May 7, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No.: FDA-2013-D-1543 - Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry

Dear Commissioner Sharpless:

On behalf of the Alliance for Patient Access (AfPA) and the Biologics Prescribers Collaborative (BPC), I thank the Food and Drug Administration (FDA) for working to determine appropriate protocol in regard to nonproprietary naming of biologics and biosimilars, and for the opportunity to comment on the updated draft guidance.

About AfPA and BPC

Founded in 2006, AfPA is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA advocates for health policies that support clinical decision making, promote personalized care and protect the physician-patient relationship as the cornerstone of quality health care. Motivated by these principles, AfPA members participate in physician working groups, advocacy initiatives, conferences, stakeholder coalitions and the creation and dissemination of educational materials. AfPA members include neurologists, rheumatologists, oncologists, gastroenterologists and other health care providers who routinely prescribe biologic medicines. AfPA has been pleased to engage with FDA as each guidance has been developed.

The Biologics Prescribers Collaborative, a project of AfPA, consists of prescriber organizations whose members utilize these biologic and biosimilar medicines. They are committed to

providing the best patient care and welcome the therapeutic options presented by biologics and biosimilars for patients with debilitating, chronic and life-threatening conditions.

Naming Conventions for Biologics and Biosimilars

AfPA and BPC alike recognize that appropriate naming practices will increase prescriber confidence, allow for better pharmacovigilance, and reduce potential confusion by patients and prescribers. Thus, the naming of biologics and biosimilars continues to be an important issue to members of both organizations.

In 2015, when FDA first proposed industry guidance, "Designation of Official Names and Proper Names for Certain Biological Products," AfPA urged distinguishable names for biologics and biosimilar medicines. When final guidance was issued in 2017, AfPA was pleased to see the FDA determine that distinct four-letter suffixes should be applied to each biological medicine. AfPA continues to support this approach.

With regard to the 2019 draft guidance update, AfPA appreciates that FDA proposes to:

- Ensure that all newly approved biologic medicines and biosimilar medicines have distinguishable non-proprietary names;
- Continue to apply a naming nomenclature that combines core names with four-letter suffixes that are random and distinguishable for all new approvals; and
- Extend the unique naming to include interchangeable biosimilar medicines, once approved.

These measures will fulfill the original objectives of the 2017 naming guidance, specifically by encouraging routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices. These also remain important measures to support physician confidence.

If FDA proceeds as proposed, this update would mean that biologic medicines approved prior to the BPCIA and the first biosimilar approval would not take on a suffix under this updated naming guidance. This is based on FDA's determination that "revising the nonproprietary names of a large number of products licensed without an FDA-designated suffix in their proper names would create a substantial burden for healthcare systems, could cause disruption for product inventory, and could cause confusion for healthcare providers and patients, as the nonproprietary names of drugs seldom change postapproval."

AfPA and BPC appreciate and recognize the analysis conducted by FDA that concluded that retroactively adding suffixes to biologics approved prior to BPCIA could create problems for healthcare systems and confusion for physicians and patients and may be unworkable.

Conclusion

With distinguishable names, physicians can worry less about a patient getting the wrong medication. The use of suffixes will also encourage robust pharmacovigilance, allowing patients and physicians alike to rely upon accurate tracing of adverse reactions. These assurances can, in turn, expand treatment options by boosting confidence in biologics and biosimilars.

AfPA and BPC recognize the complexity of the issues facing FDA and commend the agency for taking steps to improve the naming process for originator biologics, biosimilars and interchangeable biologics. If AfPA or BPC can provide further details or aid in finalizing the proposed guidance, please contact us at 202-499-4114.

Sincerely,

Brian Kennedy
Executive Director

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