



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

April 21, 2020

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

Sent via email to: Kevin.Williams@bioMerieux.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting The Petitioner hereby requests the Commissioner of the Food & Drug Administration (FDA or the Agency) to recognize recombinant Factor C (rFC) as a method equivalent to existing compendial methods of bacterial endotoxin testing [Limulus amoebocyte lysate (LAL) and *Tachypleus tridentatus* lysate (TAL)] and to amend the biologics regulations using Executive Orders 13771 and 13777.

Your petition was received by this office on 04/23/2020 and it was assigned docket number FDA-2020-P-1405. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, 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 Officer
Dockets Management Staff
FDA/Office of Operations (OO)