U.S. FOOD & DRUG ADMINISTRATION

Sarfaraz K. Niazi, Ph.D.
20 Riverside Drive
Deerfield, IL 60015

SEP 13 2019

Re: Docket No. FDA-2019-P-1236

Dear Dr. Niazi:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 14, 2019 (the Petition). The Petition requests, among other things, that FDA modify its guidance for industry on the nonproprietary naming of biological products[1] and substitute the phrase "clinically similar" for "no clinically meaningful differences" to describe the relationship of a biosimilar to its reference product (Petition at 2, 5).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

[1] See the final guidance entitled *Nonproprietary Naming of Biological Products – Guidance for Industry* (Jan. 2017), available at https://www.fda.gov/media/93218/download, as well as the draft guidance entitled *Nonproprietary Naming of Biological Products: Update - Guidance for Industry* (March 2019), available at https://www.fda.gov/media/121316/download.