Biosimilars
FORUM

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

June 3, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20851

Re: Comments to March 29, 2016 Draft Guidance: "Labeling for Biosimilar Products, Guidance for Industry"

Dear Sir or Madam:

The Biosimilars Forum appreciates the opportunity to comment on the Food and Drug Administration ("FDA") Draft Guidance[1] regarding the labeling for biosimilar products, as published in Docket No. FDA-2016-D-0643.

The Biosimilars Forum is a non-profit organization whose 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.

General Comments to the Draft Guidance

The Biosimilars Forum appreciates FDA's affirmation that the biosimilar label should specifically address the purpose articulated in the Code of Federal Regulations ("CFR") for labeling, and confirmation that the key safety and efficacy data are sourced from studies conducted by the originator. The FDA's stance that a biosimilar's label may incorporate the reference product label content without requiring a verbatim reiteration of the label text is practical and useful.

The Forum further applauds the FDA for taking the position that it is not necessary to identify in the label which indications were studied directly and which indications were extrapolated. The FDA determines on a case-by-case basis whether there is any clinically meaningful difference for approved indications, and as such the approval method for each indication is considered in that analysis.

Specific Comments to the Draft Guidance

1. The Forum suggests the inclusion of a link to drugs@FDA for each product to facilitate physician access to the review documents and the summary review.

2. The FDA proposes various approaches to product identification in section IV.A of the draft guidance. The Forum finds the current language confusing and requests further clarification. FDA's suggestions regarding when to use the biosimilar, reference, and core names are indefinite and could lead to uncertainty and inconsistent labeling. Moreover, the use of the reference product name may cause trademark or other intellectual property issues that should be addressed. The draft guidance does not address the generation, negotiation, and metrics for the finalization of four digit suffixes to be assigned to biosimilars and reference products. The Forum continues to have concerns about the proposal to

[1] Draft Guidance: Labeling for Biosimilar Products, Guidance for Industry (March 29, 2016), available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf.

use a random 4 letter identifier, rather than a meaningful suffix. The Biosimilars Forum takes no position on whether a suffix should be included in the U.S. proper name, but believes that if implemented, the FDA should allow for a meaningful suffix that is unique to the original product license holder, and that will be affixed to all biological products developed by that license holder. The Forum does not believe the name for an interchangeable should match the reference product, as it would be a burdensome and costly undertaking to change the name of the product and to incorporate the suffix of the reference product suffix without causing confusion among patients and physicians.

3. In section VI.A., the FDA states that during the lifecycle of a biological product, changes in the labeling may be necessary as new risks or new information about known risks becomes available. The Forum requests clarification as to what would be considered "new risks" or "new information" in relation to safety information compiled by use of the reference product and biosimilar product.

4. Section III of the draft guidance states that biosimilar product labeling must meet the content and format requirements of the pregnancy and lactation labeling final rule ("PLLR") as described in 21 CFR 201.57(c)(9)(i) through (iii), regardless of whether the reference product must meet such requirements. The Forum finds that it would not be feasible for biosimilars to adhere to this rule because the biosimilar manufacturer does not have access to the reference product data (i.e., clinical and non-clinical post-marketing data of product use during pregnancy and lactation). Accordingly, a biosimilar manufacturer would not be able to follow the PLLR and provide comprehensive and meaningful information until after the reference product sponsor completes the PLLR conversion of the reference product label with the required information.

Conclusion

The Biosimilars Forum appreciates the opportunity to comment on this draft guidance and asks the FDA to carefully consider the Forum's comments. The Forum has concerns regarding the use of the reference and core names in the label. In addition, to the extent the FDA decides to include a suffix in the proper name, this suffix should be unique and memorable in order to enhance safety and pharmacovigilance. The Forum requests further clarification on the method and process for updating safety information on product labels. Finally, the Forum requests that the FDA address concerns about biosimilar manufacturers ability to comply with the PLLR prior to the inclusion of relevant information on the reference product label.

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