UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- UNITED STATES FOOD AND DRUG ADMINISTRATION Defendant.	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff, as for its Complaint against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. Federal regulations require that "[a]fter a license has been issued" for a biological product by the Food and Drug Administration ("**FDA**"), "data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown." 21 C.F.R. § 601.51(e).

2. The FDA issued a license for the biological product Menveo in 2010 but has not yet disclosed the data and information in the biological product file for this product to the public.

3. The disclosure of this information is a matter of immediate public interest because a leading COVID-19 vaccine being developed by the University of Oxford and AstraZeneca (the "ChAdOx1" or "ChAdOx1 Vaccine") is using Menveo, rather than a placebo, as the control in its clinical trial; and there has been wide and up-to-the minute reporting regarding any development in this clinical trial. Furthermore, the FDA has approved the clinical trial design for the ChAdOx1 Vaccine, and the federal government has poured billions of dollars into AstraZeneca, the company manufacturing and which will sell the ChAdOx1 Vaccine.

4. The data and information underpinning the licensure of Menveo, and in particular its safety profile, is also a matter of urgent public attention because the federal and state governments may soon make ChAdOx1 Vaccine mandatory for many Americans.

5. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a non-profit organization that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. Given its mission, ICAN and its founder, Del Bigtree, have received many inquiries regarding the ChAdOx1 Vaccine. In particular, since ChAdOx1 Vaccine's safety will be compared to the safety of Menveo, instead of to a saline placebo, there is significant interest in reviewing the clinical trials and safety information for Menveo.

6. In order to gather this safety information for Menveo, plaintiff made an expedited request to the FDA pursuant to the Freedom of Information Act (5 U.S.C. §552, as amended) ("**FOIA**") for the data required to be disclosed under 21 C.F.R. § 601.51(e) regarding Menveo, including "all safety and effectiveness data and information."

7. Ignoring both 21 C.F.R. § 601.51(e) and the manifest compelling need for the documents requested, the FDA denied expedited processing for this request.

8. This FOIA request sought documents that the FDA should have easily and promptly been able to produce, as required by both 21 C.F.R. § 601.51(e) and FOIA. ICAN therefore brings this action seeking an order directing Defendant to expeditiously produce records responsive to ICAN's FOIA request.

PARTIES

9. Plaintiff Informed Consent Action Network is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

10. Defendant FDA is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. The FDA is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

FACTS

12. Menveo is a biological product licensed by the FDA on February 19, 2010.[1]

13. Federal regulations provide that "[t]he availability for public disclosure of any record in a biological product file shall be handled in accordance with the provisions of" 21 C.F.R. § 601.51. That section provides, in relevant part, as follows:

> *After a license has been issued*, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown:
>
> (1) All safety and effectiveness data and information.
> (2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61 of this chapter.
> (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:
>
> > (i) Names and any information that would identify the person using the product.
> > (ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.
>
> (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 20.81 of this chapter.

[1] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a5.htm (last visited July 17, 2020).

> (5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in § 20.61 of this chapter.
> (6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of part 20 of this chapter.

(emphasis added).

14. ICAN therefore made the following expedited FOIA request to the FDA on June 11, 2020, mirroring the language in 21 C.F.R. § 601.51(e):

> The following data and information in the biological product file for MENVEO:
>
> (1) All safety and efficacy data and information;
> (2) All protocols for a test or study;
> (3) All adverse reaction reports, product experience reports, consumer complaints, and other similar data and information;
> (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public;
> (5) An assay method or other analytical method; and
> (6) All correspondence and written summaries of oral discussions relating to the biological product file.

(**Exhibit A**).[2]

15. Later the same day, the FDA acknowledged receipt of the FOIA request and assigned the request number 2020-4378. (**Exhibit B**).

16. On June 12, 2020, Katherine Uhl, the FDA Denials and Appeal Officer, sent an email attaching a letter from Sarah B. Kotler, Director, which stated in relevant part:

> This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).
>
> The [request was for the] following data and information in the biological product file for MENVEO: (1) All safety and efficacy data and information; (2) All protocols for a test or study; (3) All adverse reaction reports, product experience reports, consumer

[2] All "Exhibits" referenced herein are appended to this pleading.

> complaints, and other similar data and information; (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public; (5) An assay method or other analytical method; and (6) All correspondence and written summaries of oral discussions relating to the biological product file.
>
> The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."
>
> I have determined that your request for expedited processing does not meet the criteria under the FOIA. *You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity*. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

(**Exhibit C**) (emphasis added).

17. Based on 21 C.F.R. § 601.51(e), obtaining the data requested by Plaintiff should not even require an expedited FOIA request because, absent "extraordinary circumstances," this data should have been "immediately available for public disclosure." 21 C.F.R. § 601.51. The FDA nonetheless disregarded this obligation and stated, without explanation, that there is no "urgency to inform the public concerning actual or alleged Federal Government activity." To the contrary, the requested data is being made by "a person primarily engaged in disseminating information" and there is clear "urgency to inform the public concerning actual or alleged Federal Government activity" regarding the licensure of Menveo, including because Menveo was licensed

by the federal government and the development and production of ChAdOx1, which is being safety tested against Menveo, is being funded by the federal government.

18. One of the leading vaccines for COVID-19 to begin trials in the United Kingdom (and very soon in the United States) is the ChAdOx1 Vaccine being developed by Oxford University and AstraZeneca.

19. Information regarding this vaccine, and in particular the safety and efficacy information, are a matter of immediate concern to the American public, especially given the extensive media and public interest in the fate of the clinical trials for preventing this virus.[3] As Oxford University has publicly explained, its "study aims to assess how well people across a broad range of ages could be protected from COVID-19 with this new vaccine called ChAdOx1. It will also provide *valuable information on safety aspects of the vaccine* and its ability to generate good immune responses against the virus."[4]

20. News outlets have widely reported about this vaccine, its clinical trials and potential timing of availability, which provides additional grounds for rendering the information requested a matter of immediate attention and concern to the American public.[5] "AstraZeneca has [also] received more than $1 billion from the U.S. Health Department's Biomedical Advanced Research and Development Authority to develop a coronavirus vaccine from the University of

[3] *See, e.g.*, https://www.nih.gov/news-events/news-releases/investigational-chadox1-ncov-19-vaccine-protects-monkeys-against-covid-19-pneumonia; https://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials; https://www.cnbc.com/2020/05/21/coronavirus-us-gives-astrazenena-1-billion-for-oxford-vaccine.html; https://www.cnbc.com/2020/06/04/astrazeneca-is-set-to-make-two-billion-doses-of-a-coronavirus-vaccine.html (last visited July 17, 2020).

[4] http://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials (emphasis added) (last visited July 17, 2020).

[5] *See, e.g.*, https://www.nih.gov/news-events/news-releases/investigational-chadox1-ncov-19-vaccine-protects-monkeys-against-covid-19-pneumonia; https://www.cnbc.com/2020/06/04/astrazeneca-is-set-to-make-two-billion-doses-of-a-coronavirus-vaccine.html (last visited July 17, 2020).

Oxford."[6] This funding is being used to start producing this vaccine, even prior to licensure, with reports explaining that AstraZeneca "has agreed to initially supply at least 400 million doses of the vaccine…with first deliveries in September."[7]

21. The study design for the Phase I/II clinical trial of the ChAdOx1 Vaccine initially provided that the control group in this clinical trial would receive a "Saline Placebo."[8] After approving this study design, the FDA inexplicably approved a change of the control from a "Saline Placebo" to "MenACWY."[9] In the United States, the brand name for the MenACWY vaccine is Menveo.[10] The Phase II/III clinical trial for the ChAdOx1 Vaccine similarly provides that the control group will receive the MenACWY vaccine.[11]

22. According to the Centers for Disease Control & Prevention and the FDA, randomized placebo-controlled trials are the standard for determining the safety and efficacy of a new drug or biological product, including new vaccines. A "placebo" is defined as "[a] substance or treatment that has no effect on human beings."[12] Clinical trials for new pharmaceutical products typically do not use a non-inert substance as a control – which is precisely what is happening with ChAdOx1 – because, due to its pharmacological effects, a non-inert substance makes it impossible to isolate the effects of just the experimental product being studied.[13]

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[6] https://www.cnbc.com/2020/05/21/coronavirus-us-gives-astrazenena-1-billion-for-oxford-vaccine.html (last visited July 17, 2020).

[7] https://www.cnbc.com/2020/05/21/coronavirus-us-gives-astrazenena-1-billion-for-oxford-vaccine.html (last visited July 17, 2020).

[8] https://clinicaltrials.gov/ct2/history/NCT04324606 (last visited July 17, 2020).

[9] https://clinicaltrials.gov/ct2/history/NCT04324606?A=1&B=2&C=merged#StudyPageTop

[10] https://www.cdc.gov/vaccines/terms/usvaccines.html (last visited July 17, 2020).

[11] https://clinicaltrials.gov/ct2/show/NCT04400838?term=ChAdOx1+nCoV-19&draw=2&rank=2

[12] https://www.cdc.gov/vaccines/terms/glossary.html (last visited July 17, 2020).

[13] Reflecting the central role of placebos in testing, on May 24, 2020, a member of the FDA's Vaccines and Related Biological Products Advisory Committee, Dr. Paul Offit, told CNN News that, in order to

23. COVID-19 primarily effects the elderly and the National Institute of Aging, an institute within the National Institutes of Health, has likewise explained that:

> In undertaking a clinical trial, researchers don't want to leave anything to chance. They want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The "gold standard" for testing interventions in people is the "randomized, placebo-controlled" clinical trial. ... A placebo is an inactive substance.[14]

24. Where an effective vaccine already exists for an infection, ethical considerations may require using the existing vaccine, rather than a placebo, as the control (an "**active control**"). The FDA's industry guidance explains that an "active control must be a drug whose effect is well defined," which means "historical placebo-controlled trials are available to define the active control effect."[15] The importance of only using an active control that has already been licensed based on a placebo-controlled trial is explained by the FDA as follows:

> The placebo-controlled trial measures the total pharmacologically mediated effect of treatment. In contrast, an active control trial … measures the effect relative to another treatment. The placebo-controlled trial also allows a distinction between adverse events due to the drug and those due to the underlying disease or background noise.[16]

25. Because there is no licensed COVID-19 vaccine, an active control is not appropriate for trials of new COVID-19 vaccines. This is precisely why the FDA, in its guidance entitled *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry*, published

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determine whether a COVID-19 vaccine is safe and effective, "we are waiting for the big trial… the large prospective placebo controlled trial, we have 20,000 people who get a vaccine, 10,000 people who get a placebo, then and only then will you know whether a vaccine is safe and effective." https://www.cnn.com/videos/health/2020/05/24/coronavirus-covid-19-vaccine-trials-vaccinologist-concern-ip-vpx.cnn (emphasis added) (last visited July 17, 2020).

[14] https://www.nia.nih.gov/health/why-are-placebos-important (last visited July 17, 2020).

[15] https://www.fda.gov/media/78504/download (last visited July 17, 2020).

[16] *Id.*

on June 30, 2020, expressly provides that "[l]ater phase trials [for COVID-19 vaccines], including efficacy trials, should be randomized, double-blinded, and **placebo** controlled."[17]

26. Thus, where Menveo is being used as the active control, in contradiction to the FDA's standards, understanding the full safety and efficacy profile of Menveo is critical for understanding the safety and efficacy profile of ChAdOx1. This need is made more acute by the fact that Menveo was not licensed based on a placebo-controlled clinical trial.[18]

27. It is therefore imperative that the public and scientific community have full access to the safety information regarding the active control, Menveo, being used in the clinical trial to license ChAdOx1. It is public knowledge that, "[t]o date AstraZeneca has concluded agreements for at least 400 million doses and secured total manufacturing capacity for 1bn billion doses of the Oxford vaccine."[19] This shows the impending nature of widespread use of this vaccine which is intended to be administered to most Americans, either voluntarily or by compulsion, with the first doses "anticipated to be available in early 2021."[20]

28. Judicial scholars have already begun to opine regarding the legality of mandating any potential COVID-19 vaccine to all adults. Alan Dershowitz, for example, recently stated that

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[17] https://www.fda.gov/media/139638/download (emphasis added)

[18] *Id*. The trade name for MenACWY vaccine in the United States is Menveo. This product was licensed for adults based on a clinical trial in which the control group of 1,966 participants received either Menomune (209 participants) or Menactra (1,757 participants). https://www.fda.gov/media/78514/download (last visited July 17, 2020). Menactra was licensed based on a clinical trial in which Menomune was the active comparator. https://www.fda.gov/media/75619/download (last visited July 17, 2020). Quizzically, the clinical trials section of the package insert for Menomune only lists the clinical trial in which it was used as a comparator against Menactra. https://www.fda.gov/media/83562/download (last visited July 17, 2020). Meaning, the same clinical trial in which Menactra was studied with Menomune as its active control is apparently relied upon by the FDA to support the safety of both of these products. Using any of these products as an active control for a COVID-19 vaccine is unscientific and unacceptable. The control should be a saline placebo.

[19] https://www.ox.ac.uk/news/2020-06-04-brazilian-health-regulatory-agency-approves-trial-oxford-covid-19-vaccine (last visited July 17, 2020).

[20] https://www.precisionvaccinations.com/vaccines/azd1222-sars-cov-2-vaccine (last visited July 17, 2020).

he would support such a mandate, adding that, "if you refuse to be vaccinated, the state has the power to literally take you to a doctor's office and plunge a needle into your arm."[21] Mr. Dershowitz appeared on ICAN's public broadcast, The HighWire with Del Bigtree, to defend this position, including specifically addressing mandating a COVID-19 vaccine for adults.[22]

29. Moreover, states are expected to mandate the vaccine for all their residents. For example, the New York State Bar Association recently issued a report on COVID-19 recommending that, "[w]hen the efficacy of a COVID-19 vaccine has been confirmed" states should "enact legislation requiring vaccination of each person unless the person's physician deems vaccination for his or her patient to be clinically inappropriate."[23] The FDA's parent department has also granted those developing and those who will sell this product broad immunity from liability for injuries.[24] The result could be a product whose administration is required by compulsion of law, where the recipient of the product cannot sue the manufacturer for injury.

30. Given (i) the right to immediate public disclosure of this data under applicable Federal regulations, (ii) the public interest in potential COVID-19 vaccines and their clinical trials, and (iii) the potential for states to mandate its use by nearly all citizens, which is antithetical to informed consent, ICAN submitted its FOIA request to the FDA.

31. The FDA has failed to abide by its duty pursuant to 21 C.F.R. § 601.51 and has failed to recognize the compelling need for this data, forcing ICAN to come before this Court to seek an order directing the FDA to grant expedited processing and production of Plaintiff's FOIA

[21] https://youtu.be/tuoM3QGSUhM (last visited July 17, 2020).

[22] *Id*.

[23] https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf (last visited July 17, 2020).

[24] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last visited July 17, 2020).

request. The information ICAN seeks is simply too important to the current public discourse regarding the COVID-19 pandemic to allow the FDA to hide or delay such information from public scrutiny.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order declaring that it was unlawful for the FDA to fail to grant expedited processing;

c. Enter an Order directing the FDA to, within 5 days, provide the requested information and data in Plaintiff's FOIA request;

d. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

e. Grant such other and further relief as the Court may deem just and proper.

Dated: July 17, 2020

SIRI & GLIMSTAD LLP

Aaron Siri
Elizabeth A. Brehm
200 Park Avenue, 17th Floor
New York, New York 10166
Tel: (212) 532-1091
Counsel for Plaintiff

Exhibit A

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST

REQUEST FOR EXPEDITED PROCESSING

VIA EMAIL June 11, 2020

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: *Safety & Efficacy Data for MENVEO (IR#0305)*

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 in electronic form:

The following data and information in the biological product file for MENVEO:

(1) All safety and efficacy data and information;
(2) All protocols for a test or study;
(3) All adverse reaction reports, product experience reports, consumer complaints, and other similar data and information;
(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public;
(5) An assay method or other analytical method; and
(6) All correspondence and written summaries of oral discussions relating to the biological product file.

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

Specifically, ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. ChAdOx1 nCoV-19 is a leading experimental vaccine against novel coronavirus, SARS-CoV-2, also known as COVID-19. Information regarding this vaccine, and in particular the safety and efficacy information regarding this vaccine, are a matter of immediate concern to the American public, given the extensive media and public interest in the fate of the clinical trials for preventing this virus. *See, e.g.,* https://www.nih.gov/news-events/news-releases/investigational-chadox1-ncov-19-vaccine-protects-monkeys-against-covid-19-pneumonia; http://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials; https://www.cnbc.com/2020/05/21/coronavirus-us-gives-astrazenena-1-billion-for-oxford-vaccine.html; https://www.cnbc.com/2020/06/04/astrazeneca-is-set-to-make-two-billion-doses-of-a-coronavirus-vaccine.html

It has been made public by University of Oxford, the sponsor for the clinical trial for ChAdOx1 nCoV-19, and by AstraZeneca, its developer, that MENVEO will be used as a "control" in its Phase II and Phase III trials of ChAdOx1 nCoV-19. *See* http://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials.; https://clinicaltrials.gov/ct2/show/NCT04400838?term=ChAdOx1+nCoV-19&draw=2&rank=1. The licensure and safety information regarding MENVEO requested herein are therefore of immediate concern to the American public. It is imperative that the public have full access to the safety information regarding the active control, MENVEO, being used in the clinical trial to license the COVID vaccine, ChAdOx1 nCoV-19, including because this vaccine is intended to be administered to most Americans, either voluntarily or by compulsion. *See, e.g.,* https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf (last visited June 2, 2020) (The New York State Bar Association report on COVID-19 recommending that "[w]hen the efficacy of a COVID-19 vaccine has been confirmed, enact legislation requiring vaccination of each person unless the person's physician deems vaccination for his or her patient to be clinically inappropriate."); https://youtu.be/tuoM3QGSUhM (Constitutional Scholar and Harvard Law Professor Alan Dershowitz stating that he would support mandating a COVID-19 vaccine and that "if you refuse to be vaccinated, the state has the power to literally take you to a doctor's office and plunge a needle into your arm.")

Moreover, news articles have widely reported about the above vaccine and its clinical trials which provide an additional ground for rendering the information requested above a matter of immediate attention and concern to the American public. *See, e.g.,* https://www.nih.gov/news-events/news-releases/investigational-chadox1-ncov-19-vaccine-protects-monkeys-against-covid-19-pneumonia; http://www.ox.ac.uk/news/2020-05-22-oxford-covid-19-vaccine-begin-phase-iiiii-human-trials; https://www.cnbc.com/2020/05/21/coronavirus-us-gives-astrazenena-1-billion-for-oxford-vaccine.html; https://www.cnbc.com/2020/06/04/astrazeneca-is-set-to-make-two-billion-doses-of-a-coronavirus-vaccine.html

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about public health safety and provide the public with information to give informed consent

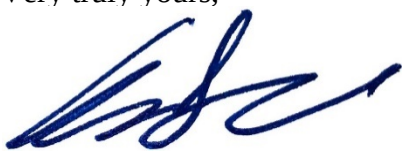
regarding related health interventions. As part of its mission, ICAN investigates and disseminates information regarding public health safety issues, including through their website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to its mission. The information requested in this FOIA request 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, at most, 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 via email at foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,



Aaron Siri, Esq.

Exhibit B

Subject: FDA Receipt of FOI Request
Date: Thursday, June 11, 2020 at 1:57:59 PM Pacific Daylight Time
From: FDA_FOI@fda.gov
To: S&G Information Request Staff

Informed Consent Action Network Informed Consent Action Network

Re: Confirmation # FDA2065541
Requester Ctrl #:
In Reply refer to: 2020-4378

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

The following data and information in the biological product file for MENVEO: (1) All safety and efficacy data and information; (2) All protocols for a test or study; (3) All adverse reaction reports, product experience reports, consumer complaints, and other similar data and information; (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public; (5) An assay method or other analytical method; and (6) All correspondence and written summaries of oral discussions relating to the biological product file.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Rochelle A. Coleman, Information Technician at 301-796-8982 or write to us at:

Division of Freedom of Information,
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Fax: 301-827-9267

You also have the right to seek dispute resolution services from:

FDA FOIA Public Liaison
Office of the Executive Secretariat
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-Mail: FDAFOIA@fda.hhs.gov

and/or:

Office of Government
Information Services
National Archives and Administration
8601 Adelphi Road - OGIS
College Park, MD 20740-6001

College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-Mail: ogis@nara.gov
Fax: 202-741-5769

Note: Do NOT reply directly to this E-mail

Exhibit C

U.S. FOOD & DRUG ADMINISTRATION

June 12, 2020

INFORMED CONSENT ACTION NETWORK
INFORMED CONSENT ACTION NETWORK
10200 US HWY 290 W
Suite 301
Austin TX 78736 US

In Reply refer to:

2020-4378

Requester Control #:

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

The following data and information in the biological product file for MENVEO: (1) All safety and efficacy data and information; (2) All protocols for a test or study; (3) All adverse reaction reports, product experience reports, consumer complaints, and other similar data and information; (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public; (5) An assay method or other analytical method; and (6) All correspondence and written summaries of oral discussions relating to the biological product file.
The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. Your appeal must be mailed within 90 days from the date of this response, to: Agency Chief FOIA Officer, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue, S.W., Washington, DC 20201; e-mail FOIARequest@PSC.hhs.gov. Please clearly mark both the envelope and your letter or email “FDA Freedom of Information Act Appeal.”

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact this office at: DFOI, 5630 Fishers Lane, Room 1035, Rockville, MD 20857, 301-796-3900, FDAFOIA@fda.hhs.gov.

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman’s office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely Yours,

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2020.06.12 10:03:05 -04'00'

SARAH KOTLER
Director