

October 27, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comment on Food and Drug Administration Draft Guidance “Nonproprietary Naming of Biological Products: Guidance for Industry” [Docket No. FDA-2013-D-1543-0001]

Dear Acting Commissioner Ostroff:

As members of the Biologics Prescribers Collaborative (BPC) and professional organizations with biologics prescribers, we support sound policies that promote the safe use of biologics, including biosimilars, for all patients. We applaud the Food and Drug Administration (FDA) for recognizing in its “Nonproprietary Naming for Biologic Products” (“draft guidance”), that each biological product needs a distinguishable non-proprietary name.

FDA’s draft guidance calls for all biological products to bear a nonproprietary name that includes a four-letter suffix. This proposal reflects FDA’s thinking that “there is a need to clearly identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable.”ⁱ BPC agrees with this reasoning, which is why we have always supported distinct nonproprietary naming.

However, our experience as biologics prescribers tells us that the suffix must be memorable, which cannot be easily accomplished when it is meaningless. A randomized four-letter code may complicate the achievement of FDA’s **goal to improve pharmacovigilance and prevent inadvertent substitution.** A memorable suffix could identify the manufacturer, which would be easily memorized by those who frequently prescribe biologics.

A suffix that reflects the license-holding manufacturer equips patients, physicians and pharmacists to accurately recall or ascertain specifics about the biosimilar that may differ from those of the originator, such as approved indications, administration routes, or delivery systems. In addition, “biological products generally consist of large, complex molecules and raise unique safety concerns [emphasis added] related to immunogenicity.”ⁱⁱ

Regarding pharmacovigilance, “safety issues that are specific to a manufacturer may arise after approval with any marketed product.”ⁱⁱⁱ The agency also notes it must be able to track adverse events to a specific manufacturer. An immediately recognizable suffix reflecting the manufacturer’s name will facilitate prompt, accurate adverse event reporting by patients and physicians to the correct manufacturer, and that manufacturer’s mandated reporting to FDA.

When FDA approved the biosimilar for the reference product Neupogen, it assigned a placeholder non-proprietary name, filgrastim-sndz. By identifying the manufacturer in a memorable way, the suffix “sndz” meets our needs as biologics prescribers in day-to-day human interactions with patients,

pharmacists, and other health care professionals. It will promote accurate prescribing, facilitate effective pharmacovigilance, and help to ensure manufacturer accountability. The BPC strongly encourages FDA to adopt a suffix format that is memorable and reflective of the manufacturer name – as illustrated by filgrastim-sndz.

In closing, we restate our support for FDA’s requirement that all biological products bear a distinguishable four-letter suffix to their nonproprietary names and we urge the agency to ensure that the manufacturer is identified through the suffix. In addition, we encourage the agency to extend this policy to interchangeable biosimilars as well.

Thank you for your consideration. Please do not hesitate to reach out to any of the undersigned organizations, should you require additional information.

Respectfully,

Alliance for Patient Access

American Association of Clinical Endocrinologists

American College of Rheumatology

Association of Black Cardiologists, Inc.

Biologics Prescribers Collaborative

Coalition of State Rheumatology Organizations

Endocrine Society

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

ⁱ FDA, [Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability](#), Federal Register, August 28, 2015.

ⁱⁱ FDA, [Designation of Official Names and Proper Names for Certain Biological Products](#), Federal Register, August 28, 2015.

ⁱⁱⁱ FDA, [Designation of Official Names and Proper Names for Certain Biological Products](#), Federal Register, August 28, 2015.