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April 2, 2020

Dockets Management Staff
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA-2019-D-5473, Draft Guidance on “Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products-Questions and Answers”

Comments submitted electronically at www.regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit these comments to the docket number: FDA-2019-D-5473, Draft Guidance on “Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products-Questions and Answers”. The Global Healthy Living Foundation (GHLF) is a 20-year-old 501(c)(3) patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events and our online support and education. GHLF works to improve the quality of life for patients living with chronic diseases by making sure their voices are heard and advocating for improved access to care. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease and migraine.

Many of the patients GHLF represents have conditions that are treated with biologics and biosimilars and as such, we are particularly interested in how information about these therapeutic products are communicated both to health providers and patients. We commend the Food and Drug Administration (FDA) on the publication of this draft guidance and hope that it will be finalized expeditiously. In particular, we are pleased that the draft guidance indicates that representations or suggestions that create an impression that a biosimilar is not highly similar to the reference product, that a reference product is safer or more effective than a biosimilar, and that there may be a clinically meaningful difference between the two may be false or misleading.

Patients understand generic versus branded drugs, but they do not easily understand biosimilars, especially in the aggressive context in which they are presented in marketing materials. Even many healthcare professionals don't understand how best to use biosimilars, and our hope is that the FDA will work to create a transparent environment for the patient – one that does not show a bias for biosimilars or biologics, allows the patient to directly benefit from a generic-like lower price, and feel positive about switching to or starting on a biosimilar. We believe that only then will a robust biosimilar market emerge for chronically ill patients.

To that end, we would also like to inform you that GHLF has endorsed the Advancing Education on Biosimilars Act of 2019 (S.1681/H.R.4400) which would create federal programs to promote the use of biosimilars, including the development of continuing education programs for healthcare providers. In addition, the bill would require the FDA to create a website to educate patients and providers about biologics and biosimilars, and that provides information about interchangeability and processes for reporting adverse events that pose a risk to patient health and safety. Please know that GHLF is advocating directly with Congress in the hopes that this legislation will be enacted this year to further support the FDA's educational efforts.

Thank you again for the opportunity to comment on the draft guidance and we encourage the Agency to quickly work to finalize it to help ensure that biosimilars are portrayed accurately in labeling and promotional materials. If we may be of further assistance, please contact me at snewmark@ghlf.org.

Sincerely,

Respectfully submitted,

A handwritten signature in black ink that reads "Steven Newmark". The signature is written in a cursive, flowing style.

Steven Newmark, JD, MPA
Director of Policy and General Counsel
Global Healthy Living Foundation

