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FDA Sticks to Its Naming Plan for Biologics and Biosimilars

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By John T. Aquino

The FDA Jan. 12 released a final guidance on the naming of biological products, including biosimilars, that is little changed from its controversial draft guidance.

The final guidance from the Food and Drug Administration proposes that biologics and biosimilars have nonproprietary or proper names that share a core drug substance name and an FDA-designated suffix composed of four lowercase letters that is unique for each product. The FDA said its plan would prevent inadvertent substitution and support safety monitoring of all biological products after they are on the market.

Michael Werner, a policy adviser for the Biosimilars Forum, told Bloomberg BNA in a Jan. 12 phone interview that it was "great to have the biosimilar guidances FDA is developing," noting that biosimilars can expand medicine choices for patients and could reduce drug costs. But the forum was disappointed that the FDA stuck with "meaningless" suffixes, such as "cznm," rather than employ "meaningful" suffixes, such as the one used for the first biosimilar approved, Zarxio (filgrastim-sndz), with "sndz" referring to the biosimilar applicant Sandoz. This would better help the FDA achieve its two goals, Werner said.

In contrast, the Biotechnology Innovation Organization (BIO), which represents biopharmaceutical companies that can be either biologic originators or biosimilar applicants, praised the final guidance.

Joanne Hawana, who counsels regulatory clients for Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C., in Washington, told Bloomberg BNA in a Jan. 12 e-mail, "It's not surprising in my view that they didn't veer from the proposed policy. It really was a 'middle ground' approach that tried to address concerns from all sides of this debate. If they had changed course too much, the criticism would have been either, you're favoring innovators, or you're favoring biosimilars."

The guidance is scheduled to be announced in a Jan. 13 Federal Register notice.

Applicants Can Suggest Suffixes

Biologics are used to treat diseases such as cancer and hepatitis C. They can, however, cost several thousand dollars a month. A biosimilar is a biological product that is approved based on a showing that it is highly similar to an already approved biological product, known as a reference product (RP). The Biologics Price Competition and Innovation Act (BPCIA) provides an abbreviated approval pathway for biosimilars that partly relies on data submitted for FDA approval of the RP. Relying on the data for the original biologic can reduce the cost of developing the biosimilar.

In the final guidance, FDA stated: "With the introduction of more biological products, FDA believes it is important to encourage routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices for biological products, irrespective of their licensure pathway and date of licensure. The designated suffix will provide a consistent, readily available and recognizable mechanism for patients and health care professionals, including providers and pharmacists, to correctly identify these products. FDA believes it is likely that FDA-designated suffixes will be used routinely when identifying, describing, and recording use of biological products if such suffixes are present in the proper names of all biological products licensed under the [Public Health Service Act]."

The FDA wrote in the final guidance that it had evaluated the comments it received in response to the draft guidance and re-evaluated its approach to designating proper names. One addition to the final guidance is that the agency will allow an applicant to submit up to 10 proposed suffixes, with the FDA noting that the acceptability of a proposed suffix will be based on its review of all information and analyses described in the guidance. The FDA released a document in June 2016 stating a version of this policy, although it retracted the document 20 days later.

Generic/Biopharma Divide

The draft guidance, which was released in August 2015 (09 LSLR 1033, 9/18/15), was criticized by the Academy of Managed Care Pharmacy (AMCP) and the Generic Pharmaceutical Association's Biosimilar Council. The council urged in the interest of patient safety that biologics and biosimilars be required to have the same international nonproprietary name (INN) with no added FDA-designated suffix because this is the procedure for naming other medicines in the U.S.

BIO praised the draft guidance, and a BIO spokesman repeated the approbations for the final guidance in a Jan. 12 e-mail to Bloomberg BNA.

"While we are still reviewing the guidance released today, we are pleased that the FDA has published final guidance on this important topic," he wrote. "We also applaud the agency's decision to assign distinguishable names for biological products by affixing a distinguishable suffix to the nonproprietary name for each approved product. Assigning distinguishable nonproprietary names to all biological products will help to prevent inappropriate substitution, facilitate postmarket surveillance of drug safety, ensure accurate attribution of adverse events to the right product, and support tracing of products in the event of the need to recall."

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For More Information

The final guidance is at http://src.bna.com/lmK.

The Federal Register notice is at http://src.bna.com/ln7.