April 13, 2016

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

Re: DOCKET Nos. FDA-2015-P-5022 and FDA-2015-P-4529 – Comment of GPhA and The Biosimilars Council Refuting BIO/PhRMA's Joint Citizen Petition Suggesting Changes to the Labeling of Biosimilars in the United States and Supporting, In Part, the UAW Retiree Medical Benefits Trust's Citizen Petition Regarding Biosimilar Labeling

Dear Sir or Madam:

The Generic Pharmaceutical Association (GPhA) and the Biosimilars Council acknowledge and appreciate the Food and Drug Administration's (FDA) interest and expertise in biosimilars labeling. We thank you for the opportunity to share our response to the joint Citizen Petition (CP) submitted by the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) on December 22, 2015[1] and the CP prepared by the UAW Retiree Medical Benefits Trust on behalf of a group of institutional investors.[2] GPhA previously submitted comments to a similar CP submitted by AbbVie, Inc. (AbbVie).[3] Because those comments are directly relevant to the BIO/PhRMA CP and set forth GPhA's position regarding the appropriate framework for labeling biosimilars and interchangeable biologics in the United States licensed under Section 351(k) of the Public Health Service Act (PHSA), we are re-submitting those comments to the above-referenced dockets and incorporating them herein by reference.[4]

[1] BIO/PhRMA Citizen Petition to U.S. Food & Drug Admin. (Dec. 22, 2015) (Docket No. FDA-2015-P-5022) [hereinafter BIO/PhRMA CP].
[2] UAW Retiree Medical Benefits Trust Citizen Petition to U.S. Food & Drug Admin. (Nov. 23, 2015) (Docket No. FDA-2015-P-4529) [hereinafter UAW CP].
[3] AbbVie, Inc., Citizen Petition to U.S. Food & Drug Admin. (June 2, 2015) (Docket No. FDA-2015-P-2000) [hereinafter AbbVie CP]. Amgen Inc. (Amgen) and Alliance for Safe Biologic Medicines (ASBM) filed comments in support of AbbVie CP. AbbVie also filed a Supplement to Citizen Petition dated August 10, 2015. GPhA's comment includes GPhA's response to AbbVie CP, AbbVie's Supplement to AbbVie CP, and Amgen and ASBM's comments.
[4] A biological product is biosimilar to a reference product, which is "the single biological product licensed under [Section 351(a)] against which a biological product is evaluated in an application submitted under [Section 351(k)]," if it is "highly similar" to the reference product relied on for approval "notwithstanding minor differences in clinically inactive components," and if there are no "clinically meaningful differences" between the products with respect to safety and effectiveness. *See* Section 351(i) of PHSA (42 U.S.C. § 262(i)). An interchangeable biologic is a biosimilar that can be substituted at the pharmacy without the intervention of a physician. *See id.*

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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. Generics represent greater than 88% of all prescriptions dispensed in the U.S., but only 28% of expenditures on prescription drugs. GPhA is the sole association representing America's generic pharmaceutical sector in the U.S. The GPhA Biosimilars Council, a Division of GPhA, works to ensure a positive regulatory, reimbursement, political and policy environment for biosimilar products, and to educate the public and patients about the safety and effectiveness of biosimilars. Areas of focus will 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.

While this letter represents the views of GPhA and our Biosimilars Council, the comments may not reflect the positions of all member companies.

In their joint CP, BIO and PhRMA request that FDA require approved prescription drug labeling for biosimilar biological products licensed under Section 351(k) of the PHS Act to contain:

- A clear statement that the product has been approved as a biosimilar for stated indications and routes of administration, with an identification of the reference product (RP);

- A description of the basis of approval for each indication by identifying the relevant data for the RP and biosimilar that support a finding of biosimilarity; and

- A statement whether or not FDA has made a determination of interchangeability with the RP, including any such FDA finding.

These requested disclosures are nearly identical to those requested in the AbbVie CP and, for the same reasons, are unnecessary and potentially confusing.

First, the information and disclosures requested by BIO, PhRMA, and AbbVie are unnecessary to the safe and effective use of biosimilars and thus can be omitted in full compliance with FDA's labeling regulations and without rendering the biosimilar's labeling "materially misleading." Indeed, FDA has never required a product's approval pathway or therapeutic equivalence code to be disclosed on prescription labeling, and such information is immaterial to prescribing decisions. Moreover, in most cases, the scientific information necessary to facilitate an understanding of how to use a biosimilar safely and effectively will be the clinical studies conducted to establish the safety and effectiveness of the RP, not the analytical, animal and clinical studies conducted to establish biosimilarity. These latter studies are intended simply to demonstrate biosimilarity – and thereby allow the biosimilar to rely upon the existing safety and effectiveness data for the RP – not to independently establish the safety and effectiveness of the biosimilar itself. As such, these data generally would not be relevant to the safe and effective use of the biosimilar and thus would not be required (or, arguably, permitted) in biosimilar labeling under FDA's existing labeling regulations.

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Second, the BPCIA does not prohibit, either expressly or by implication, the approval of biosimilar labeling that is "the same" as the RP's labeling. The BPCIA, in fact, is silent with respect to biosimilar labeling and thus grants FDA broad discretion with regard to biosimilar labeling. Given the statutory requirement that a biosimilar must be "highly similar" to a RP – with no clinically meaningful differences in terms of safety, purity, or potency – biosimilar labeling will closely track the labeling for the RP. Consequently, GPhA supports the UAW CP to the extent it recognizes that biosimilar labeling may be the same as the RP labeling, but GPhA does not agree that this is required by the BPCIA.

Finally, GPhA opposes the request in the UAW CP for a Part 15 hearing on biosimilar labeling because of concerns that this could delay FDA's issuance of a final guidance document on biosimilar labeling. GPhA supports FDA's issuance of its planned guidance document, which will allow public feedback on this issue.

In sum, the joint BIO/PhRMA CP, like the AbbVie CP before it, seeks to impede the adoption and use of biosimilar and interchangeable biological products by requiring their labeling to include unnecessary and confusing information that misleadingly suggests to healthcare professionals that such products have clinically meaningful differences from their RPs in terms of safety, purity, or potency when, in fact, they do not. FDA should reject this thinly disguised attempt to subvert the goals of the BPCIA to increase patient access to safe, effective and affordable biosimilar and interchangeable biological products.

We look forward to a continued effort of working together with FDA and other stakeholders to improve the lives of consumers by providing timely access to affordable pharmaceuticals. For these reasons, GPhA respectfully submits that BIO's and PhRMA's request to require certain statements and descriptions on the biosimilar label that would differentiate biosimilars from their RPs should be rejected.

Sincerely,

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

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