CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

May 20, 2024

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

RE: EPR Packaging Material Exemption Request

On behalf of the Consumer Healthcare Products Association (CHPA)[1] I appreciate the opportunity to provide comments regarding the "Stewardship Program for Packaging." We remain concerned about the absence of an exemption for consumer healthcare product packaging regulated by the U.S. Food and Drug Administration (FDA). As acknowledged by the Maine Legislature in the Packaging Stewardship Law itself, consumer healthcare product packaging is subject to stringent federal requirements set forth by the FDA and other federal agencies to ensure product safety, efficacy, and stability. These requirements may significantly limit or preclude manufacturers' ability to increase the recyclability or reduce the volume of packaging material. Therefore, an exemption for FDA-regulated consumer healthcare products is essential not only for compliance with the extended producer responsibility portion of the law but also, most critically, for the post-consumer recycled content requirements.

Maine Legislature Acknowledges the Uniqueness of FDA Regulated Consumer Healthcare Product Packaging

The Maine Legislature, in crafting the extended producer responsibility for packaging law, wisely recognized the unique challenges faced by producers of federally regulated consumer healthcare products (nonprescription medications, dietary supplements, and medical devices). The legislation specifically calls for the Department of Environmental Protection to review packaging material associated with these specific products and consider whether they should be excluded from the definition of "packaging material."[2] This provision acknowledges that certain products, such as drugs, medical devices, dietary supplements, and substances regulated by the Consumer Product Safety Commission, are subject to already existing stringent federal regulations that dictate specific content or construction standards for their packaging. These requirements may significantly limit or even preclude producers' ability to increase the recyclability or reduce the volume of the packaging material. By including this language in the law, the Legislature has demonstrated its understanding of the complex federal regulatory landscape and the need for targeted exemptions for FDA-regulated consumer healthcare products. As Maine implements extended producer responsibility for packaging, it is crucial to consider existing federal requirements for the safety, security and stability of nonprescription healthcare products. Aligning packaging regulations at all levels of

[1] The Consumer Healthcare Products Association is the Washington, D.C. based national trade organization representing the makers of over-the-counter medications, dietary supplements, and consumer medical devices.
[2] Section 13 : Administration and enforcement; rulemaking; fees; department report, D, 1-4 (page 16-17) https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1146&item=11&snum=130

government is imperative to maintain the safety and welfare of consumers as new sustainability initiatives are undertaken.

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.

FDA Has Issued Guidance Restricting Recycled Packaging for Use in Consumer Healthcare Products

CHPA members prioritize the safety and quality of nonprescription products to ensure the well-being of all consumers.

In the FDA guidance document titled "Container Closure Systems for Packaging Human Drugs and Biologics" issued in May 1999, the FDA states, "Postconsumer recycled plastic should not be used in the manufacture of a primary packaging component." The FDA has confirmed that this guidance applies to all human drug products, including over-the-counter (OTC) monograph products, specifically referring to the primary packaging that is in direct contact with the drug.

Furthermore, the FDA has expressed safety concerns regarding the use of post-consumer recycled (PCR) plastic materials in food-contact articles. As dietary supplements are explicitly defined as a category of food under the Dietary Supplement Health and Education Act (DSHEA) of 1994, these safety concerns also apply to the packaging of dietary supplements.

In line with the FDA's recommendations and concerns, we respectfully request an exemption from the Stewardship Program for Packaging for our primary packaging materials to maintain the highest standards of product safety and to minimize potential risks to our consumers.

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 and please feel free to contact me directly with any additional questions.

Respectfully submitted,

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