american cleaning institute®

ACI REMARKS – OMUFA II November 20, 2024 Meeting

1. Introduction

Hello, my name is James Kim, and I am the Senior Vice President of Science and Regulatory Affairs at the American Cleaning Institute (or "ACI"). ACI appreciates the opportunity to share our perspective and provide recommendations as part of the OMUFA II reauthorization process. ACI is a trade association that serves the growth and innovation of the $60 billion United States cleaning products industry. In addition to formulators and suppliers of soaps, detergents, and general cleaning products, our members include manufacturers and suppliers of consumer and healthcare topical antiseptic over-the-counter drug products sold in the US. This includes manufacturers and suppliers of topical antiseptic ingredients deferred by FDA from final rulemaking under the OTC Drug Review. ACI is leading multi-year multi-million-dollar efforts to complete the FDA-requested studies for the topical antiseptic ingredients ethanol, benzalkonium chloride, and chloroxylenol to establish the general recognition of safety and effectiveness (GRAS/E) status. We are the only industry coalition addressing these topical antiseptics active ingredients.

2. Points of Discussion

Under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the deferred antiseptic ingredients are considered lawfully marketed, although FDA has not yet made a final GRAS/E determination. We urge FDA to consider and allocate resources to support solutions to address some challenges we are experiencing in the GRAS/E finalization process. Our comments highlight areas where additional support from FDA during the OMUFA II cycle will be important to the success of our ongoing topical antiseptic programs.

A. More Definitive Direction from FDA on GRAS/E Finalization is Necessary

First, transparent, timely, and robust scientific interactions with FDA on our topical antiseptic programs are crucial. FDA has requested significant amounts of data based on numerous studies to support GRAS/E finalization. ACI has submitted multiple reports to FDA demonstrating our ongoing progress in generating safety and effectiveness data to satisfy FDA's requests. We have also met with FDA through formal meetings to discuss our study designs and data and will continue to do so as appropriate. However, we'd like FDA to help support our data development programs in two ways. We ask that FDA provide clearer, more definitive guidance on its thinking about whether our studies and data appear acceptable to support a GRAS/E determination, instead of telling us that an issue will be a "matter of review." Without clear direction from FDA as we proceed, there is a risk that we will, after significant time, energy, and expense, ultimately not meet FDA's expectations. Ideally, we're trying to prevent such a disconnect and instead, have more definitive agreement up front from the agency.

For example, some assurances at interim time points that our completed studies were designed and executed in a manner likely to satisfy the GRAS/E standards are needed before we can initiate our pivotal clinical studies, which are highly costly and time consuming. We are looking for feedback that is analogous to when FDA advises an NDA product sponsor that one of its studies or its development program, more generally, appear acceptable to support a product approval. ACI would welcome scientific dialogue and FDA's feedback on the sufficiency of our data at each step of the process, with an understanding that the GRAS/E determination in the final order will be based on the weight of all available evidence at that time. We believe that such transparency is also in the public interest because it gives us time to fill any additional data gaps, rather than risking an unfavorable GRAS/E determination due to a disconnect.

Next, we also ask that FDA provide this interim, ongoing feedback via more informal mechanisms. We'd appreciate the ability to have back and forth communications with FDA as needed to obtain the agency's thinking without having to go through the formal meeting processes. For example, we'd appreciate comments on a protocol, proposed study design, or overall development plans with review by FDA and the provision of feedback in real time to expedite the process, add clarity, and provide needed direction. Perhaps this can take the form of feedback letters, emailed comments, or something similar.

B. Importance of Scientifically Robust and Timely Advice From FDA

Additionally, we note for the agency that these studies are highly costly and time consuming. While ACI is committed to funding robust and rigorous studies, fulfilling this commitment requires us to use our limited resources efficiently. In our experience with topical antiseptics, there have been and will continue to be disagreements between us and FDA on issues of study design and data interpretation. And, while many issues can be resolved, if the parties cannot agree on a reasonable path forward, there is currently no real mechanism to resolve scientific disputes. The formal dispute resolution guidance only applies to final orders, so we would ask that FDA outline a pathway for resolving scientific disputes that occur at the data generation stage. An efficient informal dispute resolution process is necessary for manufacturers and other stakeholders, like ACI, to resolve important questions about clinical trial design, including disputes around success criteria, and to continue making progress towards GRAS/E finalization.

3. Conclusion

To conclude, ACI appreciates FDA's efforts to collaborate with our organization on finalizing GRAS/E determinations, and the agency's work during OMUFA I to set up the infrastructure under monograph reform. During OMUFA II, we hope to see FDA support industry's efforts to generate the safety and efficacy data for the lawfully marketed products requested by FDA to make a GRAS/E determination.