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August 6, 2024

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

Submitted electronically via regulations.gov

Re: Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry; Availability (FDA–2017–D–0154)

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to "Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry; Availability" (Guidance), issued on June 17, 2024.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP is committed to ensuring that patients and clinicians have access to up-to-date research and information on biological products and, for that reason, established the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) in 2015. The BBCIC is a non-profit research consortium that monitors the safety and effectiveness of biosimilars and novel biologics and provides the assurance needed to determine which medications deliver the best health outcomes. AMCP and BBCIC are committed to providing education, research, and information on biosimilars to health care providers and other stakeholders and believes this work will support a safe and effective market for the increased use of biosimilar products.

AMCP supports FDA's evolving views on when switching studies are necessary to support a demonstration of interchangeability. AMCP is pleased with the recent efforts of the FDA to reduce barriers to interchangeability status for biosimilars. This direct and clear guidance from the FDA, in its capacity as the premier agency on drug safety and efficacy, will alleviate much of the uncertainty and remove impediments to a competitive biosimilar marketplace. An interchangeability pathway that no longer requires switching studies for each condition of use for the reference product relieves the undue burden previously placed on biosimilars. AMCP also wants to acknowledge FDA for your dedication to identifying new and creative solutions to answering regulatory questions regarding interchangeability, such as through the use of real-world data (RWD).

AMCP appreciates FDA's guidance on this important topic and looks forward to continuing to work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Manager of Regulatory Affairs, Vicky Jucelin, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer