APhA
American Pharmacists Association

November 17, 2023

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

RE: Docket No. FDA-2016-D-0643: Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry; Availability

Submitted electronically via www.regulations.gov to Docket No. FDA-2016-D-0643

Dear FDA Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on the draft guidance titled "Labeling for Biosimilar and Interchangeable Biosimilar Products; Draft Guidance for Industry." APhA appreciates FDA's efforts to provide guidance on biosimilar and interchangeable biosimilar product labeling (prescribing information).

APhA's House of Delegates policy recommends the "development of programs and policies that facilitate patient access to and affordability of biologic products," as well as biosimilar and interchangeable biologic drug products for our patients. APhA also "encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes," and FDA "to expedite the development of standards and pathways that will evaluate the interchangeability of biologic products."

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA appreciates FDA's consideration of the following provisions of the draft guidance:

Removal of the Interchangeability Statement

Under previous draft guidance, FDA indicated that interchangeable biosimilar drug products should include an interchangeability statement on the label. FDA now makes it incumbent on

the prescriber or the public to consult the FDA's Purple Book to determine if the product was licensed based on biosimilarity or interchangeability similar to FDA's approach to communicate therapeutic equivalence for drugs through the Orange Book. FDA's Purple Book, which includes a list of all biosimilar and interchangeable biosimilar drug products, serves as an authoritative source of relevant information on these drug products. FDA also withdrew from an updated draft Q&A guidance on biosimilar development the corresponding question and answer recommending the inclusion of an interchangeability statement in the labeling of interchangeable biosimilars. FDA suggests the interchangeability statement was creating confusion of a separate safety and efficacy standard for interchangeable biosimilars. FDA stated that information about interchangeability is more appropriately located in the Purple Book rather than product labeling because the question of whether a biosimilar is approved as interchangeable is relevant at the point of pharmacy dispensing.

Pharmacists are very familiar with referring to FDA's official source, the "Orange Book," for information about regarding the substitutability of generic drugs. Information about equivalence is not in generic drug product labeling. Most pharmacists are now familiar with the Purple Book. With appropriate education and awareness, APhA expects that pharmacists will also become familiar with referring to the Purple Book for information regarding interchangeable biosimilar drug products. Accordingly, APhA agrees with FDA's proposal to remove the interchangeability statement from biosimilar product labeling.

Including Data from the Reference Product

APhA supports FDA's recommendation that biosimilar and interchangeable biosimilar drug products product labeling include relevant data and information from the reference product labeling when selecting biosimilar or interchangeable drug products. Updates to a biosimilar's labeling without consideration of the reference drug product could lead to confusion due to labeling variability among similar drug products.

Product Identification When the Reference Product Label Describes a Non-U.S.-Approved Biologic

The guidance expands product identification when the reference product labeling describes a clinical study conducted with a non-U.S.-approved biologic and states that the biosimilar or interchangeable biosimilar product labeling should incorporate the same terminology as the reference product labeling. As this is a new provision from the 2018 guidance, APhA urges FDA to address any challenges existing in data derived from foreign studies, including differences between the study population and the intended U.S. patient population, difficulties in extrapolating from different endpoints used to support foreign review standards and differences in disease characteristics and treatment standards. APhA supports greater clarity on

the use of foreign (non-US) data to reduce unnecessary duplication, harmonize global clinical study standards, and promote public health and innovation.

Use in Specific Populations

FDA's guidance includes example scenarios when labeling revisions are necessary, including for pediatric use in this draft guidance.

Given the importance of being able to clearly communicate risks to patients, APhA recommends a clear, standardized, and consistent labeling process to reduce unwarranted differentiation among biosimilars or interchangeable biosimilar drug products, especially information that is not clinically significant or relevant to the safety and quality of the drug product.

Incorporating Relevant Immunogenicity Data from Reference Product

FDA recommends that labeling for the biosimilar or interchangeable incorporate relevant immunogenicity information from the reference product's labeling. FDA notes the immunogenicity information from the reference product's labeling should be included on the biosimilar's or interchangeable's labeling along with the disclaimer paragraph.

APhA recommends FDA clarify scenarios when the reference product's methodology for immunogenicity evaluation precludes an assessment of the incidence of anti-drug antibodies.

Conclusion

APhA appreciates the opportunity to provide feedback on FDA's draft guidance on biosimilar and interchangeable labeling. As FDA finalizes this guidance, APhA recommends FDA continue to work with health care practitioners, including pharmacists on approaches to clearly convey relevant information on these products to patients. APhA also recommends that final guidance reduce unnecessary product references in biosimilar labeling, which could cause confusion for health care practitioners and negatively impact patients. If you have any questions or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs