UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiffs, -against- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	**STIPULATION & ORDER** 1:20-cv-05554 (JPO)

WHEREAS, federal regulations require that "[a]fter a license has been issued" for a biological product by the Food and Drug Administration ("**FDA**"), certain "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);

WHEREAS, the FDA issued a license for the biological product Menveo on February 19, 2010;[1]

WHEREAS, ICAN sought the clinical trial information for Menveo since ICAN understood it was being used as a control in the clinical trial for the AstraZeneca COVID-19 vaccine and, 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

[1] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a5.htm (last visited April 14, 2021).

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.

WHEREAS, on June 12, 2020, the FDA denied ICAN's request for expedited processing;

WHEREAS, on July 17, 2020, ICAN commenced a lawsuit in the United States District Court, Southern District of New York against the FDA demanding that it produce the documents responsive to the foregoing FOIA Request;

WHEREAS, in the interests of resolving the litigation, ICAN narrowed its requests and the FDA produced the following documents on or before the respective dates:

(1) **September 16, 2020:** Integrated Summary of Clinical Safety (ISS) dated 11 July 2008. **September 30, 2020:** the ISS-associated tables.
(2) **September 30, 2020:** the "License Action Recommendation Documents" requested by ICAN.
(3) **October 14, 2020:** available synopses for studies identified by ICAN.
(4) **October 14, 2020:** available synopses for each of the amendments to STN 125300/0 for which FDA previously provided details.
(5) **October 30, 2020:** PAERs, without appendices, submitted for STN 125300.
(6) **January 27, 2021:** Clinical trial protocols for V59P13, V59P17, V59P18, V59P6, and V59P11.

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel that:

1. Pursuant to the FDA's representations that (a) the foregoing constitutes the complete universe of responsive documents as agreed upon by the parties (b) discovered after an adequate search, the above-captioned action is voluntarily dismissed, with prejudice pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorneys' fees, and expenses;

2. ICAN reserves all rights to seek additional documents, whether or not related to this request, through pending or future FOIA requests to the FDA or any other governmental agency as appropriate and nothing herein shall restrict such right; and

3. This stipulation may be signed in counterparts and electronic (PDF) or fax signatures may be deemed originals for all purposes.

Dated: April 16, 2021
New York, New York

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Dated: April 15, 2021
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SO ORDERED:

_____
J. Paul Oetken U.S.D.J.

Dated: New York, New York
April __, 2021