May 5, 2023

The Honorable Brett Guthrie
Chair, House Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member, House Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair Guthrie and Ranking Member Eshoo:

Thank you for the opportunity to appear before the Subcommittee on Health on Thursday, March 30, 2023, to testify at the hearing entitled, "Reauthorization of the Animal Drug User Fee Programs."

Please find responses to the additional questions for the record attached. Thank you again for the opportunity to provide testimony before the Subcommittee.

Sincerely,

Dr. Rachel Cumberbatch
Vice President, Regulatory and International Affairs
Animal Health Institute

Attachment 1—Additional Questions for the Record

The Honorable Michael Burgess

1. Dr. Cumberbatch, what are some barriers to entry for new animal drugs?

While there are a multitude of unmet medical needs in animals that the animal health industry would like to address, the barriers to doing so come down to regulatory burden, uncertainty, cost of the drug approval process, and limited marketplace reward.

The growing complexity and regulatory burden of the new animal drug approval process is a significant barrier to new product approvals. While animal drugs have the same statutory requirement as human drugs to prove safety and efficacy, unique requirements for animal drug sponsors increase challenges. An example of a unique requirement is the need to provide CVM with copies of all raw data for studies. This means that the actual paper the researchers take notes on is scanned into a computer and submitted to the agency. No other FDA Center, US regulatory agency, or foreign regulatory agency requires this. The regulatory burden increases the administrative lift of preparing data for submission to the agency and has resulted in some contract research organizations leaving the animal health market, which makes research and development harder for animal drug sponsors.

Uncertainty in the data needed for approval or the time it will take to receive approval also hinders a company's ability to pursue future projects. This is particularly true for new companies or companies pursuing projects with small or inconsistent markets (minor species, minor use, or emerging diseases). Lengthening review times are coming from an increased number of cycles being needed to receive a favorable outcome. This translates to growing costs. These growing costs cannot be recouped in the marketplace due to limited exclusivity periods, which are shorter than those available in other global markets. Rising user fees have played a role in increasing the cost of approvals also.

The marketplace rewards for animal health are nothing like those that exist in human health. Animal health sales in the U.S. are roughly 2 percent of those for human health. Our marketplace is fractured: our products are used to treat 7 major animal species and many minor species. The fact there are no significant third-party payers means that there is constant pressure to deliver affordable products.

2. Do the bills we are considering address those concerns?

In part. The ADUFA agreement enacted by this bill addresses rising fees by holding total fees to an inflation-only increase. A key goal of industry in this negotiation was to implement new metrics to measure the total time it takes to get a product through the CVM approval process. This bill begins to explore and work toward such a metric, including the third-party assessment which we trust will provide some guidance on how such a metric can be adopted in the future.

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