BIOTECHNOLOGY INDUSTRY ORGANIZATION

1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

December 16, 2011

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0326, CBER 2011128. Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications

Dear Sir/Madam:

On behalf of the Biotechnology Industry Organization, thank you for the opportunity to comment on the proposed user fee program for biosimilar and interchangeable biological product applications (BsUFA). BIO supports FDA's ongoing implementation of a well-constructed, science-based pathway for the approval of biosimilar products. A transparent, predictable, and balanced regulatory framework for the review and approval of biosimilars accompanied by reasonable performance goals and a dedicated, independent funding stream will ensure that FDA can facilitate the development and evaluation of biosimilars products, while also continuing to prioritize the review of innovative drugs and biologics so that safe and effective new treatments – many for currently untreatable and serious diseases – can be made readily available to patients.

BIO represents more than 1,100 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, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

I. BIO Supports Passage of BsUFA

Throughout both the legislative consideration of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and ongoing FDA implementation of the pathway, BIO has articulated several key principles that will promote the development of an effective regulatory framework for biosimilar products:

- Ensuring Patient Safety
- Recognizing Scientific Differences Between Drugs and Biologics
- Maintaining the Physician-Patient Relationship
- Preserving Incentives for Innovation
- Ensuring Transparent Statutory and Regulatory Processes
- Continuing to Prioritize FDA Review and Approval of New Therapies and Cures

BIO believes that the proposed user fee program is consistent with these principles and supports Congressional authorization of the program.

II. FDA's Biosimilars Activities should be Supported by a Dedicated and Independent Source of User Fees

The establishment of a stand-alone, independent biosimilars user fee program is consistent with Congressional intent and precedent established under other user fee programs. BIO recognizes that 351(k) applications will raise novel and complex questions of science and law, requiring substantial time, expertise, and additional resources to ensure a thorough regulatory review. BIO believes that one of the principal goals of this new user fee program must be to ensure that workload associated with biosimilar applications does not harm the Agency's ability to efficiently review innovative drugs and biologics, and that new treatments continue to have the highest review priority. Accordingly, we agree with FDA's principle that the Agency needs sufficient review capacity and dedicated user fee resources for 351(k) applications to assure that resources are not redirected from innovator reviews.

III. User Fees should be Complemented by a Sound Base of Appropriations

Additionally, BIO recognizes that historically, most FDA user fee programs have been established on a pre-existing base of appropriations. However, given the recent establishment of the biosimilars program at FDA, only modest appropriations are currently allocated to the program, which are inadequate to meet the anticipated workload demands. To facilitate an equitable balance of fees and appropriations, FDA and industry support a trigger provision - similar to the established appropriations triggers in other user fee programs - that would ensure that FDA allocates at least $20 million per year to the program. BIO encourages Congress to recognize the importance of a well-resourced and viable biosimilars pathway at FDA and we request that adequate new funding be appropriated for the program.

IV. Biosimilar Product Development Fees are a Necessary, but Provisional Measure

The biosimilars user fee program also establishes a unique biosimilar product development fee, which is ultimately deducted from the sponsor's application fee. Since there is no established biosimilars industry, facility base, and product base to form a stable funding source for activities that occur before submission of applications, it is important to "front-load" the fees through the product development fee so that the agency has available resources to meet with sponsors during development to provide scientific advice and feedback. It should be noted, however, that the assessment of a product development fee is unique to this situation with respect to biosimilar products and should not establish any precedent for Investigational New Drug (IND) fees under the Prescription Drug User Fee Act (PDUFA) program. Additionally, any IND-associated fee should sunset permanently in FY2018 when both PDUFA and this new user fee program would sunset.

V. FDA's Ongoing Implementation of the Biosimilars Pathway

BIO appreciates this opportunity to comment on the particulars of the biosimilars user fee program, and we look forward to additional opportunities to engage with FDA and other stakeholders on the broader issues related to implementation of the biosimilars pathway. A transparent, open, and science-based implementation process that engages the public and regulated industry will only serve to strengthen the regulatory framework. For example, we look forward to commenting on FDA's pending draft guidances. We also encourage the Agency to hold additional workshops and public meetings to facilitate an ongoing dialogue.

In particular, there are three issues directly related to FDA's workload and review activities that BIO has raised in previous comments and that we continue to believe the Agency should address proactively as part of its ongoing implementation in order to promote transparency, confidence, and predictability and to assure the successful use of the pathway.

- Appropriate Delineation of Pathways: First, we encourage FDA to clarify which types of applications would be accepted for review under the 351(a) innovator pathway versus the 351(k) biosimilar route. The Agency should reiterate that 351(a) applications will require a full complement of preclinical and clinical data and may not reference or in any way seek to rely on an innovator product's prior approval or associated data. Allowing a biosimilar product to utilize the 351(a) pathway would undermine the careful balance of benefits for innovators and follow-on sponsors established in the BPCIA.

- Certification of BPCIA Compliance: Second, to ensure that limited Agency resources are directed only to those applications that are in full compliance with the statutory requirements for exchange of patent-related information, we propose that FDA institute a simple administrative certification process as part of the 351(k) marketing application acceptance process. Such a mechanism will help to ensure that any patent disputes that may impact the marketing of a biosimilar can, consistent with Congressional intent, be resolved efficiently and largely prior to biosimilar launch, while also facilitating the

Agency's prerogative to devote its resources to those applicants that are complying with the statute in good faith.

- Protection of Confidential Commercial Information: Finally, given that the same review division will review both the innovator product and biosimilar, it is critical that FDA clearly define the process for review of 351(k) applications to assure protection against disclosure of trade secret/confidential information from a reference BLA, and that approval of a 351(k) application does not rely on any data or information from the reference BLA that is not publicly available. In addition, a technical correction of FDA's disclosure regulations is necessary for harmonization with the BPCIA, reflecting the current view that biologics application information is competitively sensitive.

VI. Conclusion

In conclusion, BIO supports enactment of the proposed biosimilars user fee program, which will provide FDA with adequate resources and promote predictability in FDA's biosimilars review process, while continuing to promote the development and evaluation of innovative therapies for unmet medical needs.

Sincerely,

/S/

Andrew J. Emmett
Managing Director for Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)