



Sarfaraz K. Niazi, Ph.D.
Adjunct Professor of Pharmaceutical Sciences
University of Illinois
College of Pharmacy
833 South Wood Street
Chicago, IL 60612

February 4, 2025

Re: Docket No. FDA-2024-P-3822

Dear Dr. Niazi:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on August 10, 2024. Your petition requests that the Agency “to evoke [sic] the orders to stop the US Pharmacopeia to create modified monographs of biological drugs, allowing removal of side-by-side analytical testing of biosimilars with reference product.”

FDA has been unable to reach a decision on your petition because it raises complex issues. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett

Date: 2025.02.03 11:43:14 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research