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Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
" FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics "
February 3, 2022

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The Honorable Richard Hudson (R-NC)

1. In your testimony and throughout the hearing, you and others highlighted the impact the COVID-19 pandemic has had on biosimilars and patient access, specifically citing FDA's growing backlog of delayed foreign inspections. As you also noted, FDA's own data has shown a steep decrease in FDA's ability to meet biosimilar user fee goal dates, with on-time actions dropping significantly lower than those for other drug applications. Given the ability for biosimilars to lower the cost of some of the most expensive medicines, please explain in detail how these inspection delays have impacted the biosimilar marketplace and patient access. In addition, please explain any and all specific policies or actions the Biosimilars Forum believes are necessary to successfully address the growing backlog.

Answer: Not only has the COVID-19 related inspectional backlog had a significant impact on biosimilars but also it appears that biosimilars have been more adversely affected by these pandemic-related inspectional issues than other product areas. As reflected in my February 3, 2022 testimony, the percentage of on-time actions for biosimilars is far from the negotiated targets and has been markedly worse than for other use fee programs. FDA generally does not disclose its reasons for missing the action date for a particular application. However, FDA has explained that it will defer action (*i.e.*, miss the goal date) for an application if an inspection is deemed necessary but, in the Agency's view, cannot be completed due to factors including travel restrictions and the application otherwise meets the requirements for approval. Without FDA approval, these critical medicines cannot be marketed, undercutting the Agency's commitment to improving access through increased competition. Additionally, to reiterate from my testimony, biosimilar inspections are not considered by the Agency to be "mission critical" and thus are not being prioritized.

The Forum continues to strongly support efforts to advance a robust biosimilars program, with the corresponding benefit of increased patient access to high quality, safe, effective, and affordable therapies. We believe that there are a number of specific policy tools and actions that could help address the growing inspections backlog. For example, FDA could be authorized to leverage existing tools to enable the Agency to use Remote Interactive Evaluations (RIEs) or records requests pursuant to section 704(a) of the FD&C Act to clear Official Action Indicated and p-OAI facilities. In addition to increasing the availability of alternatives to on-site

inspections, more robust reporting requirements, such as posting real time information on the number of biosimilar facilities inspected during the prior month and the number scheduled for inspection the following month, could enhance transparency and accountability. And, recognizing that on-site inspections may be needed in certain circumstances, the Agency could coordinate with the State Department (through a statutory directive or other mechanism) to ease inspector access to foreign countries.