



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

March 15, 2019

Sarfaraz K. Niazi, Ph.D.  
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Deerfield, IL 60015

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to withdraw or amend FDA Guidance on “Nonproprietary Naming of Biological Products” and modify the official characterization of biosimilars was received by this office on 03/14/2019.

It was assigned docket number FDA-2019-P-1236. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)