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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

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April 5, 2018

Dr. Rachel Cumberbatch
Director, Regulatory Affairs, Animal Drugs
Animal Health Institute
1325 G Street, N.W.; Suite 700
Washington, DC 20005

Dear Dr. Cumberbatch:

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

1. Would you walk us through the benefits of ADUFA and AGDUFA to industry and why have these programs have a track record of success?

2. You mention in your testimony that conditional approval authority exists in other areas of animal health with the exception of major species. Why is that and how does not having this authority in major species ultimately affect public health?

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 AHI'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. Cumberbatch, 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?

Dr. Cumberbatch, I understand that FDA has been in discussions with stakeholders, pursuant to ADUFA III, to explore the possibility of pursuing statutory changes to expand the use of conditional approval beyond the current structure for minor uses and for minor species.

As currently authorized, a sponsor of an animal drug for a minor use or minor species can apply for conditional approval with FDA, which permits the sponsor to make the drug available prior to gathering all effectiveness data, but after demonstrating safety. As you noted in your testimony, the Animal Health Institute is supportive of expanding conditional approval in certain circumstances.

6. Given the lack of robust utilization of the conditional approval pathway under the minor use/minor species approach, why does industry believe this process might be more successful for other types of animal drug products?

7. Should conditional approval be expanded in certain cases for other animal drug applications, what are some examples of conditions or potential therapies that could improve animal health and could be an effective use of this process?

8. FDA's gold standard of safety and efficacy is the cornerstone by which the agency reviews new drug applications. Do you believe that by expanding conditional approval and permitting sponsors to keep products on the market while gathering effectiveness data there will ultimately be more fully approved products on the market in the long-term?

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.

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

10. Dr. Cumberbatch – 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?