DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring MD 20993

June 29, 2015

Seth D. Ginsberg
Co-Founder
Global Healthy Living Foundation
515 N. Midland Ave
Upper Nyack, NY 10960

Dear Mr. Ginsberg,

Thank you for your June 12, 2015, letter to Acting Commissioner Ostroff on behalf of the Global Healthy Living Foundation regarding the labeling of biosimilars. Your letter was forwarded to the Center for Drug Evaluation and Research for response.

On March 6, 2015, the U.S. Food and Drug Administration (FDA or agency) approved the first biosimilar product in the United States. FDA undertakes a rigorous and thorough evaluation to ensure that a biosimilar product meets the Agency's safety, efficacy, and quality standards for approval for the conditions of use described in approved product labels. Approval of a biosimilar product is based on review of evidence that may include structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamics data, clinical immunogenicity data, and other clinical safety and effectiveness data that demonstrates that the product is highly similar to the reference product and that there are no clinically meaningful differences between the biosimilar product and the reference product. Additionally, a biosimilar product can only be approved if it has the same mechanism(s) of action (to the extent known), route(s) of administration, dosage form(s) and strength(s) as the reference product, and only for indication(s) and condition(s) of use that previously have been approved for the reference product. To determine which indications have been approved for a biosimilar product, health care professionals are advised to review the prescribing information for the biosimilar product.

FDA believes that healthcare professionals should have product labels that include the essential scientific information necessary to make informed prescribing decisions for their patients. FDA expects to issue draft guidance on labels for biosimilar products in 2015. The public will also be provided with an opportunity to comment on this draft guidance when it is published. We welcome your organization's input.

To assist with provider identification of products as biosimilar or interchangeable, FDA created the "Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations." The Purple Book enables a user to see whether a biological product has been determined by the FDA to be biosimilar to or interchangeable with a reference product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. Zarxio (filgrastim-sndz) is identified as a biosimilar product (B) in the Purple Book (available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm).

Please be assured that the FDA is committed to ensuring drug safety and patient safety and I thank you for bringing your concerns to our attention.

Sincerely,

Janet Woodcock, M.D., Director
Center for Drug Evaluation and Research

cc: Stephen Marmaras, GHLF