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October 31, 2023

Commissioner Melanie Loyzim
Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

RE: Comments on EPR Conceptual Draft Rules Parts 1, 2, and 3 - Stewardship Program for Packaging

The Consumer Healthcare Products Association (CHPA), the national trade group representing the makers of over-the-counter medication, dietary supplements, and consumer medical devices, has reviewed the three conceptual draft rules for Maine's Packaging Stewardship Program. After careful consideration, we remain concerned about the lack of an exemption for packaging governed by U.S. Food and Drug Administration (FDA) regulations. As the Maine Legislature recognized in the Packaging Stewardship Law, consumer healthcare product packaging must comply with federal requirements established by the FDA and other federal agencies to ensure product safety and stability. An exemption for FDA regulated consumer healthcare products, therefore, remains necessary to include in the draft rules' concepts.

Maine Legislature Recognized Need for FDA Regulated Product Exemption

The Maine Packaging Stewardship Law requires the Maine Department of Environmental Protection (DEP) to consider potential conflicts with federal regulations from the Food and Drug Administration that govern food, drugs, cosmetics and medical devices (21 CFR and the Federal Food, Drug, and Cosmetic Act). Additionally, the law specifies that DEP must consider tamper-evident packaging requirements (21 CFR 211.132) and U.S. Consumer Product Safety Commission guidelines under the Poison Prevention Packaging Act. As Maine implements extended producer responsibility for packaging, it is critical to consider federal requirements for the safety, security and stability of consumer healthcare products. Aligning packaging regulations at all levels of government is imperative to maintain the safety and welfare of consumers as new sustainability initiatives are undertaken.

Most States Exempt FDA Regulated Consumer Healthcare Products from Packaging EPR

Most states exempt consumer healthcare products from extended producer responsibility (EPR) packaging laws because of the complexities of regulating these federally regulated products.

Many states with packaging EPR initiatives, including Oregon, Washington, California, and Colorado, have in some form excluded over-the-counter (OTC) medicines, medical devices, and dietary supplements from the scope of their laws. These exemptions acknowledge that consumer healthcare products already face strict federal packaging, labeling, and safety rules.

Imposing state-level packaging rules on consumer healthcare products could generate consumer confusion from fragmented standards, while also imposing a substantial regulatory and financial strain on manufacturers. With the FDA and the Consumer Product Safety Commission (CPSC) already regulating safety and stability of products and their packaging,

most states wisely avoid redundant oversight by exempting FDA regulated products from packaging EPR laws. Navigating conflicting federal and state rules would prove an unreasonable burden for companies working to deliver accessible and affordable healthcare solutions. At the same time, disjointed state mandates undermine national clarity and uniformity for consumers. Since federal guidelines currently govern these products, a unified national framework stands as the most effective, sustainable approach to healthcare packaging. Exempting consumer healthcare from Maine's packaging EPR law would maintain this consistent, cohesive model and prevent needless duplication and confliction of federal efforts.

FDA Regulated Drugs Already Participate in a Maine Producer Responsibility Program

OTC medications already fall under Maine's pharmaceutical stewardship program, which provides convenient disposal options to safely manage leftover, expired, or unwanted medications. Adding drugs into the new Packaging EPR program would duplicate efforts to keep these products out of landfills and waterways. Since producers of medicines are already funding and managing take-back programs under the state's drug stewardship law, it makes sense to exclude these packaged products from the packaging EPR rules. This avoids redundant, costly, and possibly conflicting regulations, while ensuring medicines are properly disposed of through the existing drug disposal law.

Conclusion

CHPA and its members share a commitment to sustainability and environmentally friendly packaging. However, packaging for over-the-counter healthcare products must adhere to strict federal safety standards and regulations. As such, CHPA believes oversight of OTC packaging for medications, dietary supplements, and medical devices should remain under federal jurisdiction alone.

Thank you for the opportunity to comment on these draft rules concepts. Please feel free to contact me directly with any additional questions.

Respectfully submitted,

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