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HSCA FILES COMMENTS ON FDA BIOSIMILAR NAMING PROPOSED RULE

Urges Biological Products to Share the Same INN, without a Suffix, to Promote Patient Safety and Biosimilar Adoption

Washington, DC (October 28, 2015) – The Healthcare Supply Chain Association (HSCA) today announced that it has filed comments in response to the U.S. Food and Drug Administration’s (FDA) draft guidance “Nonproprietary Naming of Biological Products: Guidance for Industry.” The comments urge FDA to require reference biologics and their biosimilars to share the same International Nonproprietary Name (INN), without a suffix, in order to protect patient safety and ensure widespread adoption of biosimilars.

“HSCA and our member group purchasing organizations share the FDA’s deep commitment to safety. That is why we think it is critical for biologics and biosimilars to share the same International Nonproprietary Name, without a suffix,” said HSCA President and CEO Todd Ebert, R. Ph. “We are concerned that requiring a differentiated suffix might hinder adoption of biosimilars by creating the mistaken impression that a biosimilar product will behave differently than its originator. Further, studies have shown that drug name prefix and suffix confusion accounts for approximately 10 percent of medication errors. For biosimilars to be trusted and adopted safely, they should not have unique suffixes.”

The comments cite the successful regulation of the U.S. drug market for over 60 years under the INN system. Since 2006, the European Union has also effectively regulated its biologic market, with appropriate pharmacovigilance, without using differentiated nonproprietary names.

“Adverse events and product recalls continue to be successfully facilitated under the INN (using NDC codes and lot numbers) system,” Ebert added. “There is no compelling evidence that biosimilars should be handled differently. Further, treating biosimilars differently for this purpose could undermine patient and prescriber confidence in them.”

HSCA MEMBER COMPANIES



HSCA's comments also note the increased costs that adopting suffixes would incur, resulting from software updates from across the healthcare supply chain. Read the full comments [here](#).

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About the Healthcare Supply Chain Association (HSCA)

The Healthcare Supply Chain Association (HSCA) represents the nation's leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America's hospitals, nursing homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers, to increasing competition and innovation in the market, and to being supply chain leaders in transparency and accountability. For more information, visit www.supplychainassociation.org. Follow HSCA on Twitter @HSCA.