FDA FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL June 4, 2025

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

Re: *Moderna MNEXSPIKE Biological Product File (IR#1213)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**") and Mississippi Medical Professionals for Informed Consent ("**MMPFIC**").

On May 30, 2025, the Food and Drug Administration ("**FDA**") approved the Moderna[1] COVID-19 Vaccine, marketed as MNEXSPIKE (the "**Moderna Vaccine**"), for use in individuals who have been previously vaccinated with any COVID-19 vaccine and are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. On behalf of ICAN and MMPFIC, please provide the following records to foia@sirillp.com in electronic form:

> **The entire Biologics License Application, including but not limited to all data and information enumerated in 21 C.F.R. § 601.51(e)[2] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System,[3] for the Moderna Vaccine.**

[1] For purposes of this request, Moderna shall be interpreted to include Moderna, Inc. and any of its parents, subsidiaries, and affiliates.

[2] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) 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 . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[3] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

I. EXPEDITED PROCESSING REQUESTED

ICAN and MMPFIC request expedited processing for this request as they meet the requirements for expedited processing under both FDA's Freedom of Information Act ("**FOIA**") Regulations as well as FOIA itself.

A. ICAN and MMPFIC Qualify for Expedited Processing Under FOIA

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," 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).

Here, ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety, other medical treatments, environmental pollutants and toxins, and overall health choices, and to provide the public with information needed in order to give informed consent. As part of its mission, ICAN actively investigates and disseminates scientifically-based health information regarding the safety of vaccines, other medical treatments, environmental pollutants and toxins, and governmental activities for free through its website,[4] a weekly health news and talk show,[5] and through press events and releases. The HighWire website has approximately 3.4 million weekly visitors. On X (formerly known as Twitter), The HighWire has approximately 231,000 followers and 1 to 2.5 million impressions in a 28-day period. On Rumble, The HighWire has approximately 94,000 followers and growing. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

Additionally, MMPFIC is a not-for profit organization comprised of medical professionals throughout the state of Mississippi whose mission is to raise public awareness about vaccine safety, other medical treatments, and overall health choices, and to provide the public with information needed in order to give informed consent. MMPFIC is seeking the information in this FOIA request to allow it to contribute to the public understanding of government programs and actions and any potential effects of those programs and actions on public health.

Therefore, ICAN and MMPFIC are "primarily engaged in disseminating information [] to inform the public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," which in this case is the data and information underlying the licensure of the Moderna Vaccine. Accordingly, expedited processing of this request under FOIA is warranted.

[4] https://www.icandecide.org/.

[5] https://thehighwire.com/.

B. ICAN and MMPFIC Qualify for Expedited Processing Under FDA's FOIA Regulations

Notably, separate and apart from FDA's obligation to comply with FOIA, it has an independent duty to inform the public concerning the data and information underlying a licensed vaccine. FDA's Regulations expressly provide that "[a]fter 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 . . ." 21 C.F.R. § 601.51(e)(1) (emphasis added). Thus, FDA's own regulations expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* This policy supports FDA's assurances of transparency[6] and Department of Health and Human Services Secretary Robert F. Kennedy, Jr.'s commitment to "radical transparency,"[7] as a lack of transparency erodes the confidence the medical and scientific communities and the public have in the conclusions reached by FDA. However, the fact that FDA did not release the documents following licensure necessitated this FOIA request.

But aside from FDA's duty to make immediately available the safety and effectiveness data of a licensed vaccine, FDA's FOIA regulations anticipate scenarios where FOIA requests must be expedited. Specifically, a requestor is entitled to expedited processing where:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c)(1)-(3).

ICAN and MMPFIC easily meet all three requirements. As noted above, ICAN actively investigates and disseminates scientifically-based health information, and MMPFIC is comprised of medical professionals whose mission is to raise public awareness about vaccine safety, other medical treatments, and overall health choices, and to provide the public with information needed in order to give informed consent. Therefore, ICAN and MMPFIC are certainly "primarily engaged in disseminating information to the general public." 21 C.F.R. § 20.44(c)(1).

---

[6] https://www.fda.gov/news-events/speeches-fda-officials/fostering-transparency-improve-public-health (last visited 06/03/2025).

[7] https://x.com/SecKennedy/status/1894179693533762036 (last visited 06/03/2025).

Next, there is plainly an urgent public need for transparency with regard to the data relied upon in licensing the Moderna Vaccine for at least one distinct reason beyond FDA's own regulations which admit the urgent need for transparency and disclosure of this information. As required by Congress, FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[8] 21 C.F.R. 601.2(a). There are, however, concerns regarding the adequacy of the data and information, and analyses of same, relied upon by FDA to license the Moderna Vaccine.

ICAN and MMPFIC incorporate by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm FDA's conclusion and thus increase confidence in the safety and efficacy of the Moderna Vaccine.

Finally, ICAN and MMPFIC's request meets the third requirement for expedited processing – that "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(3). Here, ICAN and MMPFIC's records request specifically concerns identifiable activities—i.e., approval of the Moderna Vaccine—by the Federal Government—to wit, FDA.

In light of the above, ICAN and MMPFIC have demonstrated that their request qualifies for expedited processing under both FDA's FOIA regulations, as well as FOIA itself. ICAN and MMPFIC certify that the information in this request is true and correct to the best of their knowledge and belief.

II. FEE WAIVER REQUEST

ICAN and MMPFIC are nonprofits and ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of

[8] FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 06/03/2025). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 06/30/2025); https://www.fda.gov/about-fda/what-we-do (last visited 06/30/2025).

the Moderna Vaccine and the clinical trials underlying FDA's approval of same. The information ICAN and MMPFIC request will not contribute to any commercial activities.

Note that in the event only a portion or 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 or can be deidentified. We further request that you describe any redacted, 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 interest of the public. Such statements may help to avoid unnecessary appeal and litigation. ICAN and MMPFIC reserve all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. 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 and MMPFIC may immediately file an administrative appeal or an action.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (240) 732-6737 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Sincerely,

/s/ Aaron Siri

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
745 Fifth Ave., Suite 500
New York, NY 10151
foia@sirillp.com
(240) 732-6737