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Congress of the United States

House of Representatives

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April 5, 2018

Dr. Steven Solomon
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Solomon:

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 what actions FDA has taken over the past few years and is currently undertaking with regard to antimicrobial resistance in animals – specifically those for consumption?

2. How do these user fee programs foster innovation in drug development?

The Honorable Frank Pallone, Jr.

Dr. Solomon, it's clear that the user fee programs for animal drugs have been a success, just as the other user fee programs at FDA have been. I'm pleased that FDA, the animal drug industry, and other stakeholders have once again worked together to reach agreement on a path forward.

1. Since the implementation of the animal drug user fee programs, how has FDA's new animal drug review process improved?

2. What has FDA learned since the first authorization of the animal drug user fees and how have the agreements evolved over time to further streamline the review process since the first authorization?

3. Without the animal drug user fee programs, would animal drug development suffer?

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?

Dr. Solomon as you have previously explained, these animal drug user fee agreements are critical to ensuring animal health and safety and streamlining FDA's animal drug approval process.

These user fee programs help to maintain a stable workforce at the agency to review new animal drug applications, while cutting down on review times and improving FDA's efficiency. In addition, the agreements also help to bring certainty to industry regarding the review and approval of innovative and generic animal drugs, provide necessary treatments for animal health providers, and ensure the health and well-being of our animals.

5. Can you explain why it is so critical that the animal drug user fee and animal generic drug user fee programs are reauthorized before the sunset date?

6. What will happen if the animal drug user fee agreements are not reauthorized in a timely manner? Could there be disruptions in the approval process?

7. Would delays impact the agency's ability to retain subject matter experts to review new animal drug applications?

A topic that often comes up in relation to the reauthorization of animal drug user fees is antimicrobial resistance given that the Center for Veterinary Medicine at FDA is also charged with evaluating antimicrobial animal drugs. Dr. Solomon, as you know, antibiotic resistance is a grave public health threat as the use of antimicrobials in food-producing animals can result in the emergence of antimicrobial resistance in bacteria that can be transferred to humans and can ultimately reduce the effectiveness of antibiotics in humans.

8. Can you discuss the steps FDA has taken recently to address the public health concerns related to antimicrobial resistance and help reduce or limit the use of antimicrobials in food-producing animals?

9. How do we balance the need for medically important uses of antimicrobials in food-producing animals with efforts to limit or reverse resistance concerns?

Recognizing the danger of antimicrobial resistance and the risk of decreasing effectiveness of antibiotics for treating human disease, Congress included as part of ADUFA II certain data collection requirements for antimicrobial drug sponsors.

10. How has access to antimicrobial drug sales and distribution data helped to improve FDA's efforts to address antimicrobial resistance?

11. For the first time this past year FDA's summary report on antimicrobials sold or distributed for use in food-producing animals included species-specific estimates. How did FDA determine these estimates and what advantage does inclusion of specific-specific estimates have in data collection efforts?

Dr. Solomon, the public health crisis resulting from antimicrobial resistance is very concerning and I'm interested in FDA's guidance on judicious use of antimicrobials for food-producing animals and whether FDA's policy has improved veterinary practice in this area.

There is wide agreement that antibiotics should only be used when necessary. As you discussed briefly in your testimony, greater awareness of the harms of antibiotic resistance should result in changes to how antibiotics are utilized in animal agriculture and how FDA is monitoring antimicrobial usage in food-producing animals.

12. Will you further discuss FDA's policy on judicious use of antimicrobials in food-producing animals, which aims to maximize therapeutic efficacy while also minimizing the selection of resistant microorganisms?

13. Why is it so important to have veterinary oversight or consultation when utilizing medically important antimicrobials in food-producing animals?

14. What is the status of implementation on FDA's judicious use policy and how has implementation progressed since the guidance was first published in 2013?

15. What additional steps do you believe FDA and industry should be taking to further address the harms of antimicrobial resistance? Are there additional tools that FDA needs to better address antimicrobial resistance?