October 27, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted electronically via www.regulations.gov

Re: FDA-2013-D-1543 – Nonproprietary Naming of Biological Products; Draft Guidance for Industry Availability

Dear Dr. Ostroff:

ASHP is pleased to submit comments to the Food and Drug Administration (FDA) on the agency's draft guidance announced in the Federal Register on August 28, 2015 on the nonproprietary naming of biological products (draft guidance). [1]ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

ASHP has had official policy on certain aspects of biosimilars since 2005. Over the past decade, this policy has changed to stay relevant to the evolving biosimilar market.[2] ASHP's current policy on biologics naming is as follows: **Nonproprietary Naming of Biological Products**

> *To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,*
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> *To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.*

1 Federal Register, Volume 80, No. 167. Pages 52296 – 52299
2 ASHP Policy 1409: Approval of Biosimilar Medications

Rationale for ASHP's Policy

ASHP supports a biological product naming convention that is consistent with international naming standards developed by recognized authorities such as the World Health Organization Programme on International Nonproprietary Names (INN), the United States Adopted Name Council (USAN), and the United States Pharmacopia. In addition, this naming convention is also supported by other national organizations, including the National Council on Prescription Drug Plans (NCPDP). These organizations have developed a harmonized biosimilar naming approach based on applying a shared nonproprietary name for originator biological products, related biological products, and biosimilar products. Under their authority, these products essentially share the same nonproprietary name (e.g., "filgrastim" for Neupogen®, Zarxio™, and Granix®), but can be individually identified through their unique National Drug Code (NDC), other unique codified identifiers, and trade names. Thus, well-accepted and widely used mechanisms for distinguishing individual products alleviate the need for deviation from these existing approaches by adding a prefix or suffix to the nonproprietary name.

FDA has proposed a nonproprietary naming process that deviates from the existing standardized approach that has been applied by international authorities such as INN and USAN. Under FDA's proposal, a unique, randomly generated suffix composed of four lowercase letters, or a suffix relating to the license holder of the product (which could change over time), would be applied to originator biological products, related biological products, and biosimilar products. ASHP is concerned that this approach varies from naming processes that are already in practice in other developed countries such as those in Europe. Furthermore, using randomly generated suffixes would be unlikely to achieve FDA's goals of product recognition and recall by prescribers, patients, and others. Four-consonant non-meaningful, unpronounceable suffixes are unlikely to be readily recalled or associated accurately with specific products.

Consistent with other standard-setting groups, national pharmacy organizations, and WHO, ASHP does not believe that there is a need to develop a naming convention that differs from the current standard. Without well-designed testing, it is unclear whether FDA's proposed naming convention would achieve high-level pharmacovigilance or would cause confusion among clinicians and patients who rely principally on proprietary names for self-reporting about branded products.

In the draft guidance, FDA notes that in addition to newly approved biosimilar products, it is proposing to change the official names for biologics with globally adopted INNs and USANs. Initially, this would apply to a small number of products, but eventually would retrospectively change the names of a broad group of existing products to include unique, randomly generated, four-letter suffixes. Such a naming regime would require extensive education and potentially require reprogramming of health information technology systems. This could result in significant risks for medication errors.

ASHP supports a biosimilar naming approach that relies on the ability to track medications by NDC or other standard product identifier. While hospitals may not have the ability to fully track drug products by NDC, they will be required to have that capability pursuant to the Drug Supply Chain Safety Act which requires package level NDC tracking by 2022. As hospitals prepare for full DSCSA implementation and

compliance, they may apply a surrogate NDC in the interim to refect an array of NDCs for related drug and biologic products.

In addition, there are at least two options available to healthcare organizations that could be implemented until a more permanent solution is developed. The first is to apply the current Vaccine Adverse Event Reporting System (VAERS) model to the other biological and biosimilar products. This regulatory framework already exists for vaccines in all clinical settings and could be applied by FDA to ensure pharmacovigilance regardless of where a patient receives the biologic. In addition, consideration could be given to greatly simplifying the vaccine reporting requirements to meet FDA's current intent.

The second option is to manually enter the NDC into the patient's electronic health record. Given that the current universe of biological and biosimilar products proposed by FDA is small, this could serve as an initial solution while a more permanent one is developed. ASHP is prepared to work closely with FDA to develop such a solution.

Request for Part 15 Hearing

ASHP believes that there is a great deal more to be discussed regarding the appropriate nonproprietary naming policy that should be employed by the FDA. We believe that it is premature to implement the draft guidance until the agency has engaged in robust stakeholder engagement. Therefore, we believe it to be in the best interest of public health for the FDA to delay finalization of the Guidance and Proposed Rule pending a meeting in accordance with part 15 (21 CFR Part 15) to hear the opinions and concerns of all relevant parties that would be impacted by a nonproprietary naming policy that deviates from current naming conventions.

ASHP appreciates the opportunity to comment on the FDA's draft guidance on nonproprietary naming of biological products. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,

Christopher J. Topoleski

Director, Federal Regulatory Affairs.