

During the previous Democratic administration, in 2014, the Surgeon General issued a "Call to Action" to make combating cancer a high priority. The next year, Biden launched a "Moonshot" program to combat skin cancer. Unfortunately, that shot came too late during the Obama Administration and no real progress on



The sunscreen industry as we know it could be rubbed out if avobenzene and the other half dozen organic UV absorbing chemical filters are banned.

implementing this ambitious effort was undertaken. A new administration with Biden as president will most definitely put combating cancer front and center again.

The US Food and Drug Administration studies published in the prestigious Journal of the American Medical Association (JAMA) in 2019 and 2020 raised the bar significantly regarding the safety of ultraviolet filters. New suggestions have emerged that extensive MUsT, DART studies and other reproductive and long-term damage tests must be conducted, not only to approve new UV filters but also to allow the use of the current filters that were deemed Category I in 1978.

The OTC Monograph Reform legislation of 2020 gave the FDA exclusive privileges to issue final regulations with minimal due process for the current manufacturers of UV filters and sunscreens. The FDA is now authorized to issue final administrative orders (AO) that will ban or approve as GRASE (Category I) the current list of UV filters. Potentially, they may ban most of the organic absorbing UV filters and possibly keep zinc oxide and titanium dioxide as the only two approved UV filters. Finally, the

OTC Reform Act has authorized substantial "administrative fees" to approve any new UV filters, or modifications in percentages permitted, for use in sunscreen formulations. Those OMUFA and OMOR fees will be levied on manufacturers of all sunscreen products in the US.

A Study on Coral

Another development, which was precipitated by the recent Hawaii legislation, called for the banning of oxybenzone, octinoxate and other UV filters due to their environmental impact on coral reefs. Several other states, and even other countries, soon followed Hawaii's lead and initiated calls for similar legislation.

Congress has authorized a study by the Environmental Protection Agency (EPA) to study the impact of UV filters on coral reefs and will also evaluate the potential public health implications associated with reduced use of sunscreen for protections against ultraviolet exposure. This study will be conducted by the National Academy of Science (NAS) sometime next year. An expert panel is being recruited and will be announced soon.



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The Public Access for Safe Sunscreens (PASS) Coalition has been in contact with the EPA, NAS and the National Oceanic and Atmospheric Administration (NOAA).

So, what is pending at the FDA concerning sunscreen regulations? Everything! For one thing, Secretary of Health and Human Service (HHS) Alex Azar recently mandated that no decisions by the FDA can be issued without his approval. A Biden appointment at the HHS will undoubtedly reverse Azar's limitations on the FDA. In addition, decreased regulations, and the reduction of restrictions on business, is the mainstay of the current Republican administration vis-a-vis the Democratic party's platform. Specifically, however, major issues confront sunscreen regulations, and regardless of who is in power, regulations must be finalized. Will that happen in our lifetime? Nobody knows!

Many Issues Remain

Currently there are many issues regarding sunscreen regulations, and it behooves us to review them to understand and appreciate the seriousness and gravity of their consequences.

The 2020 OTC Monograph Reform legislation has only issued a "Proposed Order" for the regulation of sunscreens. The FDA will soon issue "Administrative Orders" (AO) approving or disqualifying UV filters that are GRASE and Category I filters.

The testing protocols to determine the safety and efficacy of UV filters has not been finalized yet.

OMOR and OMUFA fees will be levied on all future developments and production of sunscreens.

Will the so-called Time and Extent Application (TEA) European filters be approved in the US?

If avobenzone and the other half dozen organic UV absorbing chemical filters are banned, then the industry as we know it today will cease to exist. The impact on solar radiation protection will be immense. If avobenzone is approved, will the photostability issues be addressed? Will avobenzone be allowed to be mixed with ZnO and TiO₂?

All the other issues that I have repeatedly

outlined in my previous columns will be in play, including SPF levels, spray safety, testing issues and nanoparticles.

While I have focused my column on the ongoing issues with sunscreen regulations that directly impact our industry, I am well aware of the ongoing issues that our country faces during this COVID-19

pandemic. But the fact is that, along with the pandemic, skin cancer will continue to be one of our major health concerns. They are not mutually exclusive health concerns, and concerted efforts in all facets of society and industry can work together to solve both issues and, hopefully, give us something positive in the new year. ●