May 3, 2019

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

Re: Docket No. FDA-2013-D-1543: Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments to the Draft Guidance titled Nonproprietary Naming of Biological Products: Update.

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 is committed to improve patient access to safe, effective, and affordable therapeutic choices. As such, BIO was a leader in pushing Congress a decade ago to create a statutory pathway for the approval of biosimilar and interchangeable biological products, known as the Biologics Price Competition and Innovation Act (BPCIA). BIO unequivocally believes that safe and effective biosimilars and interchangeable products are good for patients and good for the public health. More broadly, BIO has been a strong supporter of the Agency's efforts to advance implementation of the BPCIA, to which the FDA has taken important steps as demonstrated by the release of this revised guidance on nonproprietary naming.

For nearly a decade, BIO has advocated actively for a nonproprietary naming convention that ensures all biological products are distinguishable. 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. We are pleased to see the Agency's inclusion in this Draft Guidance of the use of a four-letter distinguishable suffix for biological products. BIO shares FDA's view that a distinguishable nonproprietary naming convention will best facilitate robust pharmacovigilance, promote accurate attribution of adverse events to the correct product, mitigate the risk of inappropriate or unintended substitution and unintended switching, and support unique product identification, which will help to ensure targeted regulatory action, should the need arise.

Of note, biosimilars and interchangeable biosimilars are "highly similar," but not identical, to their reference products in terms of active substance. Biologics are also inherently more complex than small molecule therapeutics and thus, require policies distinct from those for generic small molecule drugs. As the U.S. market grows and more biosimilars and

interchangeable biosimilars become available, accurate identification of prescribed and dispensed biological products will become increasingly important to facilitate an effective pharmacovigilance system. BIO firmly believes that the use of distinguishable nonproprietary names for biological products will play an important role in achieving this objective. In addition, in order to encourage widespread adoption and uptake of these products, 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. 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), and that license holders be afforded the option of using the same suffix for each biological product from that license holder.

BIO also notes the Draft Guidance acknowledges that vaccines are currently within scope of the naming convention, but that FDA is reconsidering their inclusion. BIO strongly supports the removal of vaccines from the scope of the naming convention, and believes that FDA's evaluation of vaccine identification systems will establish that they are sufficiently robust to ensure safe dispensing practices and optimal pharmacovigilance.

Robust vaccine safety monitoring systems already are in place to ensure pharmacovigilance for vaccines without requiring an additional biosimilar suffix. These programs include the Immunization Safety Office: Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Sentinel Post-licensure Rapid Immunization Safety monitoring (PRISM) system, and Clinical Immunization Safety Assessment (CISA). In addition to robust global pharmacovigilance surveillance programs by vaccine manufacturers, healthcare professionals also understand very well how and when to file suspected adverse events.

Given that vaccines are not dispensed to patients; instead they are dispensed to, and administered by, healthcare professionals only, there is no danger of a patient unknowingly administering an inappropriate vaccine to themselves. In addition, healthcare professionals record vaccine administration in patient charts, electronic health records (EHRs), or Immunization Information Systems (IISs), and the currently used vaccine identifiers work well for safety tracking and recall purposes. As an example, ISSs collect core data items that facilitate investigation of vaccine adverse events and recalls. Core data items include, among many others, vaccine type, manufacturer, lot number, and expiration date. BIO reaffirms that these mechanisms are sufficiently robust and would not be further enhanced by the addition of a suffix.

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

Sincerely,

/S/

Sesquile Ramon, Ph.D.
Director, Science & Regulatory Affairs
Biotechnology Innovation Organization