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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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April 5, 2018

Dr. Bill Zollers
Chairman
Generic Animal Drug Alliance
9 Newport Drive; Suite 200
Forest Hill, MD 21050

Dear Dr. Zollers:

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

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

Attachment

Attachment — Additional Questions for the Record

The Honorable Gus M. Bilirakis

Would you briefly explain the importance to industry and public health of efficient and predictable review periods for generic animal drugs?

The Honorable Frank Pallone, Jr.

Since the first iteration of the ADUFA and AGDUFA programs, these agreements have worked to streamline the animal drug approval process at FDA while also ensuring that animal drugs for both pets and food-producing animals are safe and effective.

I'm interested in hearing GADA's perspective on why the animal drug user fee programs are so important and why we must ensure the timely reauthorization of these programs.

1. Dr. Zollers, can you briefly summarize why you believe the ADUFA and AGDUFA programs, respectively, are critical to the development of animal drug products?

2. How has the animal health industry evolved since the implementation of ADUFA and AGDUFA and how have the animal drug user fee programs improved the animal drug application review process at FDA?

3. Can you provide examples of how the ADUFA and AGDUFA programs, respectively, have helped your industry to innovate and have resulted in bringing more products to the market?

4. In your opinion, what are the most significant new proposals in ADUFA IV and AGDUFA III and how do they further improve the animal drug review process at FDA?

5. Can you explain why it is so critical that these programs are reauthorized before the sunset date of September 30, 2018?

FDA has been working since May 2016 to finalize recommendations for the reauthorization of the animal drug user fee programs and as part of this process FDA held negotiations with the regulated animal drug and generic animal drug industries to reach agreement on both financial and performance goals for ADUFA IV and AGDUFA III.

6. What are some of the major improvements this proposal makes from the current goals and how will these proposals create new efficiencies for FDA?

7. Dr. Zollers – do you believe that the electronic submission requirements included in this discussion draft will improve the efficiency of the animal drug approval process at FDA?