November 17, 2023

Submitted electronically via https://www.regulations.gov/

Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry; Availability
[Docket No. FDA-2016-D0643]

Dear Sir or Madam,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to comment on FDA's Draft Guidance for Industry on Labeling for Biosimilar and Interchangeable Biosimilar Products. NCPDP has a decades-long history of sharing with the Agency the expert advice of its members on issues concerning biosimilar and interchangeable biosimilar products, principally through the activities of its Work Group 2 Task Group on Naming Standards for Drugs, Biologics, and Biosimilars. Most recently, NCPDP has worked closely with key staff from FDA's Office of Therapeutic Biologics and Biosimilars (OTBB) and the National Library of Medicine (NLM) on optimally leveraging *Purple Book* data via RxNorm to better support seamless electronic prescription processing for biosimilar and interchangeable biosimilar products.

FDA has long acknowledged the federal Food, Drug, and Cosmetic (FD&C) Act does not limit the manner in which a prescriber may use an approved drug.[1,2] More recently, FDA acknowledged healthcare providers can prescribe any biosimilar product in place of its reference product regardless of whether the

[1] Food and Drug Administration. Use of approved drugs for unlabeled indications. *FDA Drug Bull*. 1982; 12:4-5
[2] Food and Drug Administration. Labeling for biosimilar and interchangeable biosimilar products; draft guidance for industry; availability. *Fed Regist*. 2023; 88:63957-60

biosimilar is approved as interchangeable, since the products do not have any clinically meaningful differences.[3,4] In addition, determining how to appropriately label biosimilar and interchangeable biosimilar products and maintain labeling currency without causing undue confusion has proven challenging for FDA.[2,3] Therefore, noting in labeling whether a biosimilar is interchangeable is unlikely to be useful to prescribers.

NCPDP strongly supports FDA's proposal in its Draft Guidance to Industry[3] to no longer include in the Highlights section of labeling a statement about the interchangeability of a biosimilar product. Instead, labeling should simply state the product is biosimilar to a given reference product and the products can be used with equal confidence concerning safety and efficacy. As FDA notes, a determination of interchangeability applies at the state level where medical and pharmacy practices are regulated and, more specifically, to whether a biosimilar can be substituted for its reference product without the intervention of the prescribing healthcare provider (pharmacy-level substitution).

NCPDP agrees both biosimilar and interchangeable biosimilar products should contain the same biosimilarity statement in the Highlights of Prescribing Information but recommends FDA's proposed wording on biosimilarity be modified to indicate more clearly the confidence with which healthcare professionals can prescribe biosimilar products in place of their reference product. NCPDP is concerned that FDA's proposed wording stops short of providing such reassurance to prescribers. Therefore, the following modification (new <u>underscored</u> sentence) is recommended to provide more clarity to healthcare practitioners and the public:

> Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. <u>A biosimilar can be prescribed in place of its reference product with equal confidence it is as safe and effective.</u> Biosimilarity of [BIOSIMILAR OR INTERCHANGEABLE BIOSIMILAR PRODUCT'S PROPRIETARY NAME] has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

Despite NCPDP's support for eliminating a statement of interchangeability from the highlights section, NCPDP remains concerned about the substantial confusion and implementation burden to optimal electronic prescription processing that have resulted from the great variability in state substitution laws and regulations affecting biosimilars.[4,5] NCPDP has reached out to the National Association of Boards of Pharmacy (NABP) to discuss these concerns and remains committed to working closely with FDA's OTBB staff and NLM's RxNorm staff to enhance and more effectively leverage *Purple Book* data to support

[2] Food and Drug Administration. Labeling for biosimilar and interchangeable biosimilar products; draft guidance for industry; availability. *Fed Regist*. 2023; 88:63957-60

[3] Center for Drug Evaluation and Research Division of Drug Information. FDA releases a new draft guidance on labeling for biosimilar and interchangeable biosimilar products. Food and Drug Administration announcement. 2023 Sep 15.

[4] Cardinal Health. Biosimilar interchangeability laws─Alabama through Wyoming. 2021.

[5] Cisek S, Choi D, Stubbings J, Bhat S. Preparing for the market entry of adalimumab biosimilars in the US in 2023: a primer for specialty pharmacists. *Am J Health-Syst Pharm.* 2023; 80:1223-33.

seamless electronic prescription processing for biosimilar products. NCPDP agrees a single "source-of-truth" approach which leverages *Purple Book* data would be safer and more effective than relying on labeling to provide the most current, relevant data on biosimilar and interchangeable biosimilars.

NCPDP thanks FDA for the opportunity to share these comments and welcomes ongoing communication with the Agency to address electronic prescription processing issues affecting biosimilar products.

For direct inquiries or questions related to this letter, please contact:

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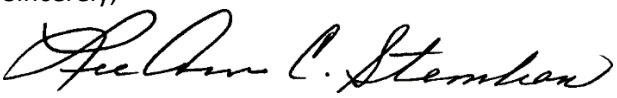
Sincerely,



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