Public Statement by Dr. Rachel Cumberbatch, AHI Director of International and Regulatory Affairs, to the CVM Public Meeting: Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs. The comments were delivered on July 16, 2019.

Thank you for the opportunity to speak today. AHI is the national trade association representing manufacturers of animal health products and contract research organizations that play an important role in conducting studies for the development of new animal medicines.

AHI commends the Center for Veterinary Medicine for hosting today's meeting, which serves as one of the first opportunities to focus discussion on key topics in alternative approaches in clinical investigations to support approval of new animal drugs.

The 4th Animal Drug User Fee Act, known as ADUFA, was signed into law by President Trump in August 2018. This program benefits pet owners, farmers, ranchers, veterinarians and consumers by ensuring the FDA has the resources necessary to review and approve animal medications in a timely fashion. These medications are vital to improving the length and quality of life for our companion animals and protecting the food supply by keeping food animals healthy. This meeting reflects congressional interest in supporting innovative clinical investigational approaches aimed at bringing new animal medicines to market. It further underscores that Congress recognizes that resources alone are not enough to improve the availability of animal drugs. Process changes also need to be modernized.

When Congress passed ADUFA in 2018, they made a key statement on the importance of efficiently bringing innovative products to market by empowering CVM to expand the Conditional Approval program. Under this program every new animal drug will continue to be required to meet the FDA's existing gold standard for safety and good manufacturing practices. Conditional approval will enable new products that address an unmet medical need to come to market as additional evidence of effectiveness is gathered.
Advancements in alternative approaches in clinical investigations will be vital to the success of this program. Submissions for these types of conditional approvals can only begin following publication of CVM guidance this fall. AHI welcomes the opportunity to continue working with CVM through the expanded conditional approval program.

While ADUFA programs have been successful in many ways, we know there is still work to be done. For example, the cost to bring a new animal drug to market is rising and the number of new animal drug approvals per annum has declined. The animal health industry and regulators must work together to reverse such trends. This is an important step and AHI is ready to collaborate with CVM on efforts that will advance work on alternative approaches to clinical investigations for new animal drugs.

Successful adoption of alternative approaches in clinical investigations may also benefit our shared commitment to reduce the number of animals used in research. CVM and AHI have a long history of working together on policies to advance the 3 R Principles: Replacement,

Reduction and Refinement. The successful development and implementation of alternative study designs holds potential for further reducing the number of animals utilized in the research and development of new animal drugs.

AHI anticipates challenges on the road to implementing innovative clinical study designs, but these will be more than offset by the opportunities. AHI supports drafting new guidance on adaptive study designs, use of real-world evidence and better utilization of foreign data. We also see great value in progressing approaches that would encourage the application of biomarkers in animal health. Success in these areas could lead to increased speed to market, reduced number of animals used in testing and increased number of innovative medicines available on the market.

Thank you.