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March 12, 2025

The Honorable Susan Donovan
Chair, House Committee on Health and Human Services
Rhode Island House of Representatives
82 Smith Street
Providence, RI 02903

RE: Opposition to H 5617 (Alzate) – The Personal Hygiene Product Safety and Toxic Metal Removal Act of 2025

Dear Chair Donovan:

On behalf of the Consumer Healthcare Products Association (CHPA), the Washington, D.C. based national trade organization representing the leading manufacturers of over-the-counter (OTC) medicines, dietary supplements, and OTC medical devices, I'm writing to express opposition to House Bill 5617. This legislation would establish strict concentration limits for several metals in personal hygiene and self-care products, mandate regular testing by manufacturers with independent lab verification, and require public education and reporting to the state.

Most concerning is that this bill, seemingly targeting personal care products, will also impact Food and Drug Administration (FDA) regulated drugs. Products with cosmetic properties but regulated as drugs—such as sunscreen, toothpaste, dandruff shampoo, and skin moisturizers—would fall under the bill's regulations as currently drafted.

FDA Safety Standards for OTC Drugs

Cosmetics and drugs are regulated differently by the FDA based on their intended uses and claims. Cosmetics are products meant to cleanse, beautify, or alter appearance without affecting bodily structure or function, and they don't require FDA pre-market approval or registration. In contrast, drugs are substances intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure/function of the body. Specifically for nonprescription (OTC) drugs, the FDA employs a unique regulatory framework through the OTC Drug Review process and OTC monographs, which establish conditions under which certain active ingredients are generally recognized as safe and effective for particular uses without requiring individual product approvals. However, these OTC drugs must still comply with labeling requirements, quality standards, and manufacturing regulations. All drugs, including OTC products, must adhere to Current Good Manufacturing Practices (CGMPs), which are significantly more stringent than the voluntary guidelines for cosmetics. For heavy metals specifically, the FDA enforces the ICH Q3D Elemental Impurities guideline for all drugs, including nonprescription medications, setting precise Permitted Daily Exposure limits for metals based on toxicological data. OTC drug manufacturers must implement validated testing methods for these contaminants and maintain documentation proving compliance with these limits throughout the product lifecycle.

The FDA Strictly Regulates OTC Drug Labeling

The FDA's comprehensive regulation of OTC drug product labeling establishes uniform national standards for consumer safety and informed usage. However, when states like Rhode Island implement additional labeling requirements that deviate from federal standards, manufacturers

face significant challenges. These state-specific mandates create a fragmented regulatory landscape that increases production costs, complicates inventory management, and disrupts national distribution systems. Drug companies must design, produce, and maintain separate inventory streams specifically for Rhode Island-bound products, potentially leading to supply chain inefficiencies and higher consumer prices. This regulatory inconsistency undermines the FDA's goal of standardized labeling and creates compliance burdens particularly onerous for smaller manufacturers with limited resources. The situation becomes especially problematic with H 5617's distinct toxic metals testing disclosure requirements, which mandate explicit labeling about testing procedures and detected levels that differ from federal protocols. This creates not only logistical hurdles but also potential consumer confusion when identical products carry different safety information across state lines. Additionally, the precedent of state-specific requirements threatens to create a patchwork of conflicting regulations across states, ultimately hampering the efficient nationwide distribution of essential OTC medications.

Unattainable concentration limits

Attaining the proposed thresholds of 0.1 ppm or 0.05 ppm for lead and other naturally occurring earth elements in drugs or cosmetics containing water, soil, or air components presents a virtually insurmountable challenge. These natural materials inherently contain trace metals at background concentrations frequently surpassing the suggested limits.

Water sources naturally contain minute quantities of lead and other metals that resist removal even through sophisticated purification techniques. Ingredients derived from soil readily accumulate metals such as lead, arsenic, cadmium, and mercury through environmental exposure, while airborne particulates can contaminate raw materials during production processes. Despite employing cutting-edge purification technologies, consistently achieving compliance with the strict 0.1 ppm restriction for lead and similar metals in these natural ingredients remains effectively impossible.

Amendment Request

To ensure this bill does not conflict with existing federal law, CHPA proposes to amend H 5617 to exempt nonprescription drugs from the scope of the bill (page. 2, beginning on line 3) as follows:

"(2) Personal hygiene and care product" means any product intended for personal cleansing, and grooming including, but not limited to, cosmetics, tampons and pads. "Personal hygiene and care product" does not include drugs regulated by the United States Food and Drug Administration pursuant to 21 U.S.C. 321(g); or an article for retail sale or professional use intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance that is otherwise regulated as a drug"

Thank you for your careful consideration of our concerns. Please feel free to contact me directly with any questions or comments on our position.

Respectfully submitted,

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Cc: House Committee Health & Human Services
The Honorable Representative Karen Alzate