Kevin L. Williams
Senior Scientist, bioMerieux
1105 N. Main Street
Lombard, IL 60148

October 15, 2020

Re: Docket No. FDA-2020-P-1405

Dear Mr. Williams:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on April 23, 2020. Your petition requests that the Agency (1) recognize recombinant Factor C (rFC) as an equivalent method to existing compendial methods for bacterial endotoxin testing, (2) amend the biologics regulations and FDA guidances to reflect the recognition of rFC as an equivalent method for endotoxin testing to obtain meaningful burden reductions under Executive Orders 13771 and 13777, and (3) issue an Emergency Use Authorization allowing the use of rFC as a tool for testing COVID-19 related medical products.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.10.15 11:53:56 -04'00'

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