March 18, 2024

VIA ELECTRONIC MAIL
(rulecomments.dep@maine.gov)

Brian Beneski
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017

Re: Comments on Proposed New Rule: Chapter 428, Stewardship Program for Packaging

Dear Mr. Beneski:

The Animal Health Institute submits the following comments for the Maine Department of Environmental Protection's (DEP's) consideration regarding its proposed new rule: Chapter 428, Stewardship Program for Packaging. AHI is a trade association that represents companies that develop, manufacture, and distribute animal health products including pharmaceuticals, biologics, flea and tick treatments, medical devices, and diagnostic tests.

AHI requests that the DEP exempt animal health products from Chapter 428's standards to conform to the DEP's mandate under Maine's Extend Producer Responsibility law, 38 M.R.S. § 2146, to exempt certain packaging if it is already required to meet stringent standards under federal regulation.

Under 38 M.R.S. § 2146(13)(D), the DEP must review packaging for certain federally regulated products to determine if that packaging should be excluded from the definition of "packaging material." At a minimum the DEP is statutorily required to review packaging for drugs, medical devices and biological products, and substances requiring special packaging under the Poison Prevention Packaging Act, although the DEP has discretion to review packaging for other products as well. In determining whether to exempt packaging, the DEP must decide whether federal regulations are so stringent as to diminish the recyclability of the packaging or the ability of a producer to reduce the volume of packaging material it uses.

AHI's products are exactly the types of products that the legislature envisioned should be exempted; they are highly regulated medical products with packaging that must meet specific requirements. As a result, AHI strongly urges the DEP to exempt AHI's products from Chapter 428's standards.

AHI members develop, manufacture, and distribute pharmaceuticals, biologics (including vaccines), flea and tick preventatives, and medical devices (including diagnostics), to veterinarians, pet owners, and food animal livestock owners. Each of these animal health products and their packaging are highly regulated by federal agencies, leaving AHI members little discretion to change their packaging.

For example, under the Food, Drug and Cosmetic Act (FDCA), the U.S. Food and Drug Agency (FDA) regulates drugs and medical devices. As part of FDA approval each drug or device has its own unique

approved packaging, which is designed to help maintain stability of the drug or device over the course of its shelf-life.

Likewise, under the Virus, Serum and Toxins Act (VST) the U.S. Department of Agriculture (USDA) regulates vaccines and biologics and diagnostic test kits. Under this regulatory framework, packaging must protect the integrity of a regulated product, including maintaining the appropriate temperature for a product. These are strict standards and there are limited options for meeting them. Additionally, packaging must meet labeling requirements.

Finally, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the U.S. Environmental Protection Agency (EPA) regulates flea and tick prevention products. FIFRA §25(c)(3) authorizes EPA to establish standards designed to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with substances regulated under FIFRA.

Recognizing the impossibility of requiring compliance with extended producer responsibility requirements, other states have exempted animal health products from such requirements.[1] We request that the DEP do the same in Maine.

We appreciate the opportunity to comment on the Department's proposed rule and the Department's consideration of these comments.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Mandy Hagan
Director, State Government Affairs

[1] *See e.g.,* Ca. Pub. Res. Code § 42070 "Plastic Pollution Prevention and Packaging and Producer Responsibility Act;" 22 C.R.S. 17-701 "Producer Responsibility Program for Statewide Recycling."

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