May 5, 2023

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Legislative Clerk
Committee on Energy and Commerce
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Ms. Brochin,

The Generic Animal Drug Alliance thanks the Subcommittee on Health and Chair Guthrie for the question following the March 30, 2023 testimony of Ms. Stephanie Batliner, GADA Chair during the Committee's hearing on "Reauthorization of the Animal Drug User Fee Programs."

The question posed to Ms. Batliner and GADA by The Honorable Earl L. "Buddy" Carter was *"...generic animal drugs, like human generic medicines, provide our nation's pets and livestock with safe and cost-effective alternatives to brand-name, or pioneer, drugs. Also like in the human drug side, animal generics face certain challenges to market entry. Can you speak to some of those challenges?"* and the Generic Animal Drug Alliance is pleased to provide the following response.

The Generic animal drug industry faces a number of challenges to product registration, market entry and proliferation in the U.S. Veterinary market, some of which differ significantly from experiences within the human generic drug industry. We appreciate the opportunity to bring some of these challenges to light. Under current constraints and obstacles, not even half of all approved brand-name (pioneer) animal drugs have a generic counterpart, and the generic animal drug industry comprises only 17.8% of total US animal pharmaceutical market (2022 data, Animalytix). Without third party payer involvement in animal health, there is no mandate for end users to choose generic animal drugs when they are available.

Regulatory framework and the animal drug approval process

The regulatory framework and interpretation of decades old legislative language places barriers to the development and registration of generic animal drugs. Pioneer animal drugs have routinely been approved by FDA across a wide range of species, indications, and routes of administration. Under current FDA policy, a generic animal drug sponsor must demonstrate bioequivalence to all major species across the full pioneer label. Additionally, and despite proven to be bioequivalent to pioneer animal drug products, FDA approved generic animal drugs are prevented from being combined with other FDA approved generic and pioneer animal drug products. The Generic Animal Drug Advancement Act, H.R. 1683 has been proposed to course correct these disadvantages for generic animal drugs.

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Each of the AGDUFA programs to date have reported significant growth in FDA-CVM review workload. While that should be good news for the generic animal drug industry, there appears to be a disconnect. More workload has not resulted in proportionally more generic animal drug approvals. Despite the millions invested in the FDA-CVM review program, and each AGDUFA program's annual Performance Report to Congress claiming significant process enhancements and efficiencies, industry is not experiencing a streamlined, efficient review program. In 2021, generic animal drug sponsors overall made nearly twice as many submissions as in 2017, however the number of generic animal drug approvals per year has remained relatively stable. More accountability is warranted to ensure an efficient FDA -CVM review program that is cost-effective, predictable and geared toward expediting the availability of FDA approved generic animal drugs based on sound science.

Unfair competition and distribution practices

Pharmacy compounding has a legitimate need in animal health, however there is widespread abuse of compounding practices, resulting in direct competition with FDA approved pioneer and generic animal drug products. The generic animal drug industry is particularly vulnerable to this unfair competition. Compounding pharmacies actively manufacture from bulk active pharmaceutical ingredients to produce direct copies of FDA approved pioneer and generic animal drug products. These illegally compounded products are then advertised online, in other media and at Veterinary conferences despite being unproven in terms of safety or efficacy. FDA enforcement action following the principles laid out in Guidance for Industry #256 is critical to maintaining the integrity of the FDA approval process, as well as protecting animal and public health.

Distribution channel practices put generic animal dugs at a disadvantage. Much of animal health pharmaceutical commerce occurs through a few major distributors. With no mandates from third party payers to use generic animal drugs when available, it becomes commonplace for certain animal health companies to enter into distribution and rebate program agreements that effectively block distributors from carrying or engaging with FDA approved generic animal drugs. Pioneer drug companies can use portfolio bundling or pricing schemes across a range of products that effectively prevent a distributor from carrying a competitive generic product. There appears to be little if any regulatory oversight of these practices.

Fiscal constraints

The AGDUFA program is not supplemental to non-user fee appropriations for review of generic animal drugs, as originally intended by Congress. Instead, the generic industry user fees funded 69% of the total AGDUFA review program (FY2021) through user fees. The generic animal drug industry has been funding its own program growth at significant impact to generic animal drug sponsors, where the application fee is now nearly $500,000 per product. This is in sharp contrast to the funding levels for the pioneer animal drug program (ADUFA), which is funded primarily through Congressional Budget Authority, with user fees contributing less than one-third (32%- FY2021) to that ADUFA review program.

We would like to convey our industry's concern that as user fees escalate, recognizing the relatively small market potential of a generic animal drug, sponsors may only choose to pursue the most lucrative products, leaving the public with fewer generic animal drug options, and underserved animal health need. The burden of user fees has increased to the point that it becomes a deciding factor in which products generic sponsors are willing to pursue. Support for the generic animal drug review program through increased appropriations should be aligned such that AGDUFA user fees become supplemental, rather than primary, such as they are within the ADUFA pioneer animal drug review program.

Thank you for the opportunity to testify and to respond to this question.

Sincerely,

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