CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

August 25, 2023

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

RE: Comments on Potential Exemptions - Packaging Stewardship Law

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to comment on proposed exemptions to Maine's Packaging Stewardship Law (38 M.R.S. § 2146). As the national association representing over-the-counter medicine, dietary supplements, and consumer medical device manufacturers, we want to ensure new state initiatives align with federal laws governing product safety, labeling, and packaging.

Specifically, we seek an exemption for all Food and Drug Administration (FDA) regulated nonprescription products drugs, dietary supplements and medical devices. The Maine Packaging Stewardship Law itself recognizes the unique nature of our packaging in paragraph 13(D) as it specifically requests the Maine Department of Environmental Protection (DEP) to consider the law's conflicts with:

- FDA regulations on food, drugs, cosmetics, and medical devices per Part 21 of the Code of Federal Regulation (CFR) and the federal Food, Drug, and Cosmetic Act (FDCA).
- Tamper-evident packaging mandates under 21 CFR 211.132.
- U.S. Consumer Product Safety Commission guidelines per the Poison Prevention Packaging Act.

It is important the State of Maine considers federal requirements on safety, security, and oversight of healthcare products when implementing any sustainable packaging solution. Cohesion between all levels of government will benefit all stakeholders and ensure recyclable packaging solutions are broadly adopted.

Consumer Healthcare Product Packaging Is Regulated by the Federal Government

FDA regulates drug product packaging under Good Manufacturing Practices regulations (GMPs) (21 C.F.R. Part 211, Subpart G), including material examination and usage criteria (§211.122), packaging and labeling operations (§ 211.130), tamper-evident packaging (§ 211.132), and expiration dating (§ 211.137).

Certain drugs are also regulated by the Consumer Product Safety Commission (CPSC) under the Poison Prevention Packaging Act (PPPA), which requires child-resistant packaging. Manufacturers are required to test and certify compliance. In addition, drug products for which packaging does not comply with PPPA packaging and labeling regulations are misbranded under the FDCA (21 U.S.C. § 352(p)).

Most States Exempt FDA Regulated Consumer Healthcare Products from EPR

Most states have exempted consumer healthcare products from extended producer responsibility (EPR) laws for packaging due to the complexities of regulating these federally regulated goods.

Many states with EPR packaging initiatives, including Oregon, Washington, California, and Colorado, have opted to exclude over-the-counter medicines, medical devices, and supplements from the scope of their laws. They grant exemptions for products regulated under the FDCA or by the FDA and CPSC. This acknowledgment stems from the understanding that healthcare products already face stringent federal packaging, labeling, and safety requirements.

Adding a separate layer of state-level packaging mandates and take-back programs risks creating confusion for consumers, who rely on consistent information and access to healthcare products. It also represents a considerable regulatory and financial burden for healthcare manufacturers who would need to navigate conflicting state and federal rules. Since the goals of safety, access, and responsible disposal are already achieved through FDA oversight, most states aim to avoid duplicative regulation by exempting consumer healthcare from packaging EPR. A unified national framework is the clearest path to effective sustainable healthcare packaging.

Conclusion

CHPA and its members are committed to sustainability, and environmentally friendly packaging. Our packaging, however, must meet stringent national standards while not compromising the safety of the American public. Regulation of OTC healthcare packaging, therefore, should be governed solely by the federal government. Consumer healthcare products have for the most part been exempt from every state packaging extended producer responsibility (EPR) law around the country, and we strongly encourage the DEP to extend those same protections to manufacturers of consumer healthcare products in the State of Maine.

Thank you for the opportunity to comment on this important matter within Maine's Packaging Stewardship Law. Freel free to contact me directly with any questions.

Respectfully submitted,

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