



October 28, 2021

Aaron Siri
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Sent via email to: aaron@sirillp.com

Re: Docket No. FDA-2021-P-0437

Dear Mr. Siri,

I am writing to inform you that the Food and Drug Administration (FDA, the Agency, we) has not yet reached a resolution of the issues raised in your citizen petition received by the Dockets Management Staff on May 6, 2021. In your petition, you request that FDA publicly release documentation sufficient to establish that the aluminum content in certain vaccines is consistent with the amount stated in its labeling and, if unable to do so, pause distribution of those vaccines until the Agency has confirmed and publicly released documentation sufficient to establish that the aluminum content in the vaccines is consistent with the amount stated in its labeling.

Because of the existence of other FDA priorities, we have not been able to complete our final responses at this time. This interim response is provided in accordance with FDA's 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,

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

cc: Dockets Management Staff