american cleaning institute®

ACI Summary of Testimony to the House Energy and Commerce Committee Hearing:

"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"

The American Cleaning Institute (ACI) appreciates the opportunity to testify about the Over-The-Counter Monograph Drug User Fee Program (OMUFA). ACI represents the $60 billion U.S. cleaning products industry, which includes suppliers and formulators of soaps, detergents, general cleaning products, and healthcare topical antiseptic drug products sold in the U.S. ACI members are currently conducting studies requested by FDA on four key antiseptic ingredients: ethanol, benzalkonium chloride, benzethonium chloride, and chloroxylenol. These ingredients have been deferred by the FDA pending the results of these studies to evaluate their safety and effectiveness as Generally Recognized as Safe and Effective (GRAS/E).

ACI is leading a member-funded effort to address the FDA's requests for additional studies, but the high costs pose challenges. Limited current incentives contribute to a "free rider" problem, where non-participating manufacturers benefit from generated data without sharing costs. ACI suggests that the FDA implement incentives to encourage greater industry participation.

While ACI acknowledges the FDA's engagement, it emphasizes the need for improved communication and clarity regarding regulatory expectations for manufacturers and the public. Ongoing state-level legislation could undermine federal consistency and FDA leadership, challenging authority over conflicting state regulations.

ACI looks forward to serving as a resource on this issue to the House Energy and Commerce Committee and remains committed to collaborating with FDA and the Committee to further shared goals.

Testimony of the American Cleaning Institute
"Examining the FDA's Regulation of Over-the-Counter Monograph Drugs"
Committee on Energy and Commerce, Subcommittee on Health
U.S. House of Representatives

April 1, 2025

The American Cleaning Institute (ACI®) appreciates the opportunity to provide testimony before the Committee on Energy & Commerce Subcommittee on Health on the Over-The-Counter Monograph Drug User Fee Program, or OMUFA.

ACI is the home of the $60 billion U.S. cleaning products industry. ACI members include suppliers and formulators of soaps, detergents, general cleaning products, and healthcare topical antiseptic drug products sold in the U.S. This includes manufacturers and suppliers of four topical antiseptic ingredients – ethanol, benzalkonium chloride, benzethonium chloride, and chloroxylenol – that were deferred by the Food and Drug Administration (FDA) from final rulemaking under the Over-the-Counter Drug Review. For these deferred ingredients, FDA has requested additional studies to evaluate their safety and effectiveness before FDA determines whether these ingredients are Generally Recognized as Safe and Effective (GRAS/E).

ACI members are currently conducting the requested studies on lawfully marketed antiseptic products under the CARES Act, which amended the Federal Food, Drug, and Cosmetic Act (FFDCA). These topical antiseptic products promote public health when used by consumers in their homes for home care of family members and other daily needs such as food preparation. It also includes institutional settings such as hospitals and schools, and settings with high traffic such as airports. These antiseptic products are essential tools for reducing bacteria on hands and keeping Americans healthy.

'FREE RIDER' PROBLEM

To fulfill the FDA's requests for additional studies on the deferred ingredients, ACI is leading a multi-year, multi-million-dollar effort with its members. To date, ACI has submitted multiple reports to the FDA demonstrating ongoing progress in generating safety and effectiveness data to satisfy FDA's requests. However, filling these data gaps is extremely costly and resource intensive.

For products that are already lawfully marketed, there are only limited incentives for companies to contribute to collecting additional data to establish general recognition of safety and effectiveness. As a result, ACI member companies funding the Agency's requested studies are a fraction of the antiseptic ingredient and product manufacturers that will ultimately benefit from the ACI member-generated data.

Under the current system, ACI member companies are shouldering all the data costs. However, the benefits derived from that data will support the continued marketing by all antiseptic manufacturers, including non-participating companies. We have previously suggested to FDA two options to consider for incentivizing industry buy-in for finalizing GRAS/E determinations:

- Include a waiver or reduction in OMUFA fees for sponsors that actively participate in the data generation process; also develop a cost-sharing or compensation system for free-riders to pay those who generate the data in exchange for the ability to market the product in the U.S.

- Extending – or at the very least maintaining – the OMUFA exclusivity period. It is important for FDA to take enforcement action against products that unlawfully compete against products with exclusivity. The current exclusivity period is short compared to the new drug application process. The protection of confidential commercial information and trade secrets is also more limited.

FDA COMMUNICATIONS

ACI appreciates the engagement from the Agency to date, including formal meetings and public hearings that help manufacturers and the public gain insight into the FDA's thinking. However, ACI believes the Agency should prioritize resources to facilitate greater informal FDA feedback and collaboration with manufacturers to optimize and complete the requested studies, make a GRAS/E

determination, and educate the public on progress being made by manufacturers towards completing the studies. More timely and productive communication from the FDA on GRAS/E studies to both manufacturers and the public would enhance this progress.

ACI has previously spoken about the need for more routine communications and greater clarity from FDA on regulatory expectations for GRAS/E studies, including informal communications and dialog, such as with routine email responses, letters, and phone conversations. Such communications are imperative for ACI and its members to continue progressing on the GRAS/E studies requested by FDA. In addition, regular Agency updates to the public can help reassure them that the safety and effectiveness of topical antiseptics containing the deferred active ingredients are continuing to be evaluated by manufacturers while reminding the public that these products may continue to be legally marketed while the studies are ongoing and a GRAS/E determination is pending.

Greater clarity and timeliness of communications from the FDA are needed, given that States undertake their own initiatives regarding three of the legally deferred ingredients. Proposed California Assembly Bill 916 would prohibit the use of the following legally marketed deferred ingredients: benzalkonium chloride, benzethonium chloride, and chloroxylenol in consumer hand soaps and body washes. Calls to ban the use of these deferred ingredients are typically accompanied by unsubstantiated claims questioning the safety and effectiveness of the deferred ingredients.

ACI believes that the public has limited understanding of the progress being made towards establishing that the deferred ingredients are GRAS/E. This is despite the tremendous efforts by ACI and its member companies to work towards this goal. Better public understanding would be strengthened by increased FDA communication.

Moreover, ACI notes that the FFDCA contains a specific express preemption provision for national regulatory uniformity for nonprescription drugs. Congress included this preemption provision in the law to ensure the ability of companies to manufacture and sell the same OTC products across the U.S. and to

highlight the primacy of federal law in this space. Because of this provision and the doctrines of implied preemption, any proposals to ban the use of the deferred ingredients contrary to federal law – such as the recently proposed legislation in California – would be federally preempted and therefore prohibited under federal law.

Ultimately, ACI believes that more timely communications by FDA to drug manufacturers and the public are needed to continue progress and to reassure the public that organizations such as ACI and its members are working diligently towards completing the GRAS/E studies requested by the FDA. ACI also believes it would be beneficial for FDA to clarify to the public that these products are: lawfully marketed; play an important role in public health; and that any state requirements that are contrary to federal law will be preempted, including proposals to ban the use of the deferred ingredients in OTC consumer antiseptics.

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ACI appreciates the opportunity to provide testimony on OMUFA. For reference, two FDA public meeting comments (October 2023 and November 2024) submitted by ACI regarding the reauthorization of the OMUFA program are attached.

ACI remains committed to collaborating with FDA and the Committee to further shared goals.

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