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June 3, 2016

Robert M. Califf, M.D., M.A.C.C.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
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Silver Spring, MD 20993-0002

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted electronically on www.regulations.gov

Re: Docket No. FDA-2016-D-0643-0002 (Labeling for Biosimilar Products; Guidance for Industry)

Dear Drs. Califf and Woodcock:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, submits these comments on the Food and Drug Administration's (FDA's) draft guidance concerning labeling for biosimilar products, or biosimilars.[1]

We agree with the FDA that labeling for biosimilars generally should not include a description of the data used to demonstrate lack of clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity, and potency, except where such data are necessary to inform safe and effective use by a health care practitioner. We also agree with the agency that biosimilar manufacturers have the same obligation as manufacturers of other

[1] Food and Drug Administration. Labeling for biosimilar products, guidance for industry. DRAFT GUIDANCE. March 2016. www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf. Accessed May 19, 2016.

biological products to promptly update product labeling should new information become available that is necessary to inform the safe and effective use of these products by health care practitioners.

1. Inclusion of Data Used to Demonstrate Biosimilarity in the Product Labeling

We agree with the FDA that data from clinical studies designed to support FDA's conclusion of biosimilarity are not likely to be relevant to inform clinical decisions made by health care practitioners regarding the safe and effective use of biosimilar products and, therefore, should not be included in product labeling.

We note that studies used to establish the bioequivalence of generic drugs approved via abbreviated new drug application are not described in the labeling of such products. Instead, the labeling of generic drugs more appropriately presents safety and effectiveness information derived from clinical testing of the reference product (often colloquially referred to as the "brand name" drug). A similar approach is appropriate for biosimilar products, which are approved based on the FDA's finding that "there are no clinically meaningful differences" between the biosimilar and the reference biologic in terms of safety, purity, and potency.[2]

We also support the FDA's decision to allow for the inclusion, within the product label, of data from a clinical study of a proposed biosimilar product where such inclusion is necessary to inform safe and effective use of that product by a health care practitioner. However, we expect that inclusion of such information should be necessary only under rare circumstances. There may be instances in which a clinical study submitted to support a demonstration of biosimilarity reveals information that is relevant to clinical decision-making, such as significant differences in rates of adverse events between the reference product and the biosimilar product. Yet we expect that in such a situation, as with the majority of other such instances where a clinical study reveals information that is relevant to clinical decision-making, the appropriate action for the FDA would be to decline to approve the product as biosimilar, given the fact that by law, a proposed biosimilar product with clinically meaningful differences in safety from the reference product cannot be approved.

2. Updating Biosimilar Labeling With New Information

We also agree with the FDA that biosimilar labeling should be updated promptly when new information becomes available to the application holder that is necessary to inform the safe and effective use of the product by health care practitioners.

As you know, in 2011, Public Citizen petitioned the FDA to allow generic-drug manufacturers to update product labeling to warn patients about newly discovered risks associated with their drugs.[3] Post-approval monitoring is essential to the safety of both drugs and biological products and is the shared responsibility of the FDA and manufacturers. As more biosimilars are introduced into the U.S. market and sales of these products increase, the manufacturers of

[2] *Ibid.*

[3] Public Citizen. Food and Drug Administration petition on generic drug labeling. August 29, 2011. www.citizen.org/fda-petition-generic-drug-labeling-2013. Accessed May 19, 2016.

biosimilars will also be responsible for an increasing share of the adverse-event reports and other forms of post-marketing data relevant to the safety and effectiveness of biological products. There may even be instances in which a reference biologic is discontinued, leaving only biosimilars on the market. Important new safety information will not reach patients and physicians if the manufacturers of biosimilars are not responsible for updating product labeling promptly as new information related to safe and effective use of the product becomes available.

3. Conclusion

We support the FDA's proposed draft guidance concerning the labeling for biosimilar products. In particular, we agree with the FDA that:

1) Biosimilar labels generally should not include a description of the data used to demonstrate biosimilarity with the reference product, except in rare cases where necessary to inform safe and effective use by a health care practitioner.
2) A biosimilar manufacturer has the same obligation as manufacturers of reference biological products to promptly update the product labeling should new information become available that would inform the safe and effective use of the product.

Thank you for taking our comments into consideration.

Sincerely,

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