The Perils of Progress in the Search for New UV Filters

The New York Society of Cosmetic Chemists (NYSCC) Suppliers' Day is growing and becoming more popular every year. This year was no exception as thousands attended and visited 560 exhibitors. It serves as a forum for the exchange of ideas, allows attendees to see and "feel" the new products and innovations by the ever-expanding pool of suppliers and users, and promotes a multitude of new products and ideas in the cosmetics industry.

At this year's NYSCC Suppliers' Day, I ran into Carl D'Ruiz, the senior manager of business development at DSM-Firmenich. He has been championing the approval process of perhaps the first new UV filter in the US this century. This is a welcomed development in our industry that has been overshadowed by superior European and Asian sunscreen products. Many of us have been fighting the fight to approve new UV filters, especially high molecular weight broad Spectrum filters to compensate for the dearth of good UV filters in the US. The FDA, in its Proposed Final ruling a few years ago, deemed zinc oxide and titanium dioxide as the only two approved GRASE filters in the US. The rest of the so-called chemical UV absorbers were relegated to category III status; i.e., requiring further safety testing before they are approved for use in the US. Thus, the remaining eight filters, the workhorse ingredients for UV protection in the US, are being evaluated by the FDA for approval.


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FDA is demanding new testing for existing sunscreens.

The main impediments in getting these eight UV filters approved by the FDA are that none of these ingredients are patented and none are the exclusive domain of any of the UV filter suppliers. No one is willing to pay the exorbitant fees the FDA demands for approval, nor is anyone willing to sponsor the expensive safety testing required (including the MUsT tests) for any of those eight filters. The PCPC intervened and established a panel to address this issue with the FDA, but to the best of my knowledge, that panel was recently disbanded. They are now at the mercy of the FDA and their own internal experts to deem them safe for use in the US. Speculations are perhaps only Avobenzone may survive and possibly Octisalate and Homosalate. Certainly Oxybenzone, Menthyl Anthranilate, Octocrylene and Octinoxate face a major hurdle for approval.

ANIMAL TESTING REQUIRED

Another issue confronting the approvals of new and existing UV filters in the US, aside from the fact that they are deemed drugs instead of the more appropriate designation of cosmetics, is the use of animal testing for approvals. The industry is split on the use of animal testing with several major cosmetic houses objecting. The Personal Care Products Council (PCPC) and the PASS Coalition still directly lobby the FDA. They also lobby members of Congress to seek their assistance in persuading the FDA to finally release the Final Administrative Order. We have been waiting for years (more than 50 years) for the issuance of the sunscreen final regulations. The 2014 Sunscreen Innovation Act mandated that the FDA would finalize a monograph in two years; unfortunately, that also has gone by the wayside!

D'Ruiz walked me through the extensive process that DSM-Firmenich had to endure. Company executives met with the FDA in February to discuss their upcoming over-the-counter (OTC) monograph order request for a GRASE determination for bemotrizinol (BEMT) 6% as a sunscreen active ingredient under the FDA's OTC Monograph M020: Sunscreen Drug Products for OTC Human Use, and their team answered questions regarding the completion of the drug devel-

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opment plan. All studies identified as being needed by FDA following their Time and Extent (TEA) and Sunscreen Innovation Act (SIA) review and as required per their 2016 sunscreen safety and efficacy (GRASE) and 2019 MUsT Guidance for Industry, have been completed. At the meeting DSM-Firmenich asked FDA to explain the next steps and their timeframes for approving the ingredient.

FDA explained that following the OTC reform provisions made under the CARES Act and their review of the data generated, DSM-Firmenich can now submit an OTC Monograph Order Request (OMOR) Tier I submission to formally begin their review process. The FDA explained that the clock will start when the OMOR is submitted with the paid user fee. Regarding the filing determination, the FDA noted that there are two parts involved:

1. New ingredient eligibility. DSM-Firmenich must provide the new ingredient eligibility determination information regarding safe nonprescription marketing and use as a condition for filing with the OMOR as described in section 505G(b)(6) of the FD&C Act.
2. Content and format. The FDA will review the content and format of the OMOR submission and make the filing determination by day 60. In addition, the FDA explained that after the OMOR is filed, the FDA will continue with the review and issue a proposed order within 12 months of receipt.

THE TIMELINE

The FDA also mentioned that when the proposed order is ready for issuance, there will be a Federal Register notice published, which will also be posted on the OTC Monographs on the FDA website. The proposed order will have a 45-day comment period. Depending on the volume and substantiveness of the comments received during the comment period, the FDA will then have either two months or seven months to review and address all public comments. Unless the volume and substantiveness of comments requires a seven-month review window, the FDA will issue the final order within 17.5 months of receipt of the OMOR. The FDA noted that if the final order contains a positive GRASE determination for BEMT for use in sunscreens up to a maximum concentration of 6%, DSM-Firmenich may begin marketing sunscreen products containing BEMT up to this concentration upon fulfilling the drug listing in the electronic Drug Registration and Listing System (eDRLS) and manufacturing (USP) requirements.

I have included here all of D'Ruiz's comments only to illustrate how frustrating the process is, as BEMT has been approved globally for 20 years now and was first reviewed under the TEA regulatory pathway in 2005, then again in 2014 under the SIA, and now under the OMOR Tier 1 regulatory approval pathway which is fee-based and includes a $537,471 review fee for 2024.

It also involves repackaging all the data submitted to the FDA in 2005 under the TEA (which is already on the OTC sunscreen docket) together with all the new data generated by DSM-Firmenich and submitted via electronic common technical document (ECTD) format under the Investigational New Drug Application (IND) for BEMT (Parsol Shield). Additionally, the data must now be formatted via the FDA's new guidance for OMOR Tier 1 submissions and broken down into size-specific PDF documents and submitted (again) via the new NextGen portal created under OTC reform. Crazy?

Nevertheless, DSM-Firmenich is close to the finish line and is now continuing down this new OMOR Tier 1 Path. It is the only company to sponsor a new and much needed UV-filter in 25 years. If all goes according to plan, approval is expected by the end of 2025 or shortly after. Keep your fingers crossed! ■