July 27th, 2017

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-3199: Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the statement of work for assessment of the Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO appreciates this opportunity to submit comments regarding FDA's Statement of Work. We support the approach described in the BsUFA II Performance Goals of establishing a review approach for biosimilars applications patterned generally after the program established under PDUFA V for New Molecular Entity (NME) and new Biological License Applications (BLAs). With respect to that earlier program, a third party evaluator determined that it has been successful in increasing the number of first-cycle approvals for those products. The underlying premise of both the previous and the proposed programs was that increased and improved communication between FDA and the application sponsor during the review would improve efficiency and reduce need for additional review cycles.

Based on our experience with the PDUFA program, we agree that enhanced and more frequent communication has been successful, and we believe it seems logical to extend this approach to biosimilar applications. However, as it was crucial in the case of the PDUFA program that a third party evaluate whether the approach achieved its hoped-for goals, it is equally important for such an evaluation to occur for the new biosimilars program. We applaud FDA's inclusion in the draft Scope of Work that the evaluation must be public, take account of input from both FDA staff and sponsors, and provide recommendations at the mid-point and at the end of the program for any changes that might be needed for the program to succeed. It is especially important, in the case of using this review approach for biosimilars applications, that the evaluator look at the relationship between the Biosimilars Development Program meetings, which occur throughout the process of development and up to application submission, and the meetings that occur during the review cycle. The question of whether and to what extent those earlier meetings could have identified and

provided time for resolution of potential problems is an important one, particularly as the proposed approach adds 60 days to the total time from application submission to BsUFA goal date. We support inclusion of this component in the draft Scope of Work.

Finally, we are pleased that FDA is – as proposed in the BsUFA II agreement – beginning the process of contracting for this evaluation now so applications can be followed beginning immediately with the start date of BsUFA II, October 1, 2017.

BIO appreciates this opportunity to submit comments on the statement of work for assessment of the Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Kay Holcombe
Senior Vice President, Science Policy
Biotechnology Innovation Organization

/S/

Sesquile Ramon, Ph.D.
Director, Science and Regulatory Affairs
Biotechnology Innovation Organization