August 2, 2022

Foster Jordan
Senior Vice President of Innovation
of Product Development
Charles River Laboratories, Inc.
1023 Wappoo Road, Suite 43B
Charleston, SC 29407

Sent via email to: foster.jordan@crl.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drugs to take action on the following:

(1) Formally rescind the Ombudsman's now-obsolete Cambrex Letter;

(2) Declare that any person engaged in the interstate commercial marketing of an end-product endotoxin test for human drugs, biological products, or medical devices which (a) includes recombinant Factor C and (b) has not been granted an effective BLA for its recombinant Factor C product is in violation of 42 U.S.C. § 262(a)(1)(A);

(3) Order any such person(s) to either (a) immediately cease marketing their unlicensed and unlawful recombinant Factor C product(s) in interstate commerce, or (b) submit a complete BLA for such a product within 60 days of the date the Commissioner takes final agency action on this petition; and

(4) Initiate prompt administrative enforcement proceedings against any person who either (a) fails to comply with the terms of the above-requested order, or (b) submits a complete BLA in accordance with the terms of such order, but fails to obtain an effective approval for such BLA within 6 months of its initial submission to FDA.

Your petition was received and processed under CFR 10.30 by this office on 08/01/2022.

It was assigned docket number FDA-2022-P-1764. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.08.02 15:08:15 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)