

# **EXHIBIT 1**

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**LATHAM & WATKINS** LLP

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September 26, 2023

**VIA ELECTRONIC MAIL AND FEDERAL EXPRESS**

CMS FOIA Officer  
Centers for Medicare & Medicaid Services  
Mailstop N2-20-16  
7500 Security Boulevard  
Baltimore, MD 21244  
[FOIA\\_Request@cms.hhs.gov](mailto:FOIA_Request@cms.hhs.gov)

**Re: Freedom of Information Act Request**

To Whom It May Concern:

Under the federal Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, Latham & Watkins LLP (“Latham”) is requesting access to the following records, including, but not limited to, emails, formal and informal policies, standard operating procedures, guidelines, internal memoranda, internal and external communications, and any other relevant material (hereinafter, “all records”):

- All records associated with the narrow exception process under which certain drugs approved under paper New Drug Applications (“NDAs”) or literature-based 505(b)(2) NDAs might be classified as a noninnovator multiple source drug (also known as an “N drug”), including, but not limited to, all materials that the Centers for Medicare and Medicaid Services (“CMS”) uses to inform the evaluation of narrow exception requests;
- All records associated with all applications seeking a determination from CMS that an applicant’s drugs qualify for the narrow exception and can be classified as noninnovator multiple source drugs (N drugs), including but not limited to the applications, and all corresponding decisions from CMS regarding these narrow exception applications;
- All records associated with all internal communications regarding the terms “literature-based 505(b)(2) New Drug Applications,” “literature-based 505(b)(2) NDAs,” “paper New Drug Applications,” and “paper NDAs” including but not limited to CMS’s definition of the terms “literature-based 505(b)(2) New Drug Applications,” “literature-based 505(b)(2) NDAs,” “paper New Drug Applications,” and “paper NDAs”; and

**LATHAM & WATKINS** LLP

- All records associated with all communications between CMS and the Food and Drug Administration (“FDA”) regarding the terms “literature-based 505(b)(2) New Drug Applications,” “literature-based 505(b)(2) NDAs,” “paper New Drug Applications,” and “paper NDAs,” including but not limited to:
  - Communications between CMS and FDA regarding the definitions of the terms “literature-based 505(b)(2) New Drug Applications,” “literature-based 505(b)(2) NDAs,” “paper New Drug Applications,” and “paper NDAs”; and
  - Communications between CMS and FDA regarding the narrow exception process and/or narrow exception applications.

In order to determine the status of this request for the purpose of assessing fees, Latham is a private business and is seeking information for use in the company’s business. If this request is denied, in whole or in part, please justify all denials by reference to specific exemptions under FOIA. Please also release all segregable portions of otherwise exempt material. Latham will pay all necessary fees.

Latham requests that the information Latham is seeking be provided in electronic format. If you have any questions about handling this request, please contact Monica Groat at 202-637-2281 or [monica.groat@lw.com](mailto:monica.groat@lw.com).

Sincerely,



Monica C. Groat  
Of Latham & Watkins LLP



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UNITED STATES DEPARTMENT of JUSTICE



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**Thank you for visiting FOIA.gov, the government's central website for FOIA.** We'll continue to make improvements to the site and look forward to your input. Please submit feedback to [National.FOIAPortal@usdoj.gov](mailto:National.FOIAPortal@usdoj.gov).

**Submission ID:** 875296

# Success!

**Your FOIA request has been created and is being sent to the Center for Medicare and Medicaid Services.**

You'll hear back from the agency confirming receipt in the coming weeks using the contact information you provided. If you have questions about your request, feel free to reach out to the agency FOIA personnel using the information provided below.

## Contact the agency

Hugh Gilmore, FOIA Officer

410-786-5353

[hugh.gilmore@cms.hhs.gov](mailto:hugh.gilmore@cms.hhs.gov)

FOIA Requester Service Center

410-786-5353

Joseph Tripline, FOIA Public Liaison

410-786-5353

[joseph.tripline@cms.hhs.gov](mailto:joseph.tripline@cms.hhs.gov)

Hugh Gilmore, FOIA Officer, North Building, Room C5-11-06

7500 Security Boulevard

Baltimore, MD 21244

[FOIA\\_Request@cms.hhs.gov](mailto:FOIA_Request@cms.hhs.gov)

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## Request summary

Request submitted on **September 26, 2023**.

The confirmation ID for your request is **875296**.

The confirmation ID is only for identifying your request on FOIA.gov and acts as a receipt to show that you submitted a request using FOIA.gov. This number does not replace the information you'll receive from the agency to track your request. In case there is an issue submitting your request to the agency you selected, you can use this number to help.

## Contact information

### Name

Monica Groat

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Suite 1000

Washington, DC 20004

United States

### Phone number

202-637-2281

### Company/organization

Latham & Watkins

### Email

[monica.groat@lw.com](mailto:monica.groat@lw.com)

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## Additional information

Sandoz - FOIA Request CMS (9.26.23).pdf

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## Fees

### What type of requester are you?

commercial

**Fee waiver**

no

**The amount of money you're willing to pay in fees, if any**

10000

**Request expedited processing**

**Expedited processing**

no



FOIA.gov

**CONTACT**

Office of Information Policy (OIP)  
U.S. Department of Justice  
441 G St, NW, 6th Floor  
Washington, DC 20530  
E-mail: [National.FOIAPortal@usdoj.gov](mailto:National.FOIAPortal@usdoj.gov)

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