



June 12, 2015

Dr. Stephen Ostroff
Acting Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff,

The Global Healthy Living Foundation (GHLF) is a 501 (c)(3) patient advocacy organization that works to improve the quality of life for people living with chronic disease by making sure their voices are heard. GHLF represents more than 80,000 chronically ill patients across the country. Many of these individuals have rheumatoid arthritis or other related autoimmune diseases, use biologics, and stand to benefit greatly from the addition of biosimilars.

GHLF believes that the introduction of biosimilars into the United States will usher in an age of unprecedented access and expansion of treatment options for the millions of Americans that live with chronic illness. Biosimilars have the potential to dramatically reduce the cost of complex biological products, simultaneously increasing overall access to life-saving medications. However, due to the inherent scientific fact that biosimilars are not generic copies of the innovator molecules, but rather are biopharmaceutical drugs designed to have similar active properties as their innovator counterparts, we approach the topic with cautious optimism and believe that certain patient protections must be in place. Patient safeguards, such as distinct labeling, can help guarantee the safe and transparent introduction of biosimilars into the American healthcare environment and will protect the consumer.

As biosimilars are not identical to their innovator molecule counterparts, their labeling should not be, either.

1. The labeling of a biosimilar drug should reflect its own clinical data, which will enable prescribers to distinguish between data derived from clinical studies of the biosimilar and data derived from clinical studies of the innovator molecule.
2. Distinguishing between these two types of data will help physicians and consumers make informed decisions about starting or discontinuing a particular biopharmaceutical drug.
3. Labeling should also clarify whether or not the FDA has determined the biosimilar in question is interchangeable with the reference innovator molecule.
4. Finally, we encourage FDA to provide guidance that communicates that distinct labeling should note which approved indications are based on extrapolation of innovator molecule clinical trials data.

While producers of biosimilars prefer duplicating the label of the reference product, it does not predict favorable outcomes for the patient. It also compromises the provider's ability to discern correct clinical data, which impedes the process of informed prescribing. By using distinct



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labeling, patient safety is made a top priority. Furthermore, distinct labeling will ensure that clinical trials data are more transparent to both the provider and consumer, resulting in heightened access to information and accurate data, and hopefully more favorable health outcomes.

Biosimilars have the potential to change patients' lives for the better. As patient advocates, we remain vigilant to ensure the debut of biosimilars is a positive one. We believe that distinct labeling of biosimilars will support consumer education and safety, promote high-quality post market safety monitoring, and build consumer and provider populations' confidence in the effectiveness and benefits of biosimilars. Consequently we urge the FDA to swiftly finalize guidance that calls for biosimilar labeling information to be reflective of the particular products contained within the package.

Thank you for your attention to this issue, which is of the utmost importance to GHLF and its members. If we can supply additional information, please do not hesitate to let us know. For questions regarding GHLF or the above comments, please contact Stephen Marmaras, Manager, State and National Advocacy: smarmaras@ghlf.org.

A handwritten signature in black ink, appearing to be "Seth D. Ginsberg".

Seth D. Ginsberg
Co-Founder, Global Healthy Living Foundation
Seth's 50 State Network