GADA Hails Introduction of Generic Animal Drug Advancement Act

Legislation would expand consumer choice for FDA-approved generic animal drugs, for the care and treatment of both pets and livestock.

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Washington, D.C. - Rep. Nancy Mace (SC-1) announced the introduction of H.R. 1683, the Generic Animal Drug Advancement Act, that will update the Federal Food, Drug, and Cosmetic Act to correct current limitations to the approval of generic animal drug applications. The legislation would expand pathways for generic animal drugs to be approved as combination products, and update FDA animal drug labeling requirements to allow generic animal drugs to gain approval for a single species, rather than all species, labeled on a pioneer drug.

"The Generic Animal Drug Advancement Act will help cut bureaucratic red tape and ensure that safe, effective, and affordable generic animal drugs are readily available. This will help our farmers and ranchers keep their livestock healthy and will allow pet owners the best ability to take care of their pets. I'm so grateful to have such great partners in GADA and its members," said Rep. Mace.

In response to the introduction of the bill, Stephanie Batliner, Chair of the Generic Animal Drug Alliance stated, "This legislation will expand the options of pet owners, ranchers and farmers who rely on safe and effective animal drugs at affordable prices. Our alliance supports these revisions to the Food, Drug, and Cosmetic Act so generic animal drug sponsors may legally market less costly alternatives to expensive name-brand medications for animals. GADA thanks Representative Mace for her leadership on this important issue. We look forward to continuing to work with her and other policymakers to ease burdens on generic animal drug sponsors and their customers to deliver cheaper alternatives."

Under current regulations, the Food and Drug Administration (FDA) is responsible for the review and approval of all new animal drugs (pioneers) and abbreviated new animal drugs (generics). Generics approved by the FDA must prove bioequivalency or "sameness" to pioneer drugs in all species listed on pioneer drugs' labels, despite the industry standard for generic drugs to treat one or a subset of species treated by a pioneer drug. Additionally, generics are unable to create combination products like pioneers. As a result, generic animal drug applications are disadvantaged in the new animal drug approval process, damaging the animal drug industry's ability to innovate and drive down prices.

GADA is the only trade association representing the interests of generic animal drug companies in the United States. GADA membership is comprised of a diverse range of companies engaged in sponsorship of Abbreviated New Animal Drug Applications (ANADAs), from the smallest to the largest, and other stakeholders engaged in consulting, material supply, and support services. GADA represents the majority of companies with generic investigational new animal drug applications (JINADs) filed with CVM/FDA, and with approved and/or pending ANADAs. More than 51% of approved ANADAs are held by GADA member companies.

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