

## **FREEDOM OF INFORMATION ACT REQUEST**

**VIA ONLINE PORTAL**

November 12, 2020

Food and Drug Administration  
Division of Freedom of Information  
Office of the Secretariat, OC  
5630 Fishers Lane, Room 1035  
Rockville, MD 20857  
[FDAFOIA@fda.hhs.gov](mailto:FDAFOIA@fda.hhs.gov)

Re: *Clinical Trial Protocols for Recombivax HB (IR#0363)*

Dear Sir or Madam:

This firm represents the Informed Consent Action Network (“ICAN”). On behalf of ICAN, please provide the following records to [foia@sirillp.com](mailto:foia@sirillp.com) in electronic form:

**All full clinical trial protocols for the following Recombivax HB clinical trials:**

<b>Clinical Trial <sup>1</sup></b>	<b>Date Initiated</b>	<b>Total Subjects in Study</b>	<b>Country</b>	<b>Lead Investigator</b>
809 and 809-2 Adults and Children	2/2/1984	22 and 11	Philadelphia, PA	Dr. Stanley Plotkin and Dr. Stuart Starr
819 Teenagers	5/12/1984	165	Greece	Dr. George Papaevangelou and Dr. Charalambos Vissoulis
843 Children		120	Singapore	Dr. Cladd Stevens and Dr. Patricia Giardina

<sup>1</sup> References to each clinical trial number can be found in Partial Production received from FDA’s response to F18-6581 CBER.

862 Infants	2/1985	300	Hong Kong	Dr. E. K. Yeoh
864 Infants	9/1/1984	134	New York, NY	Dr. C. Stevens
865 Infants and Children	2/1/1985	258	Hong Kong	Dr. E. K. Yeoh
878 Infants	7/1985	70+	China	Dr. T. Sun
891 Children	12/1985	200	China	Dr. Hu Zong-Han and Dr. Shi Guiyong
892 Infants	12/1985	200	China	Dr. Z. H. Hu

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

*/s/ Elizabeth A. Brehm*  
Elizabeth A. Brehm, Esq.