HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

October 19, 2016

Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA–2015–N–3326 Comments of the Healthcare Supply Chain Association on "Biosimilar User Fee Act; Public Meeting"

The Healthcare Supply Chain Association (HSCA) appreciates the opportunity to provide comment on the U.S. Food and Drug Administration's (FDA) proposed recommendations for the Biosimilar User Fee Act (BsUFA) reauthorization performance goals and procedures for fiscal years 2018 through 2022.

HSCA's member group purchasing organizations (GPOs) are critical partners to virtually all of America's 8,000+ hospitals, as well as the majority of its 68,000+ non-acute care providers, including nursing homes, clinics, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. We are also committed to helping hospitals and other healthcare providers deliver effective and affordable care to the patients they serve.

Biosimilars have the potential to increase patient access to life-saving medications and to reduce costs for the entire healthcare system. HSCA and its members are working with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies.

We applaud FDA for developing plans and procedures to ensure the efficacy of the biosimilar approval process. We encourage FDA to execute on the proposed plan in a way that ensures that patients have timely access to safe biosimilar medicines. A competitive market will benefit both patients and payers alike. We also urge FDA to ensure that it adopts and embraces human resource processes that provide for the appropriate staff and resources necessary to continue to meet its safety mandate, while also providing for an expeditious approval process for new biosimilar drugs.

HSCA continues to believe that reference biologics and their biosimilars should share the same International Nonproprietary Name (INN). We remain concerned that FDA's proposed unique suffixes for biosimilars might lead to clinician confusion and hinder adoption of biosimilars by creating the mistaken impression that a biosimilar product will behave differently than its originator. In addition to limiting the cost-savings potential of biosimilars, suffixes will also create

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an additional financial burden to the system, as existing software across the healthcare supply chain will require changes to account for the addition of new suffixes to INNs. We encourage FDA to move quickly to finalize its naming guidance so that appropriate education of supply chain stakeholders can take place.

The ability to safely substitute FDA-approved biosimilars for reference biologics will be critical to realizing the full cost-savings and access potential of biosimilars. As such, we urge FDA to issue clear and robust guidance on the requirements for a biosimilar product to obtain an "interchangeable" designation. FDA's guidance on interchangeability will have an impact on state-level substitution and, ultimately, provider and patient access to biosimilars.

HSCA and its members look forward to continuing to work with FDA as the agency finalizes its biosimilars guidance. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org

Sincerely,

Todd Ebert

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President and CEO