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

Comments of members of the Patient, Consumer, and Public Health Coalition
on
Labeling for Biosimilar Products; Draft Guidance
[FDA-2016-D-0643]

Members of the Patient, Consumer, and Public Health Coalition support the Food and Drug Administration's (FDA) draft guidance on "Labeling for Biosimilar Products." The draft guidance will protect patients and consumers by requiring biosimilar companies to update their labels when safety issues arise.

Background

The Biologics Price Competition and Innovation Act of 2009, signed into law as part of the Affordable Care Act, created an abbreviated pathway to license biosimilar products.[1] A product is a biosimilar if it has no clinically meaningful differences compared to the reference product in terms of "safety, purity, and potency."[1] Because there is no meaningful difference, we agree with the FDA that biosimilars labeling should include a description of the clinical data that supported safety and efficacy of the reference product. We agree with FDA that the biosimilar prescribing information (package insert) relies mainly on the safety and effectiveness information from the labeling for the reference product.[2]

Specific Recommendations on Content of Biosimilar Product Labeling
FDA also notes that biosimilar products' labels may differ from the reference product labeling (have "appropriate product-specific modifications") in order to conform to the Physician Labeling Rule (PLR) and the Pregnancy and Lactation Labeling Rule (PLLR), and other safety issues. We agree since this will add to the safer use of biosimilars. Also, according to a recent survey of European physicians, they "prefer more product-specific information in the biosimilar label."[3]

Revising Biosimilar Product Labeling
We strongly agree with the FDA that "*all* holders of marketing applications for biological products have an ongoing obligation to ensure their labeling is accurate and up to date" (emphasis added).[1] We see no reason why this should not include PLR and PLLR information for the reference product. To ensure that the product is used safely, both the reference product and the biosimilar product application holders must be able to update their labeling.

Conclusions
We strongly support the "Labeling for Biosimilar Products" draft guidance. It will protect patients and consumers by ensuring the important labeling safety information is updated for both biosimilars and the reference products.

American Medical Student Association
American Medical Women's Association
Center for Medical Consumers
Connecticut Center for Patient Safety
MAME
MRSA Survivors Network
National Center for Health Research
National Physicians Alliance
National Women's Health Network
Quinolone Vigilance Foundation
Washington Advocates for Patient Safety
WoodyMatters

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[1] Federal Register (April 4, 2016). Food and Drug Administration draft guidance "Labeling for Biosimilar Products."
[2] Food and Drug Administration (April 1, 2016). News & Events Form our perspective: Biosimilar product labeling. http://www.fda.gov/Drugs/NewsEvents/ucm493240.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery 2/3
[3] Hallersten A, Fürst W, Mezzasalma R (June 2016). Physicians prefer greater detail in the biosimilar label (SmPC) - Results of a survey across seven European countries. *Regul Toxicol Pharmacol.* http://www.ncbi.nlm.nih.gov/pubmed/27041395