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?

For public health, AGDUFA has provided additional resources for FDA-CVM to make the thorough review process more efficient and predictable in terms of timing. This capacity leads to sustainability of the regulatory review process for generic veterinary drugs. The benefit of AGDUFA to the FDA-CVM review process further protects the public health by resulting in the approval of safe and effective veterinary generic drug products. This ultimately leads to a longer, healthier lifespan for our family pets and a safer food supply for the public.

For industry, efficient and predictable review cycles allow Sponsors of veterinary drugs to plan more effectively and to choose generic drug development projects that will lead to a positive financial outcome. As mentioned in the GADA testimony on March 14, 2018, prior to the implementation of AGDUFA, a CVM review cycle of a generic drug application could take longer than 700 days. In many cases where the regulatory process required multiple review cycles, it could easily take 6 to 8 years to receive an approval for a generic drug. This was a major disincentive to the generic drug Sponsors. Without the re-authorization of AGDUFA, we fear that a lack of funding will result in a number of CVM reviewers losing their jobs, and a return to the longer and unsustainable timeframes for regulatory review cycles. This is the main reason industry is stepping forward again to support the reauthorization of AGDUFA III. Ideally, industry would like to see increases in Congressional budget appropriations to the veterinary generic drug approval process.

The Public and the Sponsors of generic drugs have a financial interest in an efficient and predictable regulatory process. For the Public, the financial interest is that generic animal drugs provide a cost-effective alternative to pioneer drugs. For the Sponsor, a predictable regulatory review and approval process ultimately leads to a better financial position. When a veterinary drug company sells high-quality, safe generic drugs, this not only leads to better lives for our family pets and a safer food supply, but it also helps to stimulate the economy, create and/or sustain jobs, and provide a return on investment to shareholders.

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?

   The ADUFA and AGDUFA programs provide key funding to assist the FDA-CVM in protecting the public health by ensuring the safety, efficacy and security of veterinary drugs and by ensuring the safety of our nation's food supply. Without

these additional ADUFA and AGDUFA resources provided by the industry, the FDA-CVM has told us that review times would increase significantly and therefore the review process would lose efficiency and increase the time to approval for generic animal drugs. The uncertainty created due to the lack of ADUFA and AGDUFA funding would set back the ability to bring new pioneer and generic drugs to the Public to promote advances in health for veterinary medicine.

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?

   The ADUFA and AGDUFA programs have created a predictable review cycle allowing the Sponsor to plan and anticipate better. To speak specifically to the AGDUFA program, part of the evolution of the generic veterinary drug industry over the last 9 years has included new CVM interpretations of the requirements for a veterinary generic drug. There is some debate as to whether all the new requirements effectively lead to safer drug products. It is a struggle for industry to balance the support for AGDUFA as we know that growing the FDA-CVM capacity is likely to lead to additional drug development requirements that may not contribute to the safety of drugs in a measurable way.

   Upon evaluation of the FY2017 AGDUFA Performance Report and the FY2017 AGDUFA Financial Report, GADA notes that over the last 9 years there are more sponsors and interest in seeking approval of generic animal drugs. This is evidenced by the reported increase in sponsors and based on the increase in the JINAD sentinel submissions, which are indicative of a significant increase in workload. However, there is not a corresponding significant increase in generic drug approvals by FDA-CVM. The output of approvals does not follow the same increased trajectory as the workload involved in the process to approval. GADA is hopeful that this increased workload, which is reflective of significant interest by the Sponsor, will show up in the number of approvals in the coming years.

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?

   Given that GADA's testimony on March 14, 2018 was focused on AGDUFA, we will speak to that User Fee program. The focus of the generic industry through the AGDUFA program has been to eliminate the backlog of submissions under review in 2008 and decrease the review cycle from greater than 700 days down to the proposed 180 days in AGDUFA III. There have been great strides in accomplishing these goals. However, this has not translated into a significant increase in the number of generic drug products approved over the last 9 years.

   There are really no good specific examples of innovative generic approval regulatory pathways that have resulted directly from the AGDUFA program. GADA continues to support innovative ways that might improve the efficiency of the review process and lessen the burdensome requirements without sacrificing safety.

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?

The GADA testimony on March 14, 2018 was focused on AGDUFA III. The most significant improvement in AGDUFA III is the reduction in the submission review cycles. For Phased submissions, the review goes from 270 days to 180 days and the reduction in the administrative ANADA review cycle goes from 100 days to 60 days. These reductions put generic drug application review cycles on par with the pioneer drug applications. These reductions in review cycle timeframes come with a very high cost to industry, as the total cost of AGDUFA III (~$95 million) will approximately double from the total cost of AGDUFA II (~$47 million to ~$50 million).

Industry willingly supports AGDUFA III. However, industry will be unwilling to increase its contribution in the future if we do not see an increase in product approvals. It will simply get to a point where it does not make financial sense. As industry has doubled our dollars going from AGDUFA II to AGDUFA III, we have not seen a similar increase in generic drug products approved. In addition, we have seen little or no increases in Congressional budget appropriations allocated to the veterinary generic drug approval process.

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

Upon sunset of the AGDUFA III User Fee program, the review cycles for generic drug applications would likely go from the current 270 days to in excess of 700 days, as was the review cycle timeframe before AGDUFA. A number of reviewers at FDA-CVM would lose their jobs because no funding would be available unless additional Congressional budget appropriations were provided. This would be a lose-lose-lose situation for FDA-CVM, industry and the public.

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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?

   In AGDUFA III, the most significant improvements for industry are the reduction in the Phased submission review cycle from 270 days to 180 days, and the reduction in the administrative ANADA review cycle from 100 days to 60 days. This puts generic drug application review cycles on par with that of the pioneer drug applications. In AGUFA III, the overcollections and offset provisions have been refined and improved to allow funding to be more effectively and efficiently ready for use by FDA-CVM to continue to improve the generic drug review process.

   GADA is cautiously optimistic that these shorter review times will not result in multiple review cycles. Overall, we are hopeful that the reduction in review times will lead to a shortened time from project initiation to approval, allowing generic products to come to market sooner.

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?

   The electronic submission process has already been available to Sponsors for a number of years. According to the FY 2017 Performance Report to Congress for AGDUFA, in FY2013, 48% of generic product related submissions were via the electronic pathway. In FY2017, 58% of generic product related submissions were via the electronic pathway. Each year, adoption of the electronic submission process increases. CVM has told industry that e-Submissions improve the efficiency of the generic drug review process.

   FDA-CVM requested that AGDUFA III include the provision that 100% of submissions be electronic. Industry has accepted this proposal, although we realize there will be an initial burden on Sponsors not currently using the e-Submission pathway. FDA-CVM is providing a webinar training series to allow Sponsors the opportunity to learn how to establish and utilize the e-Submission process. GADA is also reaching out to all of its member companies and associates to assist in connecting them to the resources needed to establish the e-Submission pathway.

   This will allow CVM to eliminate the "paper" process submission system; essentially allowing FDA-CVM to move to one system: electronic. This will save time, money and effort and CVM can invest these efficiencies in other aspects of regulatory review. GADA understands that potential efficiency gains that can be made. GADA supports the transition to 100% electronic submissions.