February 22, 2024

Honorable Foung Hawj, Chair
Minnesota Senate Environment, Climate and Legacy Committee
95 University Avenue W.
Minnesota Senate Bldg., Room 3231
St. Paul, MN 55155

Dear Chair Hawj:

On behalf of companies that make medicine for animals, we request that animal medicines of all types not be subject to the requirements of SF 3561, the Packaging Waste and Cost Reduction Act.

This legislation requires producers to implement and finance a statewide stewardship program for packaging and paper products that encourages packaging redesign to reduce risks to environmental and human health and that reduces generation of covered materials waste through waste reduction, reuse, recycling, and composting. It does not currently contain exemptions for highly regulated product packaging. Animal health products are licensed and regulated by three federal agencies, each with their own packaging standards and requirements to ensure that products can be delivered which meet requirements for purity, shelf-life and other considerations.

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.

Vaccines and biologics and diagnostic test kits are approved by the U.S. Department of Agriculture under the Virus-Serum-Toxin 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.

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 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.

There is a lengthy lead time for all phases of providing animal drugs to veterinarians, livestock producers and pet owners. The discovery, research, regulatory approval, manufacturing and distribution all require long lead times. Without this exemption, our ability to deliver safe and effective medicines for the

treatment and prevention of disease in animals will be threatened. We suggest the following exemption language:

Subd. 9. Covered material. "Covered material" means packaging and paper products sold, offered for sale, or distributed in the state. Covered material does not include packaging for drugs, biological products, parasiticides, medical devices, or in vitro diagnostics used to treat, or administered to, animals and regulated by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), by the United States Department of Agriculture under the federal Virus-Serum-Toxin Act (21 U.S.C. Sec. 151 et seq.), or by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.)."

In order for animal health companies to maintain product safety and stability while increasing the sustainability of packaging, we ask that all animal medicines be exempt from the definition of covered materials in this legislation.

Please let me know if you have any questions or if I can provide any further information. Thank you for your consideration.

Sincerely,

Mandy Hagan
Director, State Government Affairs

1325 G Street, NW ■ Suite 700 ■ Washington, D.C. 20005-3104
Telephone (202) 637-2440 ■ Fax (202) 393-1667
www.ahi.org