Exhibit 3

U.S. FOOD & DRUG ADMINISTRATION

June 6, 2022

Appeal No.: 22-0036AA
FDA Case No: 2022-908

Travis Miller
Defending the Republic
2911 Turtle Creek Blvd., Ste. 300
Dallas, TX 75219

Dear Mr. Miller:

This responds to your February 9, 2022, appeal of the Food and Drug Administration's (FDA's) decision to deny expedited processing of your February 3, 2022, Freedom of Information Act (FOIA)[1] request on behalf of Defending the Republic. Your FOIA request seeks: "all data and information submitted by Moderna relating to the FDA review and approval of Spikevax. This includes, but is not limited to, all safety and effectiveness data and information; all data and information in the biological product file; and all ingredients."

As part of your FOIA request, you asked for expedited processing on the basis that there is a "compelling need for the processing of these records: it is urgent to inform the public of the Federal Government activity informed by the requested information."

On February 9, 2022, the FDA denied your request for expedited processing, explaining that the request did not meet the FOIA's requirements of demonstrating a "compelling need" involving either an imminent threat to the life or physical safety of an individual or an urgency to inform the public about an actual or alleged Federal Government activity.

On February 9, 2022, on behalf of Defending the Republic, you appealed the FDA's decision to deny the request for expedited processing. In your appeal letter, you stated that the original denial for expedited processing should be reversed for the following reason: "the public and the medical community have an urgent and compelling interest in analyzing the data and information underlying the FDA's approval of Moderna's COVID-19 vaccine."

After conducting a thorough review of your appeal, we have determined that you have not demonstrated a compelling need for expedited processing. Therefore, we have decided to uphold the FDA's decision to deny the request for expedited processing.

Expedited Processing
The FOIA directs agencies to provide for expedited processing of FOIA requests "in cases in which the person requesting the records demonstrates a compelling need," and "in other cases as determined by

[1] 5 U.S.C. § 552

the agency."[2] Under the FOIA, a requester can show a "compelling need" in one of two ways: (1) by establishing that failure to obtain the records quickly "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual"[3]; or (2) if the requester is a "person primarily engaged in disseminating information," by demonstrating that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists.[4]

In your appeal letters, you attempted to demonstrate a "compelling need" on the basis that an expedited release of the information is necessitated by an "an urgency to inform the public about alleged government activity." Therefore, we have analyzed your request for expedited processing under the need to inform category of the "compelling need" standard.

Urgency to Inform the Public Concerning Actual or Alleged Federal Government Activity

To satisfy the threshold for the second category of the "compelling need" standard,[5] FDA's FOIA regulations specify that you must demonstrate that (1) you are "primarily engaged in disseminating information to the general public and not merely to a narrow interest group"; (2) "[t]here 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"; and (3) "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government."[6] To qualify for this category of "compelling need," you must meet all three criteria.

For the purposes of this appeal, we assume that you meet the first and third criteria with respect to whether Defending the Public is "primarily engaged in disseminating information to the general public and not merely to a narrow interest group" and that the subject of the requested records "specifically concerns identifiable operations or activities of the Federal Government." However, with respect to the second criterion, you have not demonstrated that there is an "urgent need for the requested information and that is has a particular value that will be lost if not obtained and disseminated quickly."

When evaluating whether a requester has demonstrated an "urgency to inform the public," and hence, "compelling need," it is necessary to consider at least three factors: (1) whether the request concerns a matter of exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.[7] As part of this analysis, the requester must demonstrate that 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."[8] Courts have routinely stated that in order to establish that there is an "urgency to inform" the public about the subject of a request, a "requester must show that the request concerns a 'breaking news story of general public interest,'"[9] and that there is "widespread and intense media interest in the subject matter of the request in the time period immediately prior to when the request

[2] 5 U.S.C. § 552(a)(6)(E)(i).
[3] 5 U.S.C. § 552(a)(6)(E)(v)(I).
[4] 5 U.S.C. § 552(a)(6)(E)(v)(II).
[5] 21 C.F.R. § 20.44(a)(2).
[6] 21 C.F.R. § 20.44(c).
[7] *Bloomberg, L.P. v. United States Food & Drug Admin.*, 500 F. Supp. 2d 371, 377 (S.D.N.Y. 2007) (quoting *Al-Fayed v. C.I.A.*, 254 F.3d 300, 310 (D.C. Cir. 2001).
[8] 21 C.F.R. 20.44(c)(2).
[9] *Treatment Action Grp. v. Food & Drug Admin..*, 2016 U.S. Dist. LEXIS 127877 at *27 (D. Conn. Sept. 20, 2016) (quoting *Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 123 (D.D.C. 2013)).

was made."[10] Moreover, courts have noted that it is not enough for a request to concern a topic that is newsworthy; the topic must be the subject of a currently unfolding story.[11]

The records at issue in the request are for all data and information submitted by Moderna relating to the FDA review and approval of Spikevax. Since approval of the product, the following records are available on FDA's website – Spikevax information approval package and reviews, advisory committee documents and a host of related information, including Frequently Asked Questions for Spikevax, information sheets for healthcare providers, regulatory information, and media materials (see: Spikevax and Moderna COVID-19 Vaccine | FDA). The website even includes translations of certain information in multiple languages, including Spanish, Chinese, Korean, Vietnamese, and Tagalog. Notably, FDA's website contains the package insert, the patient package insert, the Summary Basis for Regulatory Action, the Approval Letter, FDA decision memoranda, and approval history. These records often contain summaries of the information and data submitted by the applicant that FDA reviewed and assessed, as well as FDA's assessment, that support FDA's decision to license the Spikevax vaccine. You have not shown that receiving data and information not already posted to the FDA webpage regarding this approved product has particular urgency. Moreover, you have not demonstrated that these records have a particular value that would be lost if not obtained and disseminated quickly.

Finally, when considering granting expedited processing, it is necessary not to forget the interests of all requesters in having their requests treated equally, as well as the public interest in the integrity of the FOIA process. Because a decision to grant expedited processing of a FOIA request necessarily entails further delay for other requests, fairness demands that it be made only after ensuring it meets the standard for expedited processing set forth above.[12]

For the foregoing reasons, your request does not satisfy the "urgency to inform the public" standard. Your appeal letter does not demonstrate that the records requested have a particular value that will be lost if not obtained quickly, nor does it suggest that "delaying a response would compromise a significant recognized interest." As noted above, FDA has posted extensive information describing the agency's scientific analysis and basis for approval of this drug. Because you do not meet the relevant criteria for expedited processing, your request for expedited processing is denied.

At this time, FDA's Center for Biologics Evaluation and Research has placed your request in the complex queue and estimates that it will respond to your request within approximately 18-24 months. This estimate is based on the complexity of your request and the current FOIA backlog.

Moving forward, the FDA can further assist you with the processing of your request. If at any point in the FOIA process you need assistance with the processing of your request, you may contact the FDA's FOIA Public Liaison. This individual can assist you in the processing of your request, increasing transparency and understanding of the status of your request, and assisting to resolve any FOIA disputes. The FDA's

[10] *Treatment Action Grp. v. Food & Drug Admin*, 2016 U.S. Dist. LEXIS 127877 at *28 (D. Conn. Sept. 20, 2016) (citing *Wadelton*, 941 F. Supp. 2d at 123-24).
[11] *Al-Fayed*, 254 F.3d at 311.
[12] *See, e.g.*, H.R. Rep. No. 104-795, at 26 (1996) ("The public's right to know, although a significant and important value, would not by itself be sufficient to satisfy this standard…Given the finite resources generally available for fulfilling FOIA requests, unduly generous use of the expedited processing procedure would unfairly disadvantage other requestors who do not qualify for its treatment."); *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001) ("Indeed, an unduly generous approach would also disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none.").

FOIA Public Liaison can be reached using the following contact information:

FDA FOIA Public Liaison
Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room-1050
Rockville, MD 20857

E-mail: FDAFOIA@fda.hhs.gov

Finally, you may seek assistance with the processing of your request from the Office of Government Information Services (OGIS). OGIS serves as the Federal FOIA ombudsman and assists requesters and agencies to prevent and resolve FOIA disputes through mediation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov; or, via U.S. Mail at:

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

This letter constitutes the final decision of the Department of Health and Human Services regarding your appeal. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside, have your principal place of business, in which the agency records are located, or in the District of Columbia.

Sincerely,

Martina H. Varnado -S
Digitally signed by Martina H. Varnado -S
Date: 2022.06.06 09:57:58 -04'00'

Martina H. Varnado
Director, Office of Executive Secretariat