SIRI & GLIMSTAD LLP

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FREEDOM OF INFORMATION ACT REQUEST

VIA EMAIL May 30, 2019

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

Re: Letters from FDA to Merck Regarding Manufacture of Recombivax HB (IR#0121)

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 via email to alucas@sirillp.com:

> **A copy of any and all letters from FDA to Merck regarding or mentioning manufacture of Recombivax HB from January 1, 2016 to January 1, 2018.**

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.

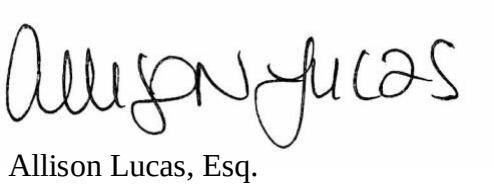
Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld 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 or alucas@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,



Allison Lucas, Esq.
Licensed in MI

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FREEDOM OF INFORMATION ACT REQUEST

VIA EMAIL June 21, 2019

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

Re: FDA Reports Used in Approving Engerix-B in 1989 (IR#0133)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, we hereby request 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").

Please provide the following records in FDA's possession to alucas@sirillp.com in electronic form:

> **A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine.**

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.

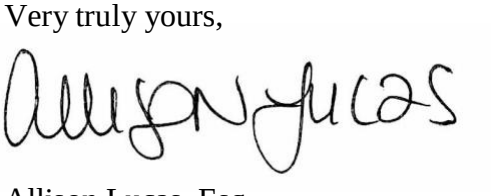
Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe

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 business hours or email me at alucas@sirillp.com. Thank you for your time and attention to this matter.

Very truly yours,



Allison Lucas, Esq.
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