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Client Alert

Sunscreen Ingredients' New Path to U.S. Market Approval

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For years, industry and consumer groups have criticized the U.S. Food and Drug Administration for the slow pace of approval of innovative new sunscreen ingredients and formulations, many of which have long been available in Europe, Asia, and Latin America. To address these concerns, in late 2014 Congress passed the Sunscreen Innovation Act (SIA) to help expedite FDA's review of new over-the-counter (OTC) sunscreen ingredients. Although there is much excitement about the SIA's potential, FDA's first tentative steps toward implementing the new law demonstrate that it is still far from clear whether the SIA's actual impact will measure up to Congress's goals.

A New Path or Just a New Name?

This is not the first time Congress has tried to hasten the introduction of new OTC ingredients to the U.S. market. Since 2000, the Time-and-Extent Application (TEA) review process has been available for manufacturers seeking to introduce OTC ingredients that have been used in foreign countries for five or more years. This pathway has proved to be seriously flawed, however, and has not led to the approval of a single new sunscreen ingredient. Far from being expedited, some efforts to gain approval of sunscreen ingredient combinations have been mired in the TEA process for over ten years.

To break this stalemate, the SIA imposes new deadlines and requirements on FDA. Although principally focused on sunscreen ingredients, the SIA also establishes a pathway for other OTC ingredients. Under the SIA's new provisions, FDA must:

- **review and respond to applications in the TEA process within shorter timelines;**
- **amend the sunscreen monograph within the next five years;**
- **establish and publish guidance regarding TEA review criteria;**

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- **amend the sunscreen monograph by 2020; and**
- **create additional review timelines for non-sunscreen ingredients submitted to the TEA process by May 26, 2016.**

FDA has already begun to comply with the SIA's requirements. By early January, the agency had published proposed orders discussing the safety and effectiveness of six sunscreen ingredients that were previously submitted under the TEA process. These orders all stated that the agency needed more information before it could decide whether the ingredients are generally recognized as safe and effective (GRASE) for their intended use, and invited public comment.

Predictions and Possible Problems

While the SIA requires FDA to take concrete steps to more quickly review TEA submissions regarding sunscreen ingredients, the SIA does not promise a quick cure-all to speed new sunscreen ingredients to market. Assuming that FDA gathers the information it needs to evaluate whether an ingredient is GRASE, it could still take up to fifteen months to reach a decision and incorporate the ingredient into the sunscreen monograph. If FDA fails to meet these new deadlines, the SIA allows the FDA Commissioner to make determinations. The SIA, however, does not specify the review criteria FDA must use to evaluate ingredients, allowing FDA to determine how much information sponsors must submit to be eligible for review. Until FDA outlines the scope of its expectations—and it is required to issue related guidance by November 26, 2016—sponsors are left to guess how FDA will evaluate responses to information requests.

It will be worth tracking the other action items required under the SIA over the next year and a half—especially FDA's SIA interpretive guidance documents, which are due by the end of 2015. For now, interested parties have until February 23, 2015 to submit comments before the next phase of review for the six ingredients that were the subject of FDA's January order. Parties who intend to use the TEA process for new sunscreen ingredients will likely want to review and comment on any released draft data submission guidance before it is finalized in late 2016, as well as track the progress of pending and new TEA submissions to see whether substantive process changes result from the SIA.

The Bottom Line: It remains to be seen whether the SIA will lead to the introduction of more and better OTC sunscreen ingredients to the U.S. market. Although the law compels faster review times, until FDA publishes guidance on review criteria and a few ingredients utilize the new timelines and guidelines, it is unclear how many ingredients will actually be *approved* through this *improved* review process.

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