



Academy of
Managed Care
Pharmacy®

May 7, 2019

Dr. Norman Sharpless
Acting Commissioner
U.S. Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

***Re: Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry;
Availability [FDA-2013-D-1543]***

Dear Acting Commissioner Sharpless:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the updated draft industry guidance on “*Nonproprietary Naming of Biological Products*” published in the Federal Register on March 8, 2019. AMCP appreciates FDA’s ongoing efforts to issue and update guidance that allow health care providers to safely and effectively use biosimilar products. However, we have concerns with the FDA’s proposed updates to its naming convention and believe that it may cause further confusion for health care providers and patients as well as impede biosimilar adoption.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

In the updated draft guidance, the FDA proposes that it will no longer retroactively modify the legacy names of biological products that have already been licensed or approved without an FDA-designated suffix. Alternatively, FDA will continue to assign suffixes to newly approved innovator biologics, all biosimilars, and interchangeable biosimilar products. Consequently, two separate naming conventions for the same class of products will be established.

In the past, the FDA has noted potential safety concerns with this approach. Specifically, in the January 2017 final guidance, “*Nonproprietary Naming of Biological Products*,” FDA stated that “applying this [suffix] naming convention only for products licensed under section 351(k) of the PHS Act—but not for the reference product licensed under 351(a) of the PHS Act—could adversely affect health care provider and patient perceptions of these new products.” Further, FDA noted that, “*such an approach could be misinterpreted as indicating that biosimilar products differ from their reference products in a clinically meaningful way or are inferior to their reference products for their*

approved conditions of use.”¹ Additionally, in the same January 2017 final guidance, FDA stated that the rationale for using a suffix is to clearly identify biological products for the purpose of improving pharmacovigilance. To that effect, the FDA’s Adverse Event Report System (AERS) Public Dashboard illustrates that only 0.9 percent of biosimilar safety reports provided to the FDA actually contain a suffix.

AMCP has previously expressed concern that the establishment of a suffix will create confusion among healthcare practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings.² Therefore, AMCP continues to support the use of the international nonproprietary name for both biologics and biosimilars with no suffix. As an alternative, AMCP supports the use of the National Drug Code (NDC) on all claims for medications, including biologics and biosimilars. The use of NDCs along with lot number and manufacturer name provides an existing mechanism to individually identify products. AMCP recognizes the need to perform diligent pharmacovigilance for biological products post-marketing and believes this can be accomplished through the continued use of existing mechanisms such as manufacturer name, NDC, and lot numbers.

Should the FDA continue to utilize a suffix in its naming convention, AMCP strongly encourages the FDA to maintain the same suffix for an interchangeable product and its biologic reference product. The use of the same suffix for interchangeable products as the biologic reference product provides a straightforward method for pharmacists to identify which biosimilar products are considered interchangeable should they not have immediate access to the Purple Book or other reference materials. Utilizing a different naming approach for an interchangeable biosimilar product is likely to lead to confusion amongst prescribers and pharmacists. Specifically, there may be confusion as to what products can be interchanged, especially when interchangeable designation is gained for an existing product that is already on the market. This may lead to delays in patient care at the pharmacy counter and increased cost for patients if they cannot access a more cost-effective interchangeable product. Additionally, inconsistent naming of biosimilars from their reference product could result in clinicians incorrectly believing that the biosimilar is clinically different than its reference product. Furthermore, utilization of a consistent naming convention is critical to the market and cost-savings as similar names result in greater price competition.³

¹ Food and Drug Administration. January, 2017. Nonproprietary Naming of Biological Products Guidance for Industry. Available at: <https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>. Accessed on April 18, 2019.

² AMCP. October, 2015. Nonproprietary Naming of Biological Products (Docket – FDA-2013-D-1542) Designation of Official Names and Proper Names for Certain Biological Products (Docket – FDA-2015-N-0648). Available at: http://www.amcp.org/uploadedFiles/Production_Menu/Policy_Issues_and_Advocacy/Letters,_Statements_and_Analysis_-_docs/2015/AMCP%20Letter%20to%20FDA%20Re%20Biosimilar%20Naming%20Draft%20Guidance%20and%20Proposed%20Rule_October%202015_Final.pdf. Accessed April 18, 2019.

³ Paradise, Jordan K. January 9, 2015. The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the U.S. Healthcare System. 41 American Journal of Law and Medicine 49 (2015). Available at: <https://ssrn.com/abstract=2555794>. Accessed on April 25, 2019.

AMCP also supports efforts for training and development of education resources, including the adoption and dissemination of existing education resources, such as AMCP's Biosimilars Resource Center (BRC)⁴ to provide neutral, unbiased education resources to pharmacists, physicians, nurses, and other health care providers. AMCP appreciates FDA's previous education efforts and believes that it should continue to build upon those efforts and use its resources and influence to enhance its current education campaign on biosimilar and interchangeable biologic products. We previously recommended that FDA should also partner with AMCP and other organizations to increase awareness.

Conclusion

AMCP urges FDA to carefully consider the ramifications of using a suffix in general and the additional consequences for health care providers and patients that could arise from having two distinct naming standards as proposed in the updated FDA guidance. Regardless of FDA's final decision on naming conventions, AMCP strongly suggests that FDA strive to ensure consistency in the naming process to avoid any additional confusion, safety concerns, and delays in patient care.

AMCP appreciates your consideration of the recommendations and concerns outlined above and looks forward to continuing work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer

⁴ The Biosimilars Resource Center (BRC) provides educational resources and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner. Biosimilars have the potential to significantly decrease health care costs in the United States and improve access to treatment for patients. The need for education of health care providers on how to prescribe and dispense cost effective biosimilars is critical to driving adoption and maximizing their use in a safe and effective manner for patients. The BRC provides access to educational tools and training materials for biosimilars, including one-pagers, web-based educational seminars, continuing education and journal articles. The BRC was launched in 2016 by the Academy of Managed Care Pharmacy in partnership with the American Association of Colleges of Pharmacy, America's Health Insurance Plans, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Hematology/Oncology Pharmacists Association, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association. For more information on the BRC, please visit <https://www.biosimilarsresourcecenter.org/>.