ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

Majority (202) 225–2927 Minority (202) 225–3641

April 5, 2018

Dr. Michael Topper President American Veterinary Medical Association 1910 Sunderland Place, N.W. Washington, DC 20036

Dear Dr. Topper:

Thank you for appearing before the Subcommittee on Health on March 14, 2018, to testify at the hearing entitled "Reauthorization of Animal Drug User Fees 2018: ADUFA and AGDUFA."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely

Michael C. Burgess, M.D.

Chairman

Subcommittee on Health

ce: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Gus M. Bilirakis

- 1. In your testimony, you mentioned the need for new and innovative medicines to fulfil unmet needs for veterinarians. Would you walk us through some of the unmet needs your members see in their practices?
- 2. Would you explain some of the challenges that exist for veterinarians and veterinary therapeutic options in the context of extralabel drug use?

The Honorable Frank Pallone, Jr.

I'm interested in your perspective on how the ADUFA and AGDUFA programs have improved animal health, as well as the nation's food supply. Animal drug development and approvals are critical to ensuring that our companion pets lead longer and healthier lives and that our food-producing animals are safe for human consumption.

- 1. Can you explain how the animal drug user fee agreements have improved animal health, both for pets and food-producing animals?
- 2. As a veterinarian, what are the benefits of increasing the efficiency of the animal drug approval process? Does ADUFA and AGDUFA help bring new and innovative products to the market faster in order to help treat animal patients?
- 3. Can you discuss why the FDA gold standard of safety and efficacy is so critical when treating animal patients?