



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 8, 2020

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

Sent via email to: aaron@sirillp.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA withdraw or suspend the approval for Engerix-B and Recombivax HB for infants and toddlers until a double-blind placebo-controlled trial of sufficient duration is conducted to assess the safety of these products was received by this office on 09/04/2020.

It was assigned docket number FDA-2020-P-1857. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)