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FREEDOM OF INFORMATION ACT REQUEST

VIA FEDEX

August 10, 2018

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Report for each Clinical Trial when approving Recombivax HB in 1986 (IR#0034)

Dear Sir or Madam:

This firm represents Informed Consent Action Network (“ICAN”). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) from the files of the Food and Drug Administration (“FDA”).

By this letter, please provide the following records in FDA’s possession to the above referenced address in electronic form on a CD or DVD:

A copy of the report for each clinical trial relied upon by the FDA when approving Recombivax HB in 1986.

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,

A handwritten signature in black ink, appearing to read 'AS', written in a cursive style.

Aaron Siri, Esq.