U.S. FOOD & DRUG ADMINISTRATION

January 27, 2023

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

Re: Citizen Petition – Docket Number FDA-2022-P-1764

Dear Mr. Jordan:

I am writing to inform you that the Food and Drug Administration (FDA, we) has not yet reached resolution of the issues raised in your citizen petition received by the Dockets Management Staff on August 1, 2022. In the petition, you request FDA take the following actions: (1) formally rescind a letter from the FDA Ombudsman dated February 24, 2003, that you state is now obsolete; (2) declare those engaged in interstate commerce of specified medical products in violation of 42 U.S.C. § 262(a)(1)(A); (3) if such a violation is found, order the violator to cease marketing or submit a complete Biologics License Application (BLA), which you state be done within 60 days of FDA action on your petition; and (4) initiate enforcement proceedings either for violation of the order to cease marketing, or for failure to obtain approval of a BLA within six months of submission.

FDA has been unable to reach a decision on your petition because it raises issues requiring further 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 yours,

Peter Marks

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff

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