Exhibit A

SIRI & GLIMSTAD LLP

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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,

Aaron Siri, Esq.

Exhibit B

August 22, 2018

Siri & Glimstad LLP
Aaron Siri, Esq.
200 Park Ave 17th Floor
New York, NY 10166

In reply refer to file: **2018-6581**

Dear Mr. Siri,

This letter is in partial response to your Freedom of Information Act (FOIA) request dated August 10, 2018, in which you requested "A copy of the report for each clinical trial relied upon by the FDA when approving Recombivax HB in 1986." Your request was received in the Center for Biologics Evaluation and Research (CBER) on August 14, 2018.

In our telephone conversation on August 21, 2018, you informed me that you would like to receive clinical related records that were previously released under FOIA regarding Recombivax HB.

Enclosed are the responsive documents discussed in our telephone conversation. The remainder of your request will be processed as soon as practicable. If you have any additional clarification to provide after seeing these records, please contact us. If these records fulfill your request, please let us know.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information.

In addition, we have withheld portions of pages information under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Information about how to appeal these withholdings will be provided with your final response.

As these records have previously been disclosed, no review charges have been assessed.

The following may be included in a monthly invoice:

Search	0.25 Hours	@ $46.00/hour	$11.50
TOTAL			**$11.50**

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

As we continue to process the remainder of your request, if we can be of further assistance please let us know by referencing the above file number. You can contact me by phone at 240-402-8079 or by e-mail at John.Hyder@fda.hhs.gov. We appreciate your patience and understanding.

Sincerely,

John M. Hyder -S

Digitally signed by John M. Hyder -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John M. Hyder -S, 0.9.2342.19200300.100.1.1=2000432462
Date: 2018.08.22 11:56:35 -04'00'

John Matthew Hyder, Consumer Safety Officer
Access Litigation and Freedom of Information Branch
Center for Biologics Evaluation and Research
Food and Drug Administration