



August 24, 2022

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

Sent via email to: aaron@sirillp.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug 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 and amend the product label for IPOL to note that: “IPOL does not prevent intestinal infection and therefore does not prevent poliovirus transmission” was received and processed under CFR 10.30 by this office on 08/23/2022.

It was assigned docket number FDA-2022-P-1998. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency’s decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

CC: Elizabeth A. Brehm, Esq (ebrehm@sirillp.com)
Catherine Cline (ccline@sirillp.com)