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OMUFA Reauthorization

September 28, 2023

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Overview

- ACI home to the $60 billion U.S. cleaning products industry.
- Representing formulators and ingredient suppliers of soaps, detergents, and general cleaning products.
- Includes manufacturers and suppliers of consumer and healthcare topical antiseptic drug products sold in the U.S.
- ACI supports FDA requested work on five topical antiseptic ingredients: ethanol, benzalkonium chloride, benzethonium chloride, chloroxylenol, and povidone-iodine.

Free Rider Problem

- Demonstrating GRASE status of deferred antiseptic ingredients is resource intensive
- Although ACI members are shouldering costs, benefits of demonstrating GRASE will support continued marketing of antiseptics by all antiseptic manufacturers, including non-participating companies
- This “free-rider” problem undermines industry investment in finalizing rulemakings

Free Rider Problem: Recommendations

- Waive or reduce sponsor facility or user fees that participate in the data generation process
- A free-rider cost-sharing or compensation system to pay data generators in exchange for free-rider ability to sell products in the U.S. market
- Extend, or at least maintain, OMOR exclusivity period
- Take enforcement action against products that unlawfully compete against those for which exclusivity has been granted

Data Confidentiality

- A robust confidentiality policy is needed to protect interests of ACI member companies who are developing requested safety and efficacy data
- A more protective confidentiality policy is supported by CARES Act language
- ACI recommends that FDA narrowly define the information submitted “in support of” an OMOR

Enhanced Transparency: Routine and Flexible Communication

- Maintain ongoing dialogue with industry through formal meetings and public hearings
- Increase routine communications (e.g., email responses, letters, phone conversations) and allow for FDA feedback flexibility
- Cap number of appeals required before administrative hearing in the formal dispute resolution process
- Clarity from FDA on expectations is critical for ACI and its members to continue making necessary investments to ensure topical antiseptic FDA requested studies can be completed

Enhanced Transparency: OMOR Content Criteria

- Set forth clear and detailed expectations for the substantive content of OMORs, including specific success criteria standards
- Communicate with advance notice plans to initiate OMOR regarding GRASE status of active ingredients

Enhanced Transparency: Data Type and Quantity

- Explain benefits of submitting an OMOR as opposed to an NDA
- Provide guidance on circumstances under which FDA may accept reduced quantities or different types of data, such as real-world evidence or foreign marketing experience
- Clarity on which official or organizational unit will be responsible for issuing final administrative orders and thus at which level formal dispute resolution will begin