ASBM Comments on
"Guidance for Industry Nonproprietary Naming of Biological Products"
October 27, 2015

Docket ID: FDA-2013-D-1543
Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)

On behalf of the Alliance for Safe Biologic Medicines (ASBM) and the stakeholder organizations listed below, we are writing to encourage the FDA to adopt a policy of distinguishable names for biosimilars, and to issue final guidance reflecting distinguishable naming to provide strong patient protections, critical transparency and promote pharmacovigilance.

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are grateful for the opportunity to comment on this Draft Guidance. Formed in 2010, ASBM is an organization of patients, physicians, pharmacists, researchers, manufacturers of both innovative and biosimilar medicines, and others who are working together to ensure patient safety remains at the forefront of the biosimilars policy discussion.

As a practicing pediatric rheumatologist and a former president of the American Society of Health-System Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like rheumatoid arthritis, diabetes, multiple sclerosis, and cancer. "Copies" of these medicines, called "biosimilars" have the potential to provide new treatment options for our patients at reduced cost. Yet unlike generic versions of chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only be similar, never the same. Even the smallest structural difference between an originator biologic and its attempted copy has the potential to result in an impact on patients. Given the complexity of biologics, their known sensitivity (for example, to factors such as manufacturing differences, environmental elements including heat, light, and handling) and their potential to create unwanted immune responses as well as the potential for clinical differences between products, both positive and negative - clear product identification of all biologics is critical for healthcare providers.

Indeed, surveys ASBM has conducted of biologic prescribers in eleven countries (all available at www.safebiologics.org) have consistently shown widespread physician support for distinguishable naming for biologics.

A soon-to-be released ASBM survey of 400 U.S. prescribers conducted in October 2015 revealed that **two-thirds of physicians (66%) support the FDA issuing distinct nonproprietary names to all biologics, including biosimilars.** Only 11 percent oppose this, while 23% had no opinion. This is consistent with what ASBM has seen in other countries:

For example, our 2014 survey of 427 Canadian physicians found that **79% supported the use of distinguishable names.**

Additionally, **94% percent of the 399 biologic prescribers we surveyed in Latin America** this year **supported the WHO's BQ proposal** (which like the FDA's proposal would use a four-

letter differentiating suffix) as a "useful" tool to help ensure that their patients receive the proper medicine.

This need and desire for clarity is not limited to physicians. Our October **2015 survey of 401 U.S. pharmacists showed 68% supported the FDA issuing distinct names for all biologics, including biosimilars.**

We commend the Food and Drug Administration (FDA) for its leadership for proposing a four-character differentiating suffix for all biologics, including biosimilars, to promote patient safety and aid in pharmacovigilance. The FDA proposal will not only protect patients in the U.S., but its compatibility with the BQ proposal paves the way for a global harmonizing of product identification and the potential for patients worldwide to enjoy the protections of distinguishable naming.

The FDA has asked stakeholders to comment on the design and content of the four-letter suffix; specifically, on the relative merits of representative suffixes as in the case of Zarxio (filgrastim-sndz) in which the provisional suffix was based upon the name of its manufacturer, Sandoz, vs. a suffix "devoid of meaning" such as (filgrastim-bflm) as called for by the Draft Guidance and Proposed Rule.

When ASBM asked U.S. physicians whether they preferred a manufacturer-derived suffix such as "sndz", or the random suffix such as "bflm" as called for by the Proposed Rule, **The majority of physicians (60%) preferred a manufacturer-derived suffix. Only 9% preferred the random suffix, while 32% held no opinion.**

This was even more pronounced among pharmacists, 77% of whom preferred the manufacturer-based suffix, 15% the random suffix, and 8% had no opinion.

When asked why they preferred manufacturer-based suffixes, both groups of health providers responded that manufacturer suffixes were easier to recognize and remember, easier to provide patients who have a preference of manufacturer with the product they want, and that suffixes tied to a manufacturer name hold those manufacturers accountable for their products.

Physicians and pharmacists know that their ability to improve patient outcomes and safety is hampered unless they can clearly distinguish similar biologic medicines from one another. For physicians, clear product identification is necessary in order to ensure patients receive the correct medicine, to maintain an accurate patient record, to make informed treatment decisions and correctly assess patient response. For pharmacists, distinguishable names are essential for tracking, reporting and discussion of specific product indications, contraindications or any potential adverse responses. To protect the hope these new agents offer in terms of additional treatment options and lower costs, clearly associating use and results accurately with each source, health providers require precise product identification.

For these reasons it is ASBM's position that the benefits of clear identification are best realized with a memorable, recognizable, and meaningful suffix rather than a random series of letters. Further, incorporating a suffix based on the name of the initial manufacturer or marketing authorization holder at the time of approval would promote the most meaningful, memorable, intuitive, and informative method of distinguishing similar biologic products from one another. It would promote accountability by efficiently associating the product with the legal entity

ultimately responsible for its production, safety, quality, and efficacy.

In the case of a product (or its manufacturer's) sale or licensing to another company, the suffix should continue to remain reflective of the first Biologic License Application (BLA) holder, to minimize confusion and unnecessary proliferation of suffixes. For these reasons we would also oppose a biosimilar product's suffix being altered were it subsequently determined to be interchangeable with its reference product.

We hope our study results and their implications will assist the FDA in its difficult tasks of finalizing its guidance and approving future biosimilar medications.

We again commend the FDA for its leadership on biologic naming and for promoting patient safety, pharmacovigilance, and improved knowledge on the best use of these miracle medications. This Draft Guidance is a significant positive step toward achieving these goals in the U.S. and globally.

Thank you for the opportunity to comment on this important issue.

Sincerely,

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ASBM Steering Committee Members:
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International Cancer Advocacy Network
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Stakeholder Groups:
1 in 9, The Long Island Breast Cancer Action Coalition
ADAP Advocacy Association (aaa+)
Advocates for Responsible Care
The AIDS Institute

Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)
American Association of People with Disabilities
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