



CONSUMER
HEALTHCARE
PRODUCTS
ASSOCIATION

Taking healthcare personally.

February 8, 2023

Senator Brian J. Feldman, Chair
Senator Cheryl C. Kagan, Vice Chair
Maryland Education, Energy, and the Environment Committee
2 West
Miller Senate Office Building
Annapolis, MD, 21401

Re: SB 222 Related to Reducing Packaging Materials - Oppose

Dear Chairman Feldman,

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 consumer medical devices, I'm writing to express opposition to SB 222 as it is currently drafted. This legislation seeks to implement a producer responsibility program for the packaging of consumer products. While the bill appropriately exempts Food and Drug Administration (FDA) regulated drugs and medical devices, it falls short of extending that same exception to dietary supplements. For that reason, we are forced to register in opposition.

FDA Regulates Consumer Healthcare Product Packaging

Manufacturers of consumer healthcare products take very seriously the types of packaging used to transport, store, and safely deliver OTC products to consumers seeking to address minor health ailments. A very complex, and highly regulated federal framework for OTC consumer healthcare packaging has been in place for decades and serves to ensure safety, efficacy, and stability of products for consumers. State action on packaging for these products likely conflicts with federal laws and regulations already in place, and could compromise safety and stability of the products themselves.

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 with the PPPA and, in fact, are deemed misbranded under the Food, Drug, and Cosmetic Act (21 U.S.C. § 352(p)) when the packaging does not comply with PPPA and labeling regulations. In addition, the Food and Drug Administration (FDA) has offered industry guidance stating specifically that recycled plastic should not be used for primary drug or dietary supplements packaging.

Amendment Recommendation

SB 222 aptly exempts federally regulated drugs, medical devices, biologics, and diagnostic products. If fails, however, to also include dietary supplements in the exemption for federally

regulated product packaging. To resolve this issue, we respectfully request expanding the existing exemption language by making the following change in red below:

(3) "PACKAGING MATERIALS" DOES NOT INCLUDE ANY PART OF A PACKAGE OR CONTAINER THAT IS SOLD OR SUPPLIED IN CONNECTION WITH:
(I) A PESTICIDE PRODUCT REGULATED BY THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT UNDER 7 U.S.C. § 136 ET SEQ. OR ANY OTHER APPLICABLE FEDERAL LAW, RULE, OR REGULATION;
(II) A FEDERALLY REGULATED DRUG, MEDICAL DEVICE, **DIETARY SUPPLEMENT**, BIOLOGIC, OR DIAGNOSTIC, INCLUDING ITEMS INTENDED FOR ANIMALS; OR
(III) A MEDICAL PRODUCT THAT IS REQUIRED TO BE STERILE OR ENCLOSED IN PACKAGING WITH TAMPER-RESISTANT SEALS TO PROTECT PUBLIC HEALTH, INCLUDING MEDICAL PRODUCTS INTENDED FOR ANIMALS.

Conclusion

CHPA and its members are committed to the health and welfare of consumers and the global environment. We applaud Senator Augustine for taking on this important issue, but unfortunately we cannot support the legislation in its current form. We look forward to continued dialogue with his office and this committee in hopes we can come to an equitable resolution.

Respectfully submitted,



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cc: Members of the Education, Energy, and the Environment Committee
The Honorable Senator Malcolm Augustine