Biosimilars FORUM

June 22, 2020

Re: Food and Drug Administration
[Docket No. FDA-2019-N-1875]
Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments

Good afternoon. I am Juliana Reed, Vice President of Corporate Affairs and Lead for Biosimilars at Pfizer. Today I'm here as President of the Biosimilars Forum and my remarks represent the views of our nine members who manufacture and market biosimilar products. The Biosimilars Forum is a non-profit organization with a mission to promote biosimilar education and support advancement of policies that will support a robust, biosimilar market in the United States to lower costs. Our intent is to expand access and availability of biosimilars that improve health care treatment options.

The Biosimilars Forum congratulates FDA for the very positive evaluation by the Alliance to Modernize Healthcare, or Health FFRDC,[1] which in its report recognized that FDA has effectively managed resources for the user fee programs.

We also acknowledge that FDA has already devised an action plan to address a number of issues raised in the Health FFRDC report.[2] Today I will highlight two key areas in the report that are not mentioned in FDA's plan, which we believe are important for the fiscal management of the BSUFA program.

Under "STANDARDIZING MANAGEMENT AND EXECUTION OF PRIOR YEAR FUNDS" [Opportunity 1.7]—the Health FFRDC report states that, "Despite a high degree of Agency management focus on prior year balances, there is inconsistency regarding how to utilize and manage these funds, especially under a Continuing Resolution."

Given the history of CRs and the high likelihood that FDA will operate under a CR this year, we ask the Agency to adopt the report's recommendations to develop a robust, standardized carryover policy and SOP for managing prior year funds, and a plan to ensure that prior year funds are fully exhausted within a two-fiscal year period before switching to current year funds. We believe this will help the Agency to function optimally under a CR.

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[1] FDA and CMS Alliance to Modernize Healthcare. Fiscal year 2018 Financial Management Evaluation for Human Drug User Fees Assessment Report. https://www.fda.gov/media/127605/download (accessed June 10, 2020)
[2] FDA Action Plan in Response to Human Drug User Fee Financial Management Study https://www.fda.gov/media/132523/download (accessed June 10, 2020)

Under IMPROVING TRANSPARENCY AND EFFICIENT EXECUTION OF TRIGGER MANAGEMENT [Opportunity 1.8]—the report addresses the user fee trigger, stating that "the trigger process can be confusing to FDA staff"—and, I might add, to industry, as well—"potentially resulting in inconsistencies as to when appropriated monies should be used vs. when user fee funds should be used."

The Forum strongly supports the Health FFRDC's recommendation to "Develop a cross-FDA focus group to evaluate the trigger management process," and specifically to:

- Conduct cross-organization training sessions on trigger management and the legal provisions that govern them.
- Consider updating the trigger provisions to standardize the multiplier adjustment factors across the user fee programs, and;
- Develop and standardize an entity-wide SOP for trigger management.

Thank you again for the opportunity to speak before you today. The Forum supports FDA's ongoing efforts to advance a robust biosimilars program and we are committed to working with the Agency and other stakeholders to ensure that patients have high-quality, safe, effective, and more affordable medicines.