



October 27, 2015

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2013-D-1543: Guidance for Industry – Nonproprietary Naming of Biological Products**

Dear Sir/Madam:

The Biotechnology Industry Organization ("BIO") thanks the Food and Drug Administration ("FDA") for the opportunity to submit comments on the Draft Guidance entitled "Nonproprietary Naming of Biological Products" ("Draft Guidance").

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

BIO strongly supports FDA's progress in implementing the Biological Price Competition and Innovation Act ("BPCIA"). As we have stated on many occasions, the BPCIA, which BIO endorsed and which passed Congress on a bipartisan basis, was intended, first and foremost, to operate in the best interest of patients by providing them and their healthcare providers with additional choices of safe and effective medicines. BIO believes that patients are best served by medicines, including biosimilars, approved by FDA on the basis of excellent science demonstrating the products' safety and efficacy and, in the case of biosimilars, demonstrating that the products are highly similar to their reference biologics. Accordingly, we are pleased to offer the following comments on FDA's Draft Guidance on Nonproprietary Naming of Biological Products.

**GENERAL COMMENTS:**

For nearly a decade, BIO has advocated actively for a nonproprietary naming convention that ensures all biological products are distinguishable. BIO believes that a distinguishable nonproprietary naming convention would best facilitate robust pharmacovigilance, ensure accurate attribution of adverse events to the correct product, mitigate the risk of inappropriate or unintended substitution and unintended switching, and support tracing of products in the event of a recall. In short, BIO strongly believes that distinguishable nonproprietary names enhance and protect public health, and serve as another important step in developing a transparent and effective regulatory framework for the review and approval of biosimilars. Thus, BIO supports the



development of a system under which nonproprietary names of biological products that are highly similar to each other in structure and function are distinguishable, but morphologically related, and easy to recognize, remember, and report accurately.

We are encouraged by the Agency's view that distinguishable nonproprietary names are in the best interest of patient safety, because they facilitate pharmacovigilance and mitigate inadvertent product substitution. This is important because neither the reference nor the biosimilar products are identical, nor are different companies' biosimilar versions of the same reference product. Moreover, shift and deviations can occur throughout the product lifecycle, resulting in the need to quickly link any potential changes or adverse events to the responsible product.

BIO shares FDA's goals of ensuring the safe use of biological products, enhancing biological product pharmacovigilance, and advancing appropriate practices and perceptions regarding biological products. To further this goal, nonproprietary names must be easily recognizable and non-confusing to physicians, nurses, pharmacists and patients. Accordingly, BIO offers the following comments regarding practical and functional implementation of a distinguishable nonproprietary naming convention.

#### Suffixes Should Be Memorable and Convey Some Meaning

The use of distinguishable suffixes for biological products provides an effective means of uniquely identifying each biological product on the market. However, in order to encourage widespread adoption and uptake, and to facilitate effective pharmacovigilance practices, it is essential that suffixes be memorable in order to allow health care practitioners to understand the distinct identity of each product and to enable pharmacovigilance.

Suffixes can acquire memorability and meaning through consistent use in labeling, marketing, and throughout the delivery chain. Such memorability will also help to encourage consistent use of the naming convention in all circumstances where the nonproprietary name is used, including labeling, prescribing, dispensing, medical literature, advertising and promotion, adverse event reporting, record keeping, etc. Even a random suffix may eventually acquire memorability through this process of use; however, it will be more difficult to achieve memorability with a random suffix, and less effective, than if the suffix was inherently memorable and meaningful.

To promote memorability, and thereby encourage uptake of the proposed naming convention, BIO recommends that the suffix for a biological product be unique to each license holder (or the entity responsible for pharmacovigilance, if different from the license holder). Further, BIO recommends that license holders be afforded the option of using the same suffix for each biological product from that license holder. The use of a memorable suffix unique to a license holder will provide a biological naming convention that reduces confusion and enables effective pharmacovigilance. This will also permit health care practitioners to associate the particular suffix of each biological product with the identity of that product. Assigning a unique suffix to each individual biological



product would result in a dramatic increase in the number of suffixes over time, increase the review workload on FDA to review the significantly greater number of suffixes, and considerably increase the complexity and potential for confusion by healthcare practitioners.

Simplifying the naming convention to, in general, provide for a suffix that is unique to each license holder and shared by each biological product from that license holder will promote better understanding by health care practitioners.

There may be limited circumstances in which this convention may not be sufficient to ensure adequate pharmacovigilance, (e.g., where a manufacturer markets two versions of a product and holds two different BLAs for those products). In such cases, it may be necessary for the license holder to request a separate suffix, or another method of distinguishing between individual biological products. BIO recommends that sponsors be permitted to request or use a separate suffix, subject to the same evaluation factors, for an individual biological product where the use of their "primary" suffix is insufficient to adequately distinguish the biological product or to promote adequate pharmacovigilance.

#### Interchangeable Biologics Should Also Bear Unique Suffixes

For all of the reasons discussed above, each interchangeable biological product also should have a unique suffix to facilitate pharmacovigilance and advance recognition that interchangeable biological products are not identical. A determination of interchangeability does not obviate the need for effective pharmacovigilance practices and the ability to trace adverse events to an individual manufacturer. Additionally, a determination of interchangeability is neither a determination that a biological product is identical to its reference product, nor to other interchangeable biosimilars of the same reference product.

Most interchangeable biological products are likely to be first licensed as biosimilar biological products, and, therefore, will already have a distinguishable suffix under FDA's proposed naming convention. Changing the suffix of a biological product to that of its reference product upon a determination of interchangeability risks creating confusion among health care practitioners and undermining the Agency's stated objectives of ensuring the safe use of biological products and enhancing biological product pharmacovigilance.

In the event that both biosimilar and interchangeable products are available for a single reference product, the need for unique nonproprietary names for all biological products, including interchangeable biologics, becomes even more important. Interchangeability will only have been designated between one interchangeable biological product and one reference product – not any other product. Therefore, it will always be necessary to distinguish any biosimilar or interchangeable biological product from every other biological product by a distinguishable name such that regulatory determinations are respected and patient safety is protected.



### Retrospective Application

BIO supports the concept of retrospective application of the naming convention to previously licensed biological products. However, as part of its implementation of any such retrospective application, BIO recommends that the Agency consider the potential impact to health care practitioners and patients that have become familiar with the marketed biologic products over the years.

BIO requests that FDA investigate and then subsequently outline additional details, including timelines and process for application and implementation, about the retrospective application of the nonproprietary naming convention by publishing guidance and allowing for public comment by stakeholders. A multi-stakeholder workshop may be an appropriate means for FDA to supplement written comments on the challenges and solutions to implementation. In particular, a wide variety of systems (operated by a wide variety of stakeholders other than Sponsors and FDA) use nonproprietary names. If existing names for approved products were to change, it is not clear how and when these other systems would be updated. Unsystematic or inconsistent implementation throughout the healthcare system could lead to increased disruption and confusion.

BIO believes that it is essential to take a "least burdensome" approach, which will include timelines that account for the resources and planning necessary to implement a change to labeling and inserts for currently marketed products and allow for sufficient flexibility for license holders to implement these changes according to their own business needs. Such a "least burdensome" approach is important to protect continuity of supply to patients who depend on these vital medicines to treat their serious diseases.

However, BIO believes that the ultimate decision of when, a license holder should apply for a distinguishable suffix and, upon the suffix being approved, implement a change to labeling and package inserts should be flexible, based on the need in the marketplace to promote effective pharmacovigilance, and should consider the potential for biosimilar development.

### Transition Biologics Should Be Treated The Same As Other Biological Products

Under Section 7002(e)(2) through (4) of the BPCIA biological products approved under applications submitted under section 505 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") will be "deemed" licensed under section 351 of the Public Health Service Act ("PHS Act") as of March 23, 2020. Although there are a number of important questions relating to "transition biologics" that the Agency has yet to answer, effective March 23, 2020, these "transition biologics" will be PHS Act Section 351 biologics. Accordingly, these "transition biologics" should be subject to the same naming conventions as biological products licensed under section 351 of the PHS Act to prevent confusion and promote appropriate practices and perceptions regarding the safety and effectiveness of biological products. To exclude transition biologics from the naming convention adopted for biological products originally licensed under section 351 of the



PHS Act ("351 biologics") would indicate that transition biologics are somehow different from 351 biologics, do not raise the same public health or pharmacovigilance concerns articulated by FDA for 351 biologics, and create confusion for health care practitioners, pharmacists, and patients.

#### WHO Harmonization

BIO supports the overarching goal of global regulatory harmonization to sound regulatory policy, and supports the efforts of the World Health Organization ("WHO") to facilitate a distinguishable suffix that can be used globally. However, for the reasons described above (e.g., adoption and uptake, pharmacovigilance), BIO can only support harmonization to a naming convention that uses memorable and meaningful suffixes, instead of random suffixes as is currently proposed.

A naming convention premised on the use of random suffixes would undermine the very goals that the Agency is seeking to achieve related to patient safety, adoption and uptake, and pharmacovigilance. Accordingly, we strongly urge FDA, in its discussions with the WHO, to encourage the WHO to implement a BQ system in which suffixes are memorable and meaningful, and in which a suffix may be unique to a license holder and shared across multiple biological products offered by that license holder.

If WHO decides to take another approach, the suffix adopted in the US can be easily mapped to the suffix assigned by the WHO. The US can most effectively assist WHO and other jurisdictions by demonstrating successful adoption of a suffix framework, including meaningful and memorable suffixes.

#### Public Stakeholder Meeting Requested

Given the complexities and the evolving regulatory landscape globally, BIO recommends that the Agency hold a public stakeholder meeting to further discuss the naming of biological products, particularly from a practical implementation perspective.

#### **SPECIFIC COMMENTS:**

Under section V of the Draft Guidance, BIO recommends that the following criteria be adjusted to accommodate the possibility that a suffix may be used for more than one biological product licensed to a given license holder:

Line 358      The Proposed Suffix **should:**

- ...
- Be unique, [with the exception of a suffix used by a biological product licensed to the same license holder or the entity responsible for pharmacovigilance](#)
- ...



- Line 366      The proposed suffix **should not:**
- ...
  - Be too similar to any other product's suffix designation, with the exception of a suffix used by a biological product license to the same license holder or the entity responsible for pharmacovigilance.

**CONCLUSION:**

BIO appreciates this opportunity to comment on the Draft Guidance "Nonproprietary Naming of Biological Products." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Scott V. McGoohan, J.D.  
Director, Science and Regulatory Affairs  
Biotechnology Industry Organization (BIO)

## **QUESTIONS FROM NOTICE OF AVAILABILITY**

<b><u>QUESTION NUMBER</u></b>	<b><u>Question</u></b>	<b><u>Answer</u></b>
<b>1</b>	<p>What are the potential benefits and challenges of designating a suffix in the proper name of a biological product that is:</p> <ul style="list-style-type: none"> <li>• Devoid of meaning versus meaningful (e.g., a suffix derived from the name of the license holder)</li> <li>• unique to each biological product versus unique to each license holder and shared by each biological product manufactured by that license holder.</li> </ul> <p>In your comments, please address how each option would impact the following: Safe use of biological products; pharmacovigilance; and market acceptance and uptake for certain products.</p>	See page 2-3 for discussion.
<b>2</b>	<p>What would be the potential benefits and challenges for an interchangeable product to share the same suffix as designated in the proper name of the reference product? Your response should consider that FDA's publicly available electronic resource, the Purple Book, will identify biological products determined by FDA to be</p>	See pages 3-4 for discussion.



<u>QUESTION NUMBER</u>	<u>Question</u>	<u>Answer</u>
	biosimilar to or interchangeable with a reference product. If an interchangeable product does share the same suffix as the reference product, how would this impact your responses to question 1, including pharmacovigilance?	
<b>3</b>	Would there be additional benefits or challenges if the suffix designated in the proper name of a biosimilar product that is subsequently determined to be interchangeable were changed to that of the reference product upon a determination of interchangeability? Would there be benefits or challenges to allowing the manufacturer of the biosimilar product that is subsequently determined to be interchangeable to have the option of retaining its original suffix or adopting the same suffix as the reference product?	See page 3 for discussion.
<b>4</b>	How could FDA and/or other Federal partners improve active pharmacovigilance systems for purposes of monitoring the safety of biological products? For example, because NDC numbers are not routinely recorded in billing and patient records in many clinical settings in which biological products are dispensed and administered, are there other identifiers besides distinguishable nonproprietary names that are routinely accessible by active	BIO believes that the use of distinguishable nonproprietary names for all biological products will best facilitate active pharmacovigilance.





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	pharmacovigilance systems and could enable as good as or better pharmacovigilance? How can FDA and/or other Federal partners help ensure that a distinguishable identifier for each biological product would be captured at the point of dispensing or administration to the patient and be routinely accessible in systems used for pharmacovigilance?	
<b>5</b>	What process and reasonable timeframe should FDA use to designate a suffix to include in the nonproprietary name of a previously licensed biological product?	See page 4 for discussion.
<b>6</b>	What criteria should FDA use to prioritize retrospective application of this naming convention to previously licensed biological products?	See page 4 for discussion.
<b>7</b>	What are the expected time frames for sponsors of previously licensed biological products to distribute products that conform to this naming convention after approval of a labeling supplement?	See page 4 for discussion of the need for a multi-stakeholder workshop to establish a timeframe.
<b>8</b>	What strategies could FDA use to enhance stakeholders' understanding of and education about this naming convention?	BIO would welcome the opportunity to work with FDA on an education plan for stakeholder education about the naming convention.
<b>9</b>	FDA notes that this naming convention (i.e., use of a suffix) has some similarities to the World Health Organization (WHO)	BIO supports the efforts of WHO to facilitate a distinguishable suffix that can be used globally. However, BIO members believe that memorable and meaningful



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	proposal, "Biological Qualifier--An INN Proposal." At the time of publication of this draft guidance, WHO was still evaluating the comments 7 received on its proposal. If WHO adopts a Biological Qualifier proposal, how should the biological qualifiers generated by WHO be considered in the determination of FDA designated proper names for the biological products within the scope of this guidance?	<p>suffixes are the most useful path forward. If WHO decides to take another approach, the suffix adopted in the US can be easily mapped to the suffix assigned by the WHO. The US can most effectively assist WHO and other jurisdictions by demonstrating successful adoption of a suffix framework, including meaningful and memorable suffixes.</p> <p>Please see page 5 for additional discussion.</p>