U.S. FOOD & DRUG ADMINISTRATION

February 16, 2023

Aaron Siri, Esq.
Siri & Glimstad LLP
745 Fifth Avenue, Suite 500
New York, NY 10151

Sent via email to: [redacted]

Re: Docket No. FDA-2022-P-1998

Dear Mr. Siri:

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 23, 2022. In your petition, you request that FDA take certain actions with respect to IPOL for infants, toddlers, and children. Specifically, you request FDA to take two actions:

1. Withdraw or suspend the approval for IPOL for infants, toddlers, and children until a properly controlled and properly powered double-blind trial of sufficient duration is conducted to assess the safety of this product.
2. Amend the product label for IPOL to note that: "IPOL does not prevent intestinal infection and therefore does not prevent poliovirus transmission."

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'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

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

cc: Dockets Management Staff

U.S. Food and Drug Administration
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