



APhA

AMERICAN PHARMACISTS ASSOCIATION
Improving medication use. Advancing patient care.

January 24, 2020

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

Re: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products (FDA-2019-D-5255)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) welcomes the opportunity to respond to the Food and Drug Administration’s (FDA’s) draft guidance, “Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products” (hereinafter, “Draft Guidance”). APhA, founded in 1852 as the American Pharmaceutical Association, has a membership of nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA appreciates FDA’s efforts to streamline efforts to support licensure of proposed biosimilar and interchangeable insulins that are intended for the treatment of patients with Type 1 and Type 2 diabetes mellitus. APhA particularly applauds FDA’s decision, which was based on an extensive multidisciplinary evaluation, to reconsider the necessity of a comparative immunogenicity study under certain circumstances for proposed biosimilar or interchangeable insulin products.

As FDA continues to advance policies related to biological products, we support the agency’s review of opportunities to streamline the approval process and increase competition while maintaining safety. APhA encourages FDA to take a similar approach for other components of a 351(k) biologics licensing application.

APhA thanks FDA’s efforts to improve patient access to safe and effective medications. Should you have any questions please contact, Michael Baxter, APhA Director of Regulatory Affairs, at mbaxter@aphanet.org or (202) 429-7538

Sincerely,

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO