

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

RE: **Docket No. FDA-2013-D-1543** Comment on Food and Drug Administration Draft Guidance  
Nonproprietary Naming of Biological Products: Guidance for Industry+

*Submitted electronically via [www.regulations.gov](http://www.regulations.gov)*

October 23, 2015

Dear Acting Commissioner Ostroff:

Patients for Biologics Safety & Access (PBSA) is a coalition of over twenty patient advocacy organizations dedicated to protecting patient access to safe and effective biologics. We want to thank the Food and Drug Administration (FDA) for issuing Nonproprietary Naming of Biological Products: Guidance for Industry+ (Draft guidance+) on the naming of biosimilars and wish to provide the patient perspective to answer the question the agency posed related to the naming of interchangeable biosimilars.

Together, our organizations represent millions of Americans who suffer from serious, life-threatening diseases that are difficult to diagnose and treat. Our members typically experience a health care system that takes years to identify appropriate providers, receive an accurate diagnosis, and identify the best course of treatment to bring greater stability for more optimal health outcomes. As patient advocates, our goal is to ensure that patient safety is paramount as the FDA implements the Biologics Price Competition and Innovation Act (BPCIA).

Biologics are medicines made from living organisms that are far more complex and much more difficult to develop and manufacture than traditional chemical drugs. The introduction of biologic products to treat chronic and/or rare diseases has been the most significant advancement in care for our communities in recent decades. Biologics have provided many patients with an effective therapy . many for the first time in their lives. Biosimilars are medicines that are highly similar, but not identical to biological medicines. Because of the uniqueness and complexity of biologics, biosimilars are **not** generic copies of biologic medicines.

For this reason, we have consistently urged FDA to adopt a policy that requires unique names for biosimilars and were pleased to see that the draft guidance is indeed proposing this approach. The shortcomings of the existing FDA Adverse Event Reporting System (FAERS) are well-known,<sup>1</sup> and we believe that a unique nonproprietary name can help improve FDA's tracking ability. In particular, a unique name would help reduce existing difficulties with identifying the correct manufacturer of a product that is causing adverse events in patients. Fixing this attribution difficulty would go a long way toward ensuring that FDA is able to quickly and accurately trace adverse events back to the exact source, while leaving related products on the market and available for patients.

We were encouraged to hear Dr. Woodcock confirm our belief in the critical role of nonproprietary names in response to a question from Senator Hatch during the September 17, 2015 hearing before the Senate Health, Education, Labor and Pensions Committee. Dr. Woodcock stated that the

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<sup>1</sup> See, e.g., Biosimilar Naming: How Do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars? by Erika Lietzan, Laura Sim, and Emily Alexander, The Food and Drug Law Institute's *Food and Drug Policy Forum*, Vol. 3, Issue 6 (March 27, 2013).

importance of the nonproprietary name in adverse event tracking for biologics and biosimilars is in part due to the fact that many biologics may be dispensed in settings that do not capture the National Drug Code (NDC). This is a fact often overlooked by those who believe the NDC can serve the exact same purpose as the INN in identifying products.

In the draft guidance, FDA notes its belief that any naming convention the agency decides to implement should help prevent inadvertent substitution. We agree with FDA's assertion in its draft guidance that for example, this could occur if a biosimilar product were licensed for fewer than all the indications and routes of administration (e.g. prefilled syringe instead of a vial) for which its reference product is licensed, or is packed in a different delivery system than approved for its reference product, which may lead to confusion and dosing errors.

As we have stated before, we agree with the risk of inadvertent substitution, which is why we urge FDA to adopt a distinguishable suffix for interchangeable biosimilars as well. If and when the agency decides that a certain biosimilar is interchangeable with its reference product, that decision can be reflected on the label and in the Purple Book. However, it is still within the treating physician's discretion to prescribe the reference product if (s)he so chooses, based on the patient's clinical history. If two products share an identical name and suffix, the risk of a physician inadvertently substituting one product for the other becomes much greater.

While it is not the subject of this guidance, we believe it is important to provide comment on a very closely related topic that we expect will be the subject of an upcoming FDA guidance on product labeling. FDA's 2012 draft guidance on *Scientific Considerations of Biosimilarity* called for labeling of biosimilars to identify the product as a biosimilar and to indicate whether or not the biosimilar is interchangeable with the reference product. We saw this as a very important element for patients to be fully informed about their care. We were very concerned that the final guidance issued on April 28, 2015, removed this language. This change violates a basic principle of transparency and denies patients important information about their health care. We were pleased to learn from Dr. Janet Woodcock at the recent hearing on biosimilars held by the Senate Health, Education, Labor and Pensions Committee that FDA has not made a change and that the agency will address this in separate labeling guidance.

When FDA approved the first biosimilar, Zarxio, in March of this year, the approved labeling for Zarxio did not include the information that FDA had identified as necessary in the 2012 draft *Scientific Considerations* guidance. It is nearly identical to the labeling for the originator product Neupogen. At FDA's announcement of the approval, the Director of the Office of New Drugs in the Center for Drug Evaluation and Research (CDER) indicated that FDA took an approach to labeling that was similar to that for small molecule generic drugs. We strongly believe that at least the level of information provided in the 2012 draft guidance must be required of all biosimilar products as a means of assuring patient safety, avoiding patient and provider confusion and to provide transparency.

In closing, we thank you for the draft guidance, which we consider an important step forward for patients, and urge you to extend the suffix requirement to interchangeable biosimilars as well.

PBSA looks forward to working with you as you continue to work on BPCIA implementation. If you have any questions about these issues or would like further information from the patient perspective, please reach out to us by contacting Larry LaMotte, Vice President, Public Policy, Immune Deficiency Foundation (IDF) at [llamotte@primaryimmune.org](mailto:llamotte@primaryimmune.org) or 443-632-2552.

Sincerely,

American Autoimmune Related Diseases Association

Arthritis Foundation  
Committee of Ten Thousand  
Crohn's & Colitis Foundation of America  
Dystonia Medical Research Foundation  
GBS/CIDP Foundation International  
Hemophilia Federation of America  
Hepatitis Foundation International  
Immune Deficiency Foundation  
International Foundation for Autoimmune Arthritis  
Jeffrey Modell Foundation  
Lupus and Allied Diseases Association  
Lupus Foundation of America  
National Alliance on Mental Illness  
National Organization for Rare Disorders  
National Psoriasis Foundation  
Platelet Disorder Support Association  
Pulmonary Hypertension Association  
Scleroderma Foundation  
Spondylitis Association of America  
United Spinal Association  
US Hereditary Angioedema Association  
U.S. Pain Foundation

