BIOTECHNOLOGY INDUSTRY ORGANIZATION
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May 14, 2012

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

Re: Docket No. FDA–2012–N–0194: Biosimilars User Fee Cover Sheet; Form FDA 3792

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the "Biosimilars User Fee Cover Sheet; Form 3792."

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.

BIO appreciates the opportunity for public review and comment of the proposed biosimilars user fee form, so that the Agency's implementation of a biosimilars pathway and review of 351(k) applications can proceed in a fair, transparent, and consistent manner. In that vein, BIO would like to make a few comments about the proposed biosimilars user fee form:

I. Application Types and Abbreviations

We note that the user fee form refers to 351(k) applications as Biologic License Applications (BLAs) for tracking and other purposes[1]. BIO believes that this terminology is confusing with respect to innovator BLA products and inconsistent with established and pending law.

Under the *Biosimilars Price Competition and Innovation Act of 2009* and the *Biosimilar User Fee Technical Agreement* (BsUFA), 351(k) products are referred to as "biosimilar biological products" or "interchangeable biosimilar biological products." Under the BPCIA, the term "BLA" is not used, but the phrase "biosimilar biological product application" is referenced in statute.

For greater clarity and to better distinguish innovator applications and biosimilar applications, we suggest that FDA utilize the term "Biosimilar Biological product Licensing Application (BBLA)." For the purposes of establishing interchangeability, FDA should refer to the product as an "Interchangeable Biosimilar biological product Application (IBLA)." We suggest that the terms BBLA and IBLA be used in this form, and for FDA application tracking purposes, indication of approval status, and general regulatory communications with regulated industry and the public.

This type of application naming and tracking is grounded in precedent as a similar distinction is made between New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).

II. Request for Product Name

BIO notes that, since this form will, in many cases, be required early in the development program of biosimilars, the proper, trade, or proprietary name would not yet be established. We therefore believe that the biosimilars user fee form should be consistent with the requirements for FDA Form 1571, as required for an investigational new drug application (IND), and request all available product names: trade, proper name, or code, as applicable.

III. Request for Clinical Data Information

BIO also notes that the form requests information regarding whether the application will require clinical data. This information is unnecessary, since the requirement to pay a user fee or the amount of the fee is not impacted by clinical data. The requirement for clinical data is intended to be made by the Agency during the development process. Accordingly, BIO feels that this information is unnecessary with respect to the need to pay the biosimilar user fee or with respect to the amount that will be owed.

[1] For example, the term BLA is referenced on the bottom of page 2 ("BLA STN Number"), middle of page 3 (Waiver), middle of page 4 (Submission Reference).

BIO appreciates this opportunity to comment on the "Biosimilars User Fee Cover Sheet; Form 3792." Specific, detailed comments are included in the following chart. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Kelly Lai
Director, Science & Regulatory Affairs
Biotechnology Industry Organization (BIO)

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
I. INSTRUCTION TABLE		
Page 2, Item 3:	"PRODUCT NAME: Include proper name and trade or proprietary name, as applicable." Since this form will, in many cases, be required early in the development program, the proper, trade, or proprietary name would not be established. The form should be consistent with the requirements for the FDA Form 1571, which is required for an IND.	Please edit the form to read: ~~"PRODUCT NAME: Include proper name and trade or proprietary name, as applicable~~." "PRODUCT NAME(S): (Include all available names: Trade, Proper Name, or Code, as applicable)."
II. FORM		
Page 4, Field 3:	"3. PRODUCT NAME" Please see comment above under "Instruction Table." Even though guidance is provided in the instructions, this field should be updated to be consistent with FDA Form 1571, which is required for INDs, and since the proper, trade, or proprietary name would not be established during early meetings with the Agency, which is when this form would be required.	Please edit the form to read: ~~"PRODUCT NAME"~~ "PRODUCT NAME(S): (Include all available names: Trade, Proper Name, or Code, as applicable)."
Page 5, Field 7:	"DOES THIS APPLICATION REQUIRE CLINICAL DATA, OTHER THAN COMPARATIVE BIOAVAILABILITY	Please remove this field.

	STUDIES, FOR APPROVAL?" This field is unnecessary because the requirement to pay the fee or the amount of the fee is not impacted by clinical data. Field 7 seeks the applicant's assessment, rather than the Agency's assessment, of whether the applicant does or does not require clinical data to support a decision of biosimilarity. The requirement for clinical data is intended to be made by the Agency during the development process. Accordingly, this is not useful information with respect to the need to pay the biosimilar user fee or with respect to the amount that will be owed.	