March 3, 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-2020-P-1857

Dear Mr. Siri,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet reached resolution of the issues raised in your citizen petition (Petition) received by the Dockets Management Staff on September 4, 2020. Your petition, submitted on behalf of the Informed Consent Action Network (ICAN), requests that FDA withdraw or suspend the approval for Engerix-B and Recombivax HB for infants (excluding infants born to mothers who test positive for HBsAg during pregnancy) and toddlers until a properly controlled and adequately powered double-blind trial of sufficient duration is conducted to assess the safety of these products as required pursuant to applicable federal statutes and regulations for licensing these products.

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)). 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