

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICA FIRST LEGAL
FOUNDATION,
611 Pennsylvania Ave., SE #231
Washington, D.C. 20003

Plaintiff,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION
1093 New Hampshire Ave.,
Silver Spring, MD 20993

and

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Ave SW
Washington, DC 20201,

Defendants.

Civil Action No.: 23-3680

COMPLAINT

1. Plaintiff America First Legal Foundation (“AFL”) brings this action against the United States Food and Drug Administration (“FDA”) and the United States Department of Health and Human Services (“HHS”), to compel compliance with the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Additionally, it may grant declaratory relief pursuant to 28 U.S.C. § 2201, *et seq.*

3. Venue is proper in this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

4. The Plaintiff, AFL, is a nonprofit organization working to promote the rule of law in the United States, prevent executive overreach, ensure due process and equal protection for all Americans, and encourage public knowledge and understanding of the law and individual rights guaranteed under the United States Constitution and the laws of the United States. AFL's mission includes promoting government transparency and accountability by gathering official information, analyzing it, and disseminating it through reports, press releases, and/or other media, including social media platforms, all to educate the public.

5. The Defendant FDA is an agency under 5 U.S.C. § 552(f), with its headquarters at 1093 New Hampshire Ave., Silver Spring, MD 20993.

6. The Defendant HHS is an agency under 5 U.S.C. § 552(f), with its headquarters at 200 Independence Ave SW, Washington, DC 20201.

7. The Defendants have possession, custody, and control of the requested records.

BACKGROUND

8. The Biden Administration has stated that it is committed to a transparent, open, and ethical government.¹

9. “Timely disclosure of records is also essential to the core purpose of FOIA.” U.S. DEPT JUST., Freedom of Information Act Guidelines (Mar. 15, 2022), <https://tinyurl.com/2yd463dv>.

AFL’S FOIA REQUESTS

Hydroxychloroquine Request to HHS

10. On August 8, 2022, AFL submitted a FOIA request to HHS seeking information related to Hydroxychloroquine over a specific time period. *Ex. A*.

11. This request sought a fee waiver. *Id.*

12. On August 9, 2022, AFL received a letter from HHS acknowledging the request and assigned it tracking number 2022-01072-FOIA-OS. *Ex. B*.

13. That email invoked an extension of ten days, for “unusual circumstances” and assigned the request to the complex processing track *Id.*

14. As of the date of this filing, Defendant HHS has not provided any records under this request.

¹ *FACT SHEET: Biden-Harris Administration Prioritizes Effectiveness, Accountability, and Transparency in Bipartisan Infrastructure Law Implementation*, THE WHITE HOUSE (Apr. 29, 2022), <https://tinyurl.com/bdhrccyk>; *Biden White House Pledges Data, Transparency, Respect for Free Press*, REUTERS (Jan. 20, 2021), <https://tinyurl.com/3fzz25mf>; *Mark Joyella, Biden’s White House Press Secretary Promises ‘Trust and Transparency,’* FORBES (Jan. 20, 2021), <https://tinyurl.com/2p8729wz>.

Hydroxychloroquine Request to FDA

15. On August 8, 2022, AFL submitted a FOIA request to FDA seeking information related to Hydroxychloroquine over a specific time period. *Ex. C.*

16. This request sought a fee waiver. *Id.*

17. On August 11, 2022, AFL received a letter from the FDA acknowledging the request and assigned it tracking number 2022-5862. *Ex. D.*

18. As of the date of this filing, Defendant FDA has not provided any records under this request.

Ivermectin Request to HHS

19. On September 14, 2022, AFL submitted a FOIA request to HHS seeking information related to Ivermectin over a specific time period. *Ex. E.*

20. This request sought a fee waiver. *Id.*

21. On September 16, 2022, AFL received a letter from HHS acknowledging the request and assigned it tracking number 2022-01186-FOIA-OS. *Ex. F.*

22. As of the date of this filing, Defendant HHS has not provided any records under this request.

CLAIM FOR RELIEF

Violation of the FOIA, 5 U.S.C. § 552

23. AFL incorporates paragraphs 1–22 by reference.

24. AFL properly requested records within the possession, custody, and control of the Defendants.

25. The Defendants failed to conduct searches for responsive records.

26. Moreover, because Defendants failed to conduct searches, they have failed to disclose any segregable, non-exempt portions of responsive records. *See* 5 U.S.C. § 552(b).

27. The Defendants have failed to respond to AFL's requests within the statutory time period. *See* 5 U.S.C. § 552(a)(6).

28. Accordingly, AFL has exhausted its administrative remedies. *See* 5 U.S.C. § 552(a)(6)(C).

29. The Defendants have violated the FOIA by failing, within the prescribed time limit, to reasonably search for records responsive to AFL's FOIA request and release nonexempt records.

PRAYER FOR RELIEF

WHEREFORE, AFL respectfully requests that this Court:

- i. Declare that the records sought by AFL's requests must be disclosed pursuant to 5 U.S.C. § 552;
- ii. Order the Defendants to search immediately, demonstrating search methods reasonably likely to lead to the discovery of responsive records;
- iii. Order the Defendants to produce by a date certain all non-exempt records responsive to AFL's FOIA requests, accompanied by a Vaughn index of any responsive records or portions of responsive records being withheld under a claim of exemption;
- iv. Order the Defendants to grant AFL's requests for fee waivers;

v. Award AFL attorneys' fees and costs incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

vi. Grant AFL such other and further relief as this Court deems proper.

Date: December 11, 2023

Respectfully Submitted

/s/ Jacob Meckler

Andrew Block (D.C. Bar No. 90002845)

Jacob Meckler (D.C. Bar No. 90005210)

Tel: (972) 861-2132

E-mail: Jacob.Meckler@aflegal.org

AMERICA FIRST LEGAL FOUNDATION

611 Pennsylvania Avenue SE #231

Washington, D.C. 20003

Counsel for the Plaintiff

America First Legal Foundation



August 8, 2022

Via FOIA Portal

U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Freedom of Information Act Request: Hydroxychloroquine Use for COVID-19 Treatment

Dear FOIA Officer:

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 the law and individual rights guaranteed under the Constitution and laws 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 communicate with a national audience through traditional and social media platforms. AFL's email list contains over 34,000 unique addresses, our Facebook page has over 42,000 followers, our Twitter page has over 17,000 followers, the Twitter page of our Founder and President has over 196,000 followers, and we have another 30,000 followers on GETTR.

AFL requests the following records under the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

I. Custodians

- a. Janet Woodcock
- b. Rick Bright
- c. Gary Disbrow
- d. Denise Hinton

611 Pennsylvania Ave SE #231

Washington, DC 20003

II. Requested Records

The timeframe for each request is March 1, 2020, to September 1, 2020:

- A. For all custodians, all records, including but not limited to email, texts, memoranda, and handwritten notes including the words “hydroxychloroquine” or “HCQ,” or “early treatment,” or “early (drug) treatment,” or “remdesivir.”
- B. For all custodians, all calendar items that contain the terms “hydroxychloroquine” or “HCQ,” or “early treatment,” or “early (drug) treatment,” or “remdesivir.”
- C. All communications, including but not limited to emails between Janet Woodcock and Rick Bright.

III. Processing Requirements

The Department must comply with the processing guidance in the Attorney General’s Memorandum on Freedom of Information Act Guidelines.¹

IV. Fee Waiver

Per 5 U.S.C. § 552(a)(4)(A)(iii) and 6 CFR § 5.11(k), AFL requests a waiver of all search and duplication fees associated with this request. We believe AFL’s non-commercial commitment to public education and transparency justify this fee waiver. We are, of course, available to provide additional information in writing or offline in support of this request.

V. 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, please provide responsive 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 Ave SE #231, Washington, DC 20003.

VI. 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

¹ U.S. Dep’t Just. (Mar. 15, 2022), <https://tinyurl.com/4duy4r5k>.

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/ Reed D. Rubinstein
Reed D. Rubinstein
America First Legal



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2022-01072-FOIA-OS**

August 09, 2022

Sent via email:

Reed Rubinstein

foia@aflegal.org

Dear Mr. Rubinstein:

This acknowledges receipt of your August 08, 2022, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning "See PDF Attached (Date Range for Record Search: From 03/01/2020 To 09/01/2020)". We received your request on August 09, 2022.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ruhma Sufian at Ruhma.Sufian@hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - <https://requests.publiclink.hhs.gov/>. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division



August 8, 2022

Via FOIA Portal

U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Freedom of Information Act Request: Hydroxychloroquine Use for COVID-19 Treatment

Dear FOIA Officer:

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 the law and individual rights guaranteed under the Constitution and laws 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 communicate with a national audience through traditional and social media platforms. AFL's email list contains over 34,000 unique addresses, our Facebook page has over 42,000 followers, our Twitter page has over 17,000 followers, the Twitter page of our Founder and President has over 196,000 followers, and we have another 30,000 followers on GETTR.

AFL requests the following records under the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

I. Custodians

- a. Janet Woodcock
- b. Rick Bright
- c. Gary Disbrow
- d. Denise Hinton

611 Pennsylvania Ave SE #231

Washington, DC 20003

II. Requested Records

The timeframe for each request is March 1, 2020, to September 1, 2020:

- A. For all custodians, all records, including but not limited to email, texts, memoranda, and handwritten notes including the words “hydroxychloroquine” or “HCQ,” or “early treatment,” or “early (drug) treatment,” or “remdesivir.”
- B. For all custodians, all calendar items that contain the terms “hydroxychloroquine” or “HCQ,” or “early treatment,” or “early (drug) treatment,” or “remdesivir.”
- C. All communications, including but not limited to emails between Janet Woodcock and Rick Bright.

III. Processing Requirements

The Department must comply with the processing guidance in the Attorney General’s Memorandum on Freedom of Information Act Guidelines.¹

IV. Fee Waiver

Per 5 U.S.C. § 552(a)(4)(A)(iii) and 6 CFR § 5.11(k), AFL requests a waiver of all search and duplication fees associated with this request. We believe AFL’s non-commercial commitment to public education and transparency justify this fee waiver. We are, of course, available to provide additional information in writing or offline in support of this request.

V. 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, please provide responsive 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 Ave SE #231, Washington, DC 20003.

VI. 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

¹ U.S. Dep’t Just. (Mar. 15, 2022), <https://tinyurl.com/4duy4r5k>.

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/ Reed D. Rubinstein
Reed D. Rubinstein
America First Legal



August 11, 2022

AMERICA FIRST LEGAL FOUNDATION
REED RUBINSTEIN
611 Pennsylvania Ave SE #231, Washington
Washington, D.C. DC 20003 US

In Reply refer to
FOIA Control #:
2022-5862

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

I. Custodians a. Janet Woodcock b. Rick Bright c. Gary Disbrow d. Denise Hinton II. Requested Records The timeframe for each request is March 1, 2020, to September 1, 2020: A. For all custodians, all records, including but not limited to email, texts, memoranda, and handwritten notes including the words "hydroxychloroquine" or "HCQ," or "early treatment," or "early (drug) treatment," or "remdesivir." ETC

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see <http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Sarah B. Kotler, Director, Division Of Freedom Of Information, at (301) 796-8976 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services and/or
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director



September 14, 2022

Via FOIA Portal

U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

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: Ivermectin Use for COVID-19 Treatment

Dear FOIA Officer:

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 the law and individual rights guaranteed under the Constitution and laws 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 communicate with a national audience through traditional and social media platforms. AFL's email list contains over 34,000 unique addresses, our Facebook page has over 61,000 followers, our Twitter page has over 20,000 followers, the Twitter page of our Founder and President has over 212,000 followers, and we have another 31,000 followers on GETTR.

AFL requests the following records under the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

I. Custodians

- a. Janet Woodcock
- b. Rick Bright

611 Pennsylvania Ave SE #231
Washington, DC 20003

- c. Gary Disbrow
- d. Denise Hinton

II. Requested Records

We request the following records for the above four custodians during the timeframe of March 1, 2020, to August 1, 2021:

- A. All records, including but not limited to email, texts, memoranda, and handwritten notes, including the words “ivermectin,” “early (drug) treatment,” “early treatment,” “remdesivir,” or “horse.”
- B. All calendar items that contain the terms “ivermectin,” “early (drug) treatment,” “early treatment,” “remdesivir,” or “horse.”
- C. All communications, including but not limited to emails, between Janet Woodcock and Rick Bright.
- D. All records of or regarding the processing of this request.

III. Processing Requirements

The Department must comply with the processing guidance in the Attorney General’s Memorandum on Freedom of Information Act Guidelines.¹

IV. Fee Waiver

Per 5 U.S.C. § 552(a)(4)(A)(iii) and 6 CFR § 5.11(k), AFL requests a waiver of all search and duplication fees associated with this request. We believe AFL’s non-commercial commitment to public education and transparency justify this fee waiver. We are, of course, available to provide additional information in writing or offline in support of this request.

V. Production

To accelerate the 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, please provide responsive 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 Ave SE #231, Washington, DC 20003.

¹ U.S. Dep’t Just. (Mar. 15, 2022), <https://tinyurl.com/4duy4r5k>.

VI. 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 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/ Reed D. Rubinstein

Reed D. Rubinstein
America First Legal



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2022-01186-FOIA-OS**

September 16, 2022

Sent via email:

Reed Rubinstein
foia@aflegal.org

Dear Reed Rubinstein:

This acknowledges receipt of your **September 14, 2022** Freedom of Information Act (FOIA) request submitted to the Department of Health and Human Services FOI/Privacy Acts Division concerning ***“FOIA about Ivermectin. See attached PDF.***

I. Custodians

- a. Janet Woodcock***
- b. Rick Bright***
- c. Gary Disbrow***
- d. Denise Hinton***

II. Requested Records

We request the following records for the above four custodians during the timeframe of March 1, 2020, to August 1, 2021:

A. All records, including but not limited to email, texts, memoranda, and handwritten notes, including the words “ivermectin,” “early (drug) treatment,” “early treatment,” “remdesivir,” or “horse.” ...

(Date Range for Record Search: From 03/01/2020 To 08/01/2021)”.

We received your request on **September 14, 2022** and are referring it to the Food and Drug Administration (FDA) regarding (**Janet Woodcock** and **Denise Hinton**) and to the National Institutes of Health (NIH) regarding (**Rick Bright**) for direct response to you. Because HHS FOIA administration is decentralized, your request will be process in this office for **Gary Disbrow**.

Upon receipt, the FDA and NIH will log your request, and provide you with a new tracking number for your reference. You may check the status of your request with FDA at (301) 796-3900 or email: fdafioia@fda.hhs.gov and NIH at (301) 496-5633 or email [nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov) for assistance. With this Office using the above number **2022-01186-FOIA OS**.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely,

Ray Noussoukpoe

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICA FIRST LEGAL FOUNDATION

Plaintiff

v.

D STATES FOOD AND DRUG ADMINISTRATION

Defendant

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Civil Action No. 23-3680

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* U.S. Department of Justice
U.S. Attorney's Office for the District of Columbia
Civil Process Clerk
601 D St. NW
Washington, DC 20530
Email Service to: USADC.ServiceCivil@usdoj.gov

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jacob Meckler
America First Legal Foundation
611 Pennsylvania Ave SE #231
Washington, DC 20003

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 23-3680

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICA FIRST LEGAL FOUNDATION

Plaintiff

v.

D STATES FOOD AND DRUG ADMINISTRATION

Defendant

Civil Action No. 23-3680

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* The Honorable Merrick Garland
U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530-0001

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jacob Meckler
America First Legal Foundation
611 Pennsylvania Ave SE #231
Washington, DC 20003

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 23-3680

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICA FIRST LEGAL FOUNDATION

Plaintiff

v.

D STATES FOOD AND DRUG ADMINISTRATION

Defendant

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Civil Action No. 23-3680

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* General Counsel
Department of Health and Human Services
200 Independence Ave. S.W.
Washington, DC 20201

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jacob Meckler
America First Legal Foundation
611 Pennsylvania Ave SE #231
Washington, DC 20003

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 23-3680

PROOF OF SERVICE*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* _____
 was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
 _____ on *(date)* _____; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
 _____, a person of suitable age and discretion who resides there,
 on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
 designated by law to accept service of process on behalf of *(name of organization)* _____
 _____ on *(date)* _____; or

☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICA FIRST LEGAL FOUNDATION

Plaintiff

v.

D STATES FOOD AND DRUG ADMINISTRATION

Defendant

Civil Action No. 23-3680

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
10903 New Hampshire Ave., Silver Spring, MD 20993-0002.
Email Service to: OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov
Michael Ding
America First Legal Foundation

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

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Washington, DC 20003

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☐ I returned the summons unexecuted because _____; or

☐ Other *(specify)*: _____.

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I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS AMERICA FIRST LEGAL FOUNDATION, 611 Pennsylvania Ave., SE #231 Washington, D.C. 20003 (b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____ (EXCEPT IN U.S. PLAINTIFF CASES)	DEFENDANTS UNITED STATES FOOD AND DRUG ADMINISTRATION 1093 New Hampshire Ave., Silver Spring, MD 20993 COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT 11001 (IN U.S. PLAINTIFF CASES ONLY) <small>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</small>																								
(c) ATTORNEYS (FIRMNAME, ADDRESS, AND TELEPHONE NUMBER) Jacob Meckler (D.C. Bar No. 90005210) Tel: (972) 861-2132 AMERICA FIRST LEGAL FOUNDATION 611 Pennsylvania Avenue SE #231 Washington, D.C. 20003	ATTORNEYS (IF KNOWN)																								
II. BASIS OF JURISDICTION (PLACE AN x IN ONE BOX ONLY)	III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!																								
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="radio"/> 1 U.S. Government Plaintiff </div> <div style="width: 45%;"> <input type="radio"/> 3 Federal Question (U.S. Government Not a Party) </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input checked="" type="radio"/> 2 U.S. Government Defendant </div> <div style="width: 45%;"> <input type="radio"/> 4 Diversity (Indicate Citizenship of Parties in item III) </div> </div>	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> </tr> </thead> <tbody> <tr> <td>Citizen of this State</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td>Incorporated or Principal Place of Business in This State</td> <td style="text-align: center;"><input type="radio"/> 4</td> <td style="text-align: center;"><input type="radio"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td style="text-align: center;"><input type="radio"/> 5</td> <td style="text-align: center;"><input type="radio"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="radio"/> 6</td> <td style="text-align: center;"><input type="radio"/> 6</td> </tr> </tbody> </table>		PTF	DFT		PTF	DFT	Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4	Citizen of Another State	<input type="radio"/> 2	<input type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5	Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6
	PTF	DFT		PTF	DFT																				
Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4																				
Citizen of Another State	<input type="radio"/> 2	<input type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5																				
Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6																				

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

<input type="radio"/> A. Antitrust <input type="checkbox"/> 410 Antitrust	<input type="radio"/> B. Personal Injury/Malpractice <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Medical Malpractice <input type="checkbox"/> 365 Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Product Liability	<input type="radio"/> C. Administrative Agency Review <input type="checkbox"/> 151 Medicare Act <u>Social Security</u> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <u>Other Statutes</u> <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 890 Other Statutory Actions (If Administrative Agency is Involved)	<input type="radio"/> D. Temporary Restraining Order/Preliminary Injunction Any nature of suit from any category may be selected for this category of case assignment. *(If Antitrust, then A governs)*
<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <input checked="" type="radio"/> E. General Civil (Other) </div> <div>OR</div> <div style="text-align: center;"> <input type="radio"/> F. Pro Se General Civil </div> </div>			
<u>Real Property</u> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent, Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property <u>Personal Property</u> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<u>Bankruptcy</u> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <u>Prisoner Petitions</u> <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Conditions <input type="checkbox"/> 560 Civil Detainee – Conditions of Confinement <u>Property Rights</u> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent – Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 (DTSA)	<u>Federal Tax Suits</u> <input type="checkbox"/> 870 Taxes (US plaintiff or defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609 <u>Forfeiture/Penalty</u> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <u>Other Statutes</u> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 430 Banks & Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 462 Naturalization Application	<input type="checkbox"/> 465 Other Immigration Actions <input type="checkbox"/> 470 Racketeer Influenced & Corrupt Organization <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act (TCPA) <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

<input type="radio"/> G. Habeas Corpus/ 2255 <input type="checkbox"/> 530 Habeas Corpus – General <input type="checkbox"/> 510 Motion/Vacate Sentence <input type="checkbox"/> 463 Habeas Corpus – Alien Detainee	<input type="radio"/> H. Employment Discrimination <input type="checkbox"/> 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	<input type="radio"/> I. FOIA/Privacy Act <input checked="" type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	<input type="radio"/> J. Student Loan <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (excluding veterans)
<input type="radio"/> K. Labor/ERISA (non-employment) <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="radio"/> L. Other Civil Rights (non-employment) <input type="checkbox"/> 441 Voting (if not Voting Rights Act) <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 Americans w/Disabilities – Employment <input type="checkbox"/> 446 Americans w/Disabilities – Other <input type="checkbox"/> 448 Education	<input type="radio"/> M. Contract <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholder's Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="radio"/> N. Three-Judge Court <input type="checkbox"/> 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN
☒ 1 Original Proceeding
 ☐ 2 Removed from State Court
 ☐ 3 Remanded from Appellate Court
 ☐ 4 Reinstated or Reopened
 ☐ 5 Transferred from another district (specify)
 ☐ 6 Multi-district Litigation
 ☐ 7 Appeal to District Judge from Mag. Judge
 ☐ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
 Violation of FOIA, 5 U.S.C. § 552, failing to release responsive, non-exempt records

VII. REQUESTED IN COMPLAINT

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

JURY DEMAND:

Check YES only if demanded in complaint
 YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY

(See instruction)

YES ☐ NO ☒

If yes, please complete related case form

DATE: 12/11/2023

SIGNATURE OF ATTORNEY OF RECORD /s/ Jacob Meckler

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil coversheet. These tips coincide with the Roman Numerals on the cover sheet.

- I.** COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.
- III.** CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV.** CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.
- VI.** CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII.** RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.