May 17, 2022

VIA ELECTRONIC MAIL – FDAFOIA@fda.hhs.gov

Director, Office of the Executive Secretariat
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857

Freedom of Information Act Request: Food and Drug Administration's Handling of the Recent Nationwide Shortage of Baby Formula

Dear Sir or Madam:

America First Legal Foundation is a national, nonprofit organization working to promote the rule of law in the United States, prevent executive overreach, and ensure due process and equal protection for all Americans, all to promote public knowledge and understanding of our laws and of the individual rights guaranteed under the Constitution of the United States. To that end, we file Freedom of Information Act (FOIA) requests on issues of pressing public concern, then disseminate the information we obtain, making documents broadly available to the public, scholars, and the media. Using our editorial skills to turn raw materials into distinct work, we distribute that work to a national audience through traditional and social media platforms. AFL's email list contains over 25,000 unique addresses, our Twitter page has over 13,000 followers, the Twitter page of our Founder and President has over 170,700 followers, and we have another 29,000 followers on GETTR.

Pursuant to 5 U.S.C. § 552(a), AFL requests the following records.

I. Custodians

We request relevant records from the following specific Food and Drug Administration (FDA) custodians:

A. Robert M. Califf, M.D.
B. Janet Woodcock, M.D.
C. Julia C. Tierney, J.D.
D. Mark Raza
E. Jacqueline A. O'Shaughnessy, Ph.D.
F. Andi Lipstein Fristedt
G. Frank Yiannas

H. James Sigg
I. Erica Jefferson
J. RADM Richardae Araojo, Pharm. D.
K. Kaveeta Vasisht, M.D., Pharm. D.
L. Judith A. Meekin, Pharm. D.
M. Patrizia Cavazzoni
N. Susan T. Mayne, Ph.D.

In addition to the above specific custodians, we request relevant records from all political appointees, and all career employees with a grade equivalent to GS-14 or higher, in the following FDA components:

A. Office of the Commissioner
B. Office of Food Policy and Response
C. Office of Operations
D. Office of External Affairs
E. Office of Minority Health and Health Equity
F. Office of Women's Health
G. Center for Food Safety and Applied Nutrition

II. Records Request

The timeframe for each request is February 1, 2022, to the date this records request is processed.

A) All calendar items that reference or include the terms "formula" and any of the following: "shortages," "safety", or "import."

B) All records of or referencing baby formula shortages or safety issues with the manufacture or importation of baby formula.

C) All records containing the terms "price gouging" and "formula."

D) All records containing or referencing proposals to import internationally manufactured baby formula.

III. Processing

The Food and Drug Administration must comply with the processing guidance in the Attorney General's Memorandum on Freedom of Information Act Guidelines.[1] This means, among other things, the following.

[1] U.S. Dep't Just. (Mar. 15, 2022), https://www.justice.gov/ag/page/file/1483516/download.

- The Food and Drug Administration may withhold responsive records only if: (1) the agency reasonably foresees that disclosure would harm an interest protected by one of the nine exemptions that FOIA enumerates; or (2) disclosure is prohibited by law.

- Information that might technically fall within an exemption should not be withheld from AFL unless FDA can identify a foreseeable harm or legal bar to disclosure. In case of doubt, openness should prevail.

- If FDA determines that it cannot make full disclosure of a requested record, then the FOIA requires that it consider whether partial disclosure of information is possible and take reasonable steps necessary to segregate and release nonexempt information.

- The Food and Drug Administration must properly apply the foreseeable harm standard. That means it must confirm and demonstrate to AFL that it has considered the foreseeable harm standard when reviewing records and applying FOIA exemptions.

- Redactions are disfavored as the FOIA's exemptions are exclusive and must be narrowly construed. If a record contains information responsive to a FOIA request, then FDA must disclose the entire record, as a single record cannot be split into responsive and non-responsive bits. Our request includes any attachments to those records or other materials enclosed with a record when transmitted. If an email is responsive to our request, then our request includes all prior messages sent or received in that email chain, as well as any attachments.

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics. In conducting your search, please give full effect to all applicable authorities and broadly construe our request and your obligations to provide responsive records.

- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA. It is not adequate to rely on policies and procedures that require officials to move records to official systems within a certain time. AFL has a right to records in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.

- Please use all available tools to conduct a complete and efficient search for potentially responsive records. Many agencies have adopted the National Archives and Records Administration ("NARA") Capstone program or similar policies. These provide options for searching emails and other electronic records in a manner reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; you may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- If some portions of the requested records are properly exempt from disclosure, then please disclose any reasonably segregable non-exempt portions of the requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.

- Please take appropriate steps to ensure that records responsive to this request are not deleted before our requests are processed. If potentially responsive records are subject to potential deletion, including on a scheduled basis, please prevent deletion by instituting a litigation hold or other appropriate measures.

IV. Fee Waiver Request

Per 5 U.S.C. § 552(a)(4)(A)(iii), AFL requests a waiver of all search and duplication fees associated with this request.

First, AFL is a qualified non-commercial public education and news media requester. AFL is a new organization, but it has already demonstrated its commitment to the public disclosure of documents and creation of editorial content through regular substantive analyses posted to its website. For example, its officials routinely appear on national television and use social media platforms to disseminate the information it has obtained about federal government activities. In this case, AFL will make your records and your responses publicly available for the benefit of citizens, scholars, and others. The public's understanding of your policies and practices will be enhanced through AFL's analysis and publication of the requested records. As a nonprofit organization, AFL does not have a commercial purpose and the release of the information requested is not in AFL's financial interest. This has previously been recognized by the Departments of Defense, Education, Energy, Interior, and Homeland Security, and the Office of the Director of National Intelligence.

Second, waiver is proper as 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."[2]

[2] 5 U.S.C. § 552(a)(4)(A)(iii).

V. Request for Expedited Processing

AFL requests expedited processing for the above-requested items under 5 U.S.C. § 552(a)(6)(E) and 21 C.F.R. § 20.44(a)(2). This section states as follows: "With respect to a request made by a person primarily engaged in disseminating information, [when] there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government Activity", then, "The Food and Drug Administration will provide expedited processing of a request for records."[3]

As other federal agencies have acknowledged in granting AFL expedited processing, AFL is primarily engaged in disseminating information. Additionally, as reflected by the widespread and exceptional media interest in and attention to the baby formula crisis, there is an urgency to inform the public regarding the circumstances surrounding the sudden shortage of baby formula and the FDA's efforts to ease the shortage.[4] The subject is of pressing import to the millions of families struggling to pay for baby formula that has spiked in price, and for the millions more who cannot find formula at all.[5]

In support of its request for expedited processing, AFL certifies its compelling need for expedited processing under 5 U.S.C. § 552(a)(6)(E) and 21 C.F.R. § 20.44(a)(2), and certifies that the contents of this letter are true and correct to the best of AFL's knowledge and belief, as required by 21 C.F.R. § 20.44(d).

VI. Production

To accelerate release of responsive records, AFL welcomes production on an agreed rolling basis. If possible, please provide responsive records in an electronic format by email. Alternatively, records in native format or in PDF format on a USB drive. Please send any responsive records being transmitted by mail to America First Legal Foundation, 611 Pennsylvania Avenue, SE, #231, Washington, D.C. 20003.

VII. Conclusion

If you have any questions about how to construe this request for records or believe further discussions regarding search and processing would facilitate a more efficient production of records of interest to AFL, please do not hesitate to contact me at

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[3] 21 C.F.R. § 20.44(a).

[4] Rob Wile, *FDA Says it Will Take 'Weeks' to Replenish Baby Formula Stock*, NBC NEWS (May 17, 2022), https://tinyurl.com/2p8y3pay: Janelle Randazza, *Baby Formula 101: Everything You Need to Know During the Baby Formula Shortage*, USA TODAY (May 17, 2022), https://tinyurl.com/mw26zhfw.

[5] Khaleda Rahman, *Baby Formula Shortage 2022: Authorities Warn Sellers Against Price Gouging*, NEWSWEEK (May 12, 2022), https://tinyurl.com/2p932pkr.

FOIA@aflegal.org. Finally, if AFL's request for a fee waiver is not granted in full, please contact us immediately upon making that determination.

Sincerely,

/s/ John A. Zadrozny
John A. Zadrozny
America First Legal Foundation