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FDA Wants Biosimilars to Have Suffixes

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The FDA has proposed adding a 4-letter suffix to the names of biosimilars to distinguish them from their biologic counterparts.

This new naming convention would also prevent substitution of non-interchangeable products and avert "inaccurate perceptions of the safety and effectiveness of biological products based on their licensed pathways," the FDA stated.

The first biosimilar approved in the United States is Sandoz's tbo-filgrastim (Zarxio), but under the proposed guidance, it would be named filgrastim-bflm instead.

"Our current thinking is that shared nonproprietary names are not appropriate for all biological products," read the recently released draft guidance. "There is a need to clearly identify biological products for the purpose of pharmacovigilance, and for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable."

Opponents to this guidance, which include companies that develop biosimilars, would prefer to use the same nonproprietary or generic names as brand-name drugs. Even the Academy of Managed Care Pharmacy (AMCP) issued a statement calling the draft guidance "disappointing."

AMCP CEO Edith A. Rosato, RPh, IOM, pointed out that the current naming convention using the same nonproprietary name has worked well in Europe.

"AMCP is concerned that any departure from the currently accepted nonproprietary naming system will create confusion amongst health care practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings," Rosato stated.

AMCP added that pharmacovigilance could be achieved by identifying factors such as manufacturer name, national drug code, and lot numbers.

Biosimilars Council chairman Bertrand C. Liang also expressed concerns about the proposed naming convention preventing patients from accessing new and more affordable medicines.

"Adding a random collection of letters to the product's nonproprietary name confers no additional safety benefit, and in fact would require the health care professional to be armed at all times with a code-breaking reference," Liang stated.

Meanwhile, the FDA argued that its new naming process would make it easier to track biological product use.

Janet Woodcock, MD, and Karen Midthun, MD, directors of the FDA's Center for Drug Evaluation and Research and the FDA's Center for Biologics Evaluation and Research, respectively, said the naming convention would "support safety monitoring of all biological products after they are on the market, by making it easier to accurately track usage of biological products in all settings of care, such as outpatient, hospital, and pharmacy settings."

The FDA is now asking for feedback on whether the nonproprietary name for interchangeable biological drugs should have a unique suffix or share the same suffix as their reference products. Products deemed interchangeable will eligible for substitution at pharmacies "without the intervention of the health care provider who prescribed the referenced product," according to the FDA.