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Re: Recycling Reform Rulemaking – Chapter 173-950 WAC

On behalf of the Consumer Healthcare Products Association (CHPA)[1], thank you for the opportunity to provide comments in connection with the Washington State Department of Ecology's (Ecology or "the Department") development of proposed rules implementing the Packaging Producer Responsibility Act. I write to respectfully urge Ecology to reconsider its preliminary position and to confirm that secondary and tertiary packaging for products regulated by the United States Food and Drug Administration (FDA) as drugs, medical devices, or dietary supplements falls within the exemption established by RCW 70A.208.020(d). We believe the statute's text, structure, and evident purpose compel this reading, and that the Department's contrary interpretation would produce results the legislature did not intend and that industry cannot practically accommodate.

At the very least, Ecology should recognize that secondary and tertiary packaging for FDA regulated products satisfies the criteria for temporary exclusion under proposed WAC 173-950-510, and to establish a streamlined, presumptive pathway for such exclusions rather than requiring individualized case-by-case petitions.

Statutory Text Supports Exemption of the Entire Packaging System

RCW 70A.208.020(d) exempts "packaging for a product regulated as a drug, medical device, or dietary supplement" and expressly includes "associated components and consumable medical equipment." The legislature's choice of the broad phrase "packaging for a product" – rather than limiting language such as "immediate container," "primary packaging," or "retail packaging" – signals a clear intent to capture the full packaging chain that accompanies FDA regulated products into commerce. Notably, FDA regulated drugs, medical devices, and dietary supplements are each expressly named in the statute. Had the legislature wished to confine the exemption to the innermost layer of packaging, it could have said so plainly. It didn't.

The modifier "including associated components" reinforces this reading. For over-the-counter (OTC) drugs, the outer carton bearing FDA required Drug Facts labeling, lot number, expiration date, and tamper-evidence disclosures is quintessentially an "associated component" of the regulated article's packaging. For OTC medical devices – products such as adhesive bandages, elastic bandage wraps, non-sterile examination gloves, and digital thermometers – the outer retail carton that carries the device's required labeling under 21 C.F.R. Part 801, including intended use statements, directions for use, and applicable

[1]Consumer Healthcare Products Association is the national trade association based in Washington, D.C. that represents the manufacturers of over-the-counter (OTC) medications, dietary supplements, and OTC medical devices.

warnings, is equally "associated" in a regulatory and functional sense. For dietary supplements, the outer shipper that protects child resistant closures and preserves label integrity required under 21 C.F.R. Part 101 is no less "associated" with the regulated product. Nothing in the text compels reading one in and other out.

Finally, the preamble to section (d) – "materials, or any portion of materials, that are" – demonstrates the legislature's intent to construe exemptions generously. Where a shipment of OTC drugs, dietary supplements, or medical devices consist partly of primary packaging and partly of secondary or tertiary packaging, the latter are plainly "portions" of the overall materials associated with the regulated product. Excluding them would render the "any portion" language unnecessary, and contrary to established principles of statutory construction.

FDA's Regulatory Footprint Extends Throughout the Packaging Chain

The exemption's premise is that FDA already regulates these products and their packaging comprehensively, making duplicative state packaging mandates unnecessary and potentially inconsistent with federal requirements. The same logic extends to secondary and tertiary packaging for all three product categories I have previously addressed.

For OTC drugs, FDA regulations under 21 C.F.R. Parts 201 and 211 govern not only primary containers but also outer cartons and labeling. Secondary packaging must display the complete Drug Facts panel required by 21 C.F.R. § 201.66, lot and batch identification, expiration dating, and tamper-evident features mandated by 21 C.F.R. § 211.132. Current Good Manufacturing Practice (cGMP) requirements under Part 211 dictate material specifications and integrity standards for secondary packaging. These are not design choices producers make freely; they are conditions of lawful distribution.

For OTC medical devices, the relevant federal constraints are grounded primarily in the general device labeling requirements of 21 C.F.R. Part 801 and the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 352). These requirements apply to the label and labeling of a device, which FDA interprets broadly to encompass all written, printed, or graphic matter accompanying the article—including secondary cartons and package inserts. A producer of adhesive bandages, elastic compression wraps, non-sterile examination gloves, reading glasses, or digital thermometers cannot distribute those products without secondary packaging that carries the device identification, intended use, directions for use, and applicable warnings required by Part 801. The outer carton is not optional packaging; it is the primary vehicle for federally mandated labeling for many OTC devices that lack space on the immediate container to carry required information. Additionally, many OTC device categories are subject to the Poison Prevention Packaging Act and its implementing regulations at 16 C.F.R. Part 1700, which impose constraints on packaging design, including secondary packaging, that producers cannot override in response to EPR incentives. Tertiary shippers for OTC devices must preserve the integrity of these mandatory labeling and packaging features through the distribution chain, fixing material and structural parameters that are not freely alterable.

For dietary supplements, FDA regulations under 21 C.F.R. Parts 101 and 111 establish labeling requirements that extend to outer cartons and impose cGMP standards on packaging operations, including secondary packaging used in distribution. The Poison Prevention

Packaging Act imposes child-resistant closure requirements that shape the design of both primary and secondary packaging for certain supplement products. Outer shippers must preserve the integrity of these mandatory packaging features throughout the supply chain.

An interpretation that exempts primary packaging while subjecting secondary and tertiary packaging to EPR obligations would impose Washington's producer responsibility framework on packaging that is designed, specified, and constrained by federal law across all three of these product categories. This creates an irreconcilable conflict for consumer healthcare product manufacturers: compliance with Washington's EPR program may require packaging changes that federal law forbids.

The Legislative Purpose Supports a Broad Reading of the Exemption

The exemptions in RCW 70A.208.020 reflect a considered legislative judgment that certain packaging categories are already subject to adequate oversight through other regulatory arrangements, or present policy considerations that counsel against inclusion in the EPR framework. For OTC drugs, medical devices, and dietary supplements, the legislature evidently concluded that federal oversight is sufficiently robust, and the design constraints sufficiently limiting, that state EPR obligations would be redundant at best and counterproductive at worst.

That rationale applies with equal weight to secondary and tertiary packaging. If anything, it applies with greater emphasis: while primary packaging is often consumer-facing and visible at retail, secondary and tertiary packaging for these three product categories is predominantly a function of supply chain logistics and federal safety, labeling, and integrity requirements. The EPR program's goals—incentivizing producers to reduce unnecessary packaging and increase recyclability—have limited effectiveness on packaging whose form is dictated by federal regulation rather than commercial optimization. A producer of adhesive bandages, OTC analgesics, or dietary supplements, is not free to simply reduce or redesign its secondary and tertiary packaging in response to EPR incentives; it is legally constrained in ways that producers of conventional consumer goods are not.

Conclusion and Recommendation

For these reasons, we respectfully urge the Department, in future rulemaking, to clarify and confirm that secondary and tertiary packaging for OTC drugs, medical devices, and dietary supplements are exempt from program requirements. This packaging bears FDA required labeling, is subject to cGMP and other federal regulatory constraints, and is often required to preserve mandatory packaging features through the distribution chain. This reading is compelled by the statute's text, consistent with its purpose, and necessary to avoid placing producers in an untenable conflict between state EPR obligations and federal regulatory requirements.

We appreciate the Department of Ecology's consideration of these comments and welcome the opportunity to discuss these issues further at a mutually convenient time.

Respectfully,

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