U.S. FOOD & DRUG ADMINISTRATION

May 26, 2020

Anthony T. Pierce and Daniel D. Graver
Counsel to Petitioner Verax Biomedical Incorporated
Akin Gump Strauss Hauer & Feld LLP
2001 K Street NW
Washington, DC 20006

Re: Citizen Petition [Docket No. FDA-2019-P-5800]

Dear Mr. Pierce and Mr. Graver:

I am writing to inform you that the Food and Drug Administration (FDA, the Agency, or we) has not yet reached resolution of the issues raised in your Citizen Petition to Refrain from Administrative Action (Petition) filed on behalf of Petitioner, Verax Biomedical Incorporated (Petitioner) and received by the Dockets Management Staff on December 10, 2019. In your petition, you request that the Commissioner of Food and Drugs (the Commissioner) refrain from taking a number of actions. You also request that FDA "apply consistent regulatory standards and precedents in reviewing data in support of such products or expanded claims." Because of the existence of other FDA priorities, we have not been able to reach a decision on the petition at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)(iv)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

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

cc: Division of Dockets Management

U.S. Food and Drug Administration
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