Oral Testimony of

Mrs. Ginny Siller, on behalf of the Animal Health Institute

On rulemaking topics for the *Stewardship Program for Packaging Law*, 38 M.R.S. § 2146.

Maine Department of Environmental Protection
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My name is Ginny Siller and I am the Director, Government Affairs at the Animal Health Institute the national trade association representing companies that make medicines for animals – the drug, vaccines, flea and tick products and medical devices all used to keep animals healthy.

Our members are sponsors for most of the pioneer animal drugs used by veterinarians and producers in Maine. As such, we have an interest in the rulemaking process for the *Stewardship Program for Packaging Law* (38 M.R.S. § 2146(13)(D) and request that animal health products be exempt from its requirements.

The animal health industry is committed to improved sustainability in all facets of the supply chain, including the packaging used to deliver safe products to customers. Sustainability is one factor among many that animal health companies must consider in the packaging equation. Medical products for animals are required to be sterile or enclosed in packaging with tamper-resistant seals to protect public health. Also, depending on the requirements from the governing federal agency, products may be labeled with specific instructions on disposal.

Our sustainability efforts take place in the context of meeting requirements by federal regulators. Animal health products are licensed and regulated by three different federal agencies, each with their own unique packaging standards and requirements.

> **Drugs and devices are approved by the U.S. Food and Drug Administration under the Food, Drug and Cosmetic Act (FFDCA).** Sponsors must specify for the agency the materials of construction and packaging used for each product and provide data showing those factors will maintain stability of the product over its shelf life. Consequently, each product has its own unique approved packaging. Changes to product packaging take months of development followed by full FDA review and approval.
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> **Vaccines and biologics and diagnostic test kits are approved by the U.S. Department of Agriculture under the Virus, Serum, Toxins Act (VST).** Manufacturers are required to ensure packaging maintains the integrity of the product, so temperature is a major consideration. Packaging must also accommodate detailed USDA labeling requirements.
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> **Flea and tick prevention products are approved by the U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).** FIFRA §25(c)(3) authorizes EPA to establish standards with respect to the package, container, or wrapping in which a pesticide or device is enclosed to protect children and adults from serious injury or

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illness resulting from accidental ingestion or contact with pesticides or devices regulated under FIFRA. Additionally, FIFRA §25(c)(3) requires EPA's CRP standards to be consistent with those established under the Poison Prevention Packaging Act of 1970.

Additionally, other states that have enacted producer responsibility packaging and recycling programs have excluded animal health products.

- The California program enacted in 2022 exempts products intended for animals that are regulated as animal drugs, biologics, parasiticides, medical devices, or diagnostics used to treat, or administered to, animals under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

- The Colorado program enacted in 2022 exempts packaging material used to contain a product that is regulated as a drug, medical device, or dietary supplement by the Federal Food and Drug Administration under the "Federal, Food, Drug and Cosmetic Act," 21 U.S.C Sec. 301 ET Seq., amended or any federal regulation promulgated under the act, or any equipment and materials used to manufacture such products; Packaging material used to contain a product that is regulated as animal biologics, including vaccines, bacterins, antisera, diagnostic kits and other products of biological origin under the Federal "Virus-Serum-Toxin Act", 21 U.S.C. SEC. 151 ET SEQ., as amended; Packaging material used to contain a product that is regulated under the "Federal Insecticide, Fungicide, and Rodenticide Act", 7 U.S.C. SEC. 136 ET SEQ., as amended.

- The Oregon program enacted in 2021 exempts packaging and paper products sold or supplied in connection with drugs that are used for animal medicines, including but not limited to parasiticide drugs for animals.

The Maine statute specifically points the agency to the regulation of human drugs, devices and biologics as products that should receive an exemption. In order to treat animal medicines in an analogous manner, exemptions should include products for animals regulated under Federal Food, Drug and Cosmetic Act, Virus Serum Toxic Act and Federal Insecticide, Fungicide and Rodenticide Act.

We appreciate the opportunity to provide testimony today and thank you for your consideration.

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