



April 19, 2021

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

Sent via email to: aaron@sirillp.com

Re: Docket No. FDA-2020-P-2136

Dear Mr. Siri,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet reached a resolution of the issues raised in your citizen petition (Petition) received by the Dockets Management Staff on October 28, 2020. In your petition, you request that the Commissioner of Food and Drugs require that all manufactures of acellular pertussis-containing vaccines be required to amend their package inserts of these products to disclose that they do not prevent infection and transmission of pertussis.

Because of the existence of other FDA priorities, we have not been able to complete our final response 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 yours,

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

cc: Dockets Management Staff