Biosimilars
FORUM

800 17th Street, NW Suite 1100, Washington, DC 20006

October 19, 2016

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Comments on FDA Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (Docket No. FDA-2015-N-3326)

Dear Commissioner Califf:

The Biosimilars Forum ("the Forum") appreciates the opportunity to comment on the Food and Drug Administration ("FDA") Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (hereinafter, "Commitment Letter").

The Forum is a non-profit trade association representing biosimilars manufacturers and dedicated to expanding patient access to biosimilars in the United States. When negotiations began for the Biosimilar Biological Product User Fee program for FY2018 - FY2022 ("BsUFA II"), Biosimilars Forum members represented the majority of U.S. biosimilar programs in development. The Forum's mission is to advance biosimilars in the United States with the intent of expanding access and availability of biological medicines and improving health care. The Forum works on a consensus basis to develop policy positions to ensure the United States has a competitive, safe and sustainable biosimilars market, providing more options to patients and physicians.

The Forum is proud to have participated in industry negotiations with the FDA, and greatly appreciates the cooperation of the Agency and the other industry groups represented during the negotiations. We feel the resulting commitments will provide the necessary time and resources needed by the FDA to support a successful biosimilars program. This letter reflects our support of the enhancements described in the Commitment Letter. The Biosimilars Forum believes that the Commitment Letter meets the Forum's overarching goal of providing ongoing support to this important program which ultimately will benefit patients by advancing biosimilar approvals and access in the U.S.

Brief Summary of the Commitment Letter

In the BsUFA II Commitment Letter, the FDA outlines significant enhancements to the User Fee program that support the review and approval of biosimilar medicines in the U.S. These agreed to enhancements include a revised review process meant to increase transparency and communication between the FDA and biosimilars sponsors that is expected to facilitate an increase in the likelihood of first cycle approval; Agency commitments to complete and publish several draft and final guidance documents that will provide industry with additional clarity and certainty regarding the biosimilars development and review process; Agency commitments to augment and strengthen biosimilars staffing; and enhancements to the user fee structure and management that will allow greater transparency, predictability and long-term stability of biosimilar development programs in the U.S.

Comments on the Commitment Letter

The Forum applauds the efforts made by the FDA to work with industry toward a more efficient and transparent review process. The Forum believes the negotiations resulted in improvements in communication and accountability between sponsors and FDA, and the focusing of the industry's contributions of BsUFA funds on matters related to the FDA's biosimilars review program. The goals set out in the Commitment Letter will help ensure timely and more transparent review of biosimilar products, to the benefit of patients who need these products.

While the Forum supports the Commitment Letter in its entirety, it highlights its support for the following provisions in particular:

Enhanced Biosimilars Review Program

The Forum supports the creation of the revised review model described in the Commitment Letter. The new program, which is based on an existing program for review of New Molecular Entity New Drug Applications and original Biologics Licensing Applications, provides flexibility to FDA reviewers, while offering sponsors additional and more frequent opportunities to communicate with reviewers. The review model also is designed to facilitate more first-cycle approvals, minimizing the number of additional review cycles for sponsors. The additional predictability and increased communication will speed patient access to biosimilars, and an independent third party assessment of the program will ensure transparency and accountability.

Meeting Management Enhancements

The agreement between industry and the FDA also allows the FDA more flexibility in the scheduling and format of formal meetings, but allows sponsors to have more consistent expectations by requiring the provision of early Agency feedback in advance of Biosimilar Biological Product Development (BPD)Type 2 meetings. In addition, the Agency will update the current draft or final guidance document Best Practices for Communication Between IND Sponsors and FDA During Drug Development to specify its application to formal biosimilars meetings. The Forum supports these enhancements.

FDA Staffing Enhancements

The Forum supports the commitment to additional capacity for biosimilars review, which will ensure that the FDA can meet its performance goals, resulting in speedier availability of biosimilars to patients. Enhancements in staff capacity for the development of regulations, policy and guidance will allow for quicker issuance of important interpretations and clarifications, and more comprehensive answers to questions that may arise during product development. This, in turn, will help to provide additional uniformity and predictability regarding biosimilars review and marketing.

User Fee Structure and Management Enhancement

Revisions to the user fee structure and resource capacity planning will increase the program's efficiency and ensure predictable user fee funding. Modernized time reporting will improve the accuracy of resource planning, and a third party assessment of program resource management will ensure transparency and accountability. The Forum supports these efforts to ensure efficiency and transparency.

Periodic Assessment of the Biosimilars Program

In the BsUFA II Commitment Letter, the Agency has agreed to meet with biosimilars sponsors to "periodically and regularly assess the progress of the biosimilar biological product review program throughout BsUFA II… to identify emerging challenges and develop strategies to address these challenges."

The Forum strongly supports these opportunities to coordinate and collaborate on efforts to make the biosimilars program stronger.

Conclusion

The Biosimilars Forum is pleased to have been part of efforts to enhance the biosimilars review program and to ensure stability and viability for the program going forward in BsUFA II. The Forum believes the Commitment Letter reflects the BsUFA II priorities shared by its members and reflects its overriding goals of contributing to putting the biosimilars program on solid financial footing, improving communication between sponsors and FDA, and ensuring transparency regarding the expenditure of BsUFA funds.

We encourage Congress to support the BsUFA II agreement and also to provide the FDA with the necessary government resources it needs to continue building its biosimilar program. The commitments by the FDA, combined with the financial support of Congress and industry ultimately will benefit patients by getting these important products to market.

If you have any questions or need any additional information, please contact Michael Werner at 202.419.2515 or at michael.werner@hklaw.com.