U.S. FOOD & DRUG ADMINISTRATION

October 29, 2021

Appeal No.: 21-037AA
FDA Case No: 2021-4770

Gene Hamilton
America First Legal Foundation
600 14th Street, NW
5th Floor
Washington, DC 20005

Dear Mr. Hamilton:

This responds to your July 28, 2021, appeal of the Food and Drug Administration's (FDA's) decision to deny expedited processing of your July 16, 2021, Freedom of Information Act (FOIA)[1] request. Your FOIA request seeks:

1. All records, including, but not limited to, electronic mail, texts, memoranda, and handwritten notes, of, regarding, referring, or relating to any efforts to flag COVID-19 or COVID-19 vaccine related "misinformation" or "disinformation" to any social media company, including but not limited to Facebook, Twitter, TikTok, Instagram, Snapchat, Reddit, YouTube, LinkedIn, Tumblr, and Pinterest. The timeframe for this request is January 20, 2021, to date the records request is processed.
2. All records, including, but not limited to, electronic mail, texts, memoranda, and handwritten notes sufficient to show any and all communications with any social media company, including but not limited to Facebook, Twitter, TikTok, Instagram, Snapchat, Reddit, YouTube, LinkedIn, Tumblr, and Pinterest, regarding any efforts to flag COVID-19 or COVID-19 vaccine related "misinformation" or "disinformation". The timeframe for this request is January 20, 2021, to date the records request is processed.
3. All records, including, but not limited to, communications with any email address for a White House office or individual serving in the White House, including those ending in "@who.eop.gov" or "@nsc.eop.gov" of, regarding, or relating to the "flagging" of "disinformation" to any social media company, including but not limited to Facebook, Twitter, Instagram, TikTok, Snapchat, Reddit, YouTube, LinkedIn, Tumblr, and Pinterest. The timeframe for this request is January 20, 2021, to date the records request is processed.
4. All records, including, but not limited to, electronic mail, texts, memoranda, and handwritten notes sufficient to show how FDA and/or the Administration will determine the veracity of any given post.
5. All records, including, but not limited to, electronic mail, texts, memoranda, and handwritten notes, sufficient to show who will decide what is

[1] 5 U.S.C. § 552

> "misinformation" and the basis on which they will make that determination.
> 6. All records, including, but not limited to, electronic mail, texts, memoranda, and handwritten notes, sufficient to show who will decide what is "disinformation" and the basis on which they will make that determination.
> 7. All communications with any email address ending in "@facebook.com". The timeframe for this request is January 20, 2021, to date the records request is processed.
> 8. All communications with any email address ending in "@twitter.com". The timeframe for this request is January 20, 2021, to date the records request is processed.
> 9. All communications with any email address ending in "@instagram.com". The timeframe for this request is January 20, 2021, to date the records request is processed.
> 10. All communications with any email address ending in "@youtube.com". The timeframe for this request is January 20, 2021, to date the records request is processed.
> 11. All records sufficient to show the identities of every natural or legal person engaged in "disinformation research and tracking" referenced by Ms. Psaki. The time frame for this request is January 20, 2021, to the date this records request is processed.
> 12. All records sufficient to show the identities of each of the "members of our senior staff" referenced by Ms. Psaki.

As part of the FOIA request, you asked for expedited processing. On July 26, 2021, the FDA denied the 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 made by a person primarily engaged in disseminating information.

On July 28, 2021, 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 urgency to inform the public should be self-evident. The activity described involves the federal government engaging in content moderation and viewpoint discrimination, with the help of the largest online companies in the world. This is a blatant attack on the heart of the rights protected by the First Amendment to the United States Constitution and a matter of intense public interest.

You further state that there is a compelling need because "given the strength of the public interest, and the strong possibility the public will have only a limited amount of time to express its opinions on this matter before those opinions themselves are deemed "disinformation" and censored, expedited processing is proper."

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 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 letter, you attempted to demonstrate a "compelling need" on the basis that an expedited release of the information is necessitated by a "urgent need to inform the public about actual or alleged Federal 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, it is not disputed that you meet the first and third criteria with respect to whether American First Legal is "primarily engaged in disseminating information to the general public and not merely to a narrow interest group" or 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

[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).

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 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]

Your appeal does not demonstrate that this matter is the subject of a currently unfolding story for which there is widespread media interest. Although you refer to a few articles written immediately after the statements made by the White House Press Secretary, you have not provided evidence that this issue became the subject of widespread public interest. FDA routinely works on many matters that are the subject of great public interest and great debate. It is not unusual for ten or more news outlets across the country to report on a matter related to the agency's work, and FDA must respond to FOIA requests across all the matters of significant public interest that it covers.

You also have not demonstrated that the records you seek have a particular value that will be lost if not obtained and disseminated quickly. Your appeal focuses solely on your view that the matter is of great public interest. You state that "given the strength of the public interest, and the strong possibility the public will have only a limited amount of time to express its opinions on this matter before those opinions themselves are deemed 'disinformation' and censored, expedited processing is proper." You have not, however, provided any support for this assertion. We find, therefore, that you have not satisfied this requirement to justify expedited processing. FDA will process the request for any responsive records when the request comes up in the queue.

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 concerning actual or alleged Federal government activity" standard. Your appeal does not demonstrate that the request involves a topic that is the subject of a "breaking news story of general public interest," nor does it suggest that "delaying a response would compromise a significant recognized interest." Because you do not meet the "compelling need" standard in 21 CFR 20.44(a)(2), including the relevant criteria for expedited processing, FDA's decision to deny your request for expedited processing is upheld and your appeal is denied.

At this time, FDA's Office of the Commissioner 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

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[9] *Treatment Action Grp.*, 2016 U.S. Dist. LEXIS 127877 at *27 (quoting *Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 123 (D.D.C. 2013)).
[10] *Treatment Action Grp.*, 2016 U.S. Dist. LEXIS 127877 at *28 (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.").

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 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: 2021.10.29 11:04:57 -04'00'

Martina H. Varnado
Director, Office of Executive Secretariat