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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Comments of the Generic Pharmaceutical Association and the Biosimilars Council regarding Docket FDA-2013-D-1543: Nonproprietary Naming of Biological Products; Draft Guidance for Industry.

The Generic Pharmaceutical Association (GPhA) and the Biosimilars Council, a Division of GPhA, (or The Council) acknowledges the efforts of the FDA on **Docket Number FDA-2013-D-1543 naming for biosimilar and biologic products**. We would also like to thank you for giving us the opportunity to share our thoughts on this important public health issue.

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than three billion prescriptions every year. Generics represent greater than 86% of all prescriptions dispensed in the U.S., but only 27% of expenditures on prescription drugs. GPhA is the sole association representing America's generic pharmaceutical sector in the U.S., while this response letter represents the views of the association these comments may not reflect all member company positions.

The Council works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and works to educate the public and patients about the safety and effectiveness of biosimilars. Areas of focus include education, access, the nascent regulatory environment, reimbursement and legal affairs. Member organizations include any company or stakeholder organization working to develop biosimilar products with the intent to compete in the U.S. market.

Biosimilars and interchangeable biological products hold great promise not just for consumers and the pharmaceutical industry but for sustaining a healthcare system with finite resources. By 2016 it is predicted that eight of the top ten most dispensed pharmaceuticals in the U.S. will be biologics. The significance is the fact that the average daily cost of a brand biologic product is approximately 22 times greater than a traditional drug.¹ When biosimilars and interchangeable

¹ AARP, Leigh Purvis, "Sense of Déjà vu: The Debate Surrounding Sate Biosimilar Substitution Laws," September 2103



biological products are approved – patient access and affordability of these critical treatments will increase and will also afford the healthcare system in providing a wider array of treatment options for healthcare providers to increase patient outcome and compliance. Express Scripts estimates potential savings of \$250 billion in the next decade with the approval of just 11 biosimilar products.²

Consistent International Naming of Biologic and Biosimilar Products

GPhA and the Council support the licensure of high quality biosimilar products that meet the statutory and regulatory standard of high similarity and no clinically meaningful differences from the Reference Protein Product (RPP). When it comes to naming of biosimilars that have demonstrated biosimilarity to the RPP, both products should share the same International Nonproprietary Name (INN).

The current INN system is working well in Europe, U.S., and Canada for all biologics. Creating a new naming convention with unique INNs will instill uncertainty, compromise safety and limit ability to improve patient access to biologics. In the U.S., multiple different products share the same INN and pharmacovigilance issues have not been identified. Unique names could disrupt the current naming system and inhibit market creation for biosimilars. Fewer barriers and increased access to biosimilar products will increase the affordability of these life-saving, yet frequently costly, products.

Biosimilar products should share the same INN or proper name. Adding a suffix to the proper name is unnecessary and does not achieve the Agency's stated goals as it will lead to confusion among prescribers and patients, potentially resulting in medication errors and mistranscription in medical records.

Therefore, we believe consistent non-proprietary naming will ensure robust market formation that ultimately supports patient access and affordability, supports pharmacovigilance systems currently in place, allows for unambiguous prescribing, and builds upon the successful foundation of the global INN system that has been used successfully for more than six decades for both small molecule brand and generic products and large molecule biologic products.

The INN/USAN has never been the name of the final, formulated product itself but rather of the active substance in the product. In addition to the INN/USAN, a product will have other names and/or unique identifiers for distinct recognition; including a brand name, company name, a lot number and a national drug code (NDC) number that readily distinguish it from other products that share the same INN/USAN. These products also have barcodes to convey information to the pharmacist. All of these unique identifiers already allow for tracking and monitoring of these products in a situation where some adverse events have occurred. Finally, the active substance does not change from the biologic innovator to the biosimilar, thus the name should be the same.

² Express Scripts, Inc., "INFOGRAPHIC: Two Biosimilars to Save \$22.7 Billion," December 4, 2014, <http://lab.express-scripts.com/insights/drug-options/infographic-two-biosimilars-to-save-227-billion>



A major goal of the Biologic Price Competition Innovation Act (BPCIA) is to create competition in the marketplace for biologics, thereby expanding access to, and increasing the affordability of, these critical medicines. As its title suggests, the BPCIA also is intended to stimulate innovation and investment in the next generation of originator biologics, and it is mutually beneficial if this happens alongside the availability of biosimilars. The decisions that FDA makes about how to name these therapies will affect patient access, market competition, and standards. Therefore, GPhA and the Council recommend that you maintain the same naming convention that has been in place for more than 60 years. Thus, when it comes to naming of biosimilars that have demonstrated biosimilarity to the RPP, both products should share the same International Nonproprietary Name (INN).

Sincerely,

A handwritten signature in black ink, appearing to read "D.R. Gaugh".

David R. Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs



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Biosimilar Council Current Membership List

Amneal Biosciences
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Momenta Pharmaceuticals Inc.
Mylan N.V.
Pfenex Inc.
Sandoz Inc.
Sun Pharmaceutical Industries, Inc.
Teva Pharmaceuticals USA
Therapeutic Proteins International, LLC
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