



FREEDOM OF INFORMATION ACT & PUBLIC HEALTH ADVOCACY



Much of the written information created or received by federal agencies is available to the public. The Freedom of Information Act, a law designed to protect public access to government information, is the tool to get access to this information.

The Freedom of Information Act (FOIA), enacted in 1966, establishes a statutory right of access to many federal agency records.¹ FOIA compels agencies to automatically disclose certain documents and information, including frequently requested records.² The law also establishes exemptions protecting specific documents from disclosure.³ These provisions are intended to protect interests such as national security, personal privacy, privileged communications, and law enforcement.



A FOIA request is an important tool that the public health community can use to maximize its impact on federal regulation of key issues affecting health. Many of an agency's documents and written communications may be available under FOIA. Access to this information can help inform and improve the public health community's engagement in the federal regulatory process. Learning what the industry is saying and what information it is providing to an agency can enable public health professionals to counter industry arguments and rebut false or misleading information.

I. What kind of information can be requested?

An FOIA request can be made for any agency record.⁴ The requester may also specify the format in which they wish to receive the records.⁵ However, FOIA does not require an agency to do research, analyze data, answer written questions, or create records in response to a request.

FOIA in Practice: Using FOIA at the U.S. Food and Drug Administration (FDA)

Increasing Transparency in Commercial Tobacco Control

The FDA Center for Tobacco Products (CTP) has generated and collected a large repository of correspondence, reports, and other documents of interest to the public health community. Some document collections have become more accessible to the public over time, in part due to public health advocates' use of FOIA to raise public awareness. For example, Tobacco Product Problem Reports have been frequently requested under FOIA; however, only recently the CTP proactively began publishing these reports on its website to increase public access to this information.

Delving into Industry Influence on Food Safety and Nutrition Standards

Sunlight Foundation, an advocacy group for government transparency and accountability, has used FOIA to demonstrate the influence of industry on decision making within the FDA's Center for Food Safety and Applied Nutrition (CFSAN).⁶ In 2013, the organization used FOIA to obtain memoranda of CFSAN meetings showing a significant overrepresentation of industry group advocates involved in meetings with the agency compared to consumer and public health advocates.

Using FOIA to obtain memoranda like these can inform public health advocates regarding industry advocacy areas and highlight opportunities for consumer and public health advocates to increase engagement with the agency.

II. What is the process for requesting documents using FOIA?

The process for requesting records under FOIA is simple and informal. Requests must be in writing (which includes electronic requests) and submitted directly to the agency subject to the request. Requests must "reasonably describe" the records being sought.⁷ Identifying the records as specifically as possible may reduce copying costs and increase accuracy of the results and will avoid bogging down agency staff with retrieval of unnecessary documents. In addition, a request for specific records may be processed more quickly than a general request for "all information" on a particular subject.

All FOIA requests should include: (1) the requester's name, address, and telephone number; (2) a description of the records being sought, identified as specifically as possible; and (3) a statement regarding willingness to pay fees.

FOIA in Practice: Submitting a FOIA Request to the FDA

In addition to FOIA, a requester should consult the Department of Health and Human Services (HHS) and FDA implementing regulations.⁸

The FDA will accept FOIA requests three ways:*

- Submitted online
- Faxed to (301) 827-9267
- Sent via U.S. mail to: Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

To determine applicable fees, the FDA maintains a FOIA fee schedule on its website.

Upon receipt of a FOIA request, the FDA will send an acknowledgement letter. You can also contact the relevant Center's FOIA chief to check on the status of your request, to see if additional information is needed to expedite processing, to clarify the documents you want, and to help resolve disputes.

* In response to the COVID-19 pandemic, the FDA has asked that all FOIA requests be submitted electronically.

III. Can an agency refuse to disclose information?

FOIA does not mandate that an agency release all requested records. Congress has established certain categories of information that are not required to be released in response to a FOIA request because release would be harmful to governmental or private interests. These categories are called "exemptions" from disclosures. There are nine disclosure exemptions in FOIA:

- 1 Information that is classified to protect national security.⁹ To qualify for this exemption, the material must be properly classified under an Executive Order.

- 2 Information that is related solely to the internal personnel rules and practices of an agency.¹⁰
- 3 Information that is prohibited from disclosure by another federal law.¹¹
- 4 Information that concerns business trade secrets or other confidential commercial or financial information.¹²
- 5 Information that concerns communications within or between agencies that are protected by legal privileges.¹³ Such privileges include attorney work product privilege, attorney-client privilege, and presidential communications privilege, among others.¹⁴
- 6 Information that, if disclosed, would invade another individual's personal privacy.¹⁵
- 7 Information compiled for law enforcement purposes if a specified harm would occur.¹⁶ For example, law enforcement information is exempt if it would deprive a person of their right to a fair trial.
- 8 Information that concerns the supervision of financial institutions.¹⁷
- 9 Geological information on wells.¹⁸

The U.S. Supreme Court has concluded that "[t]hese exemptions are specifically made exclusive' ... and must be narrowly construed."¹⁹ This interpretation means that an agency cannot broadly apply the statutory exemptions to exclude as much information as possible. Rather, the agency must start from the assumption that most of the agency's information is available to the public unless it clearly fits into a specific exemption.

It is important to note that agencies **are not required** to invoke the statutory exemptions. Even where an exemption applies, agencies may use their discretion to release information when there is no foreseeable harm in doing so and disclosure is not otherwise prohibited by law.²⁰ Consequently, even if a requested document falls within one of the nine exemptions, you can ask the agency to release it anyway as an exercise of its discretionary powers.

When a requested document contains **some** information that falls under one of the exemptions, FOIA requires that all non-exempt portions of the record **must still be released**. FOIA provides that any "reasonably segregable portion" of a record must be disclosed after the redaction of any parts that are exempt.²¹ This is an important aspect of FOIA because it prohibits agencies from withholding an entire document merely because a small portion is exempt.

FOIA in Practice: Exemptions Claimed for Tobacco Industry Documents

Generally, the exemption most likely related to FOIA requests submitted to the FDA's Center for Tobacco Products is the exemption for business trade secrets or confidential commercial information.²² The trade secret exemption protects from public disclosure two types of information: (1) trade secrets; and (2) information that is (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential.²³ Congress intended this exemption to protect the interests of both the government and submitters of information. Its existence encourages submitters to voluntarily furnish useful commercial or financial information to the government, and it correspondingly provides the government with an assurance that such information will be reliable.

IV. Will a requester be charged any fees for documents requested under FOIA?

While there is no initial fee required to submit a FOIA request, the law does allow agencies to charge fees in some instances.²⁴ Agencies can charge for the time it takes to search for records and for duplication of those records. However, if the request is made by news media or an educational or noncommercial scientific institution for noncommercial research purposes, an agency may charge fees for document duplication only.

If you are unwilling or unable to pay these fees, you may choose to include in your request letter a specific statement limiting the amount that you are willing to pay in fees. If the agency estimates that the total fees for processing your request will exceed \$250, it will notify you in writing of the estimate and offer you an opportunity to narrow your request in order to reduce the fees. If you agree to pay fees for a records search, be aware that you may be required to pay such fees even if the search does not locate any responsive records or if the records are determined to be wholly exempt from disclosure.

You may also request a waiver of fees for uses determined to be in the public interest. Under FOIA, fee waivers are limited to situations in which a requester can show that: (1) the disclosure of the requested information "[i]s in the public interest because it is likely to contribute significantly to public understanding of the operations and activities of the [g]overnment; and (2) [i]t is not primarily in the commercial interest of the requester."²⁵ Unfortunately, a requester's inability to pay fees is not a legal basis for granting a fee waiver. Fee waivers are only available where the criteria described above are met.

V. How long is the typical wait for a response?

Responses to record requests are sent via U.S. mail unless you have requested another form of delivery. Federal agencies are required to respond to FOIA requests within 20 business days; if unable to fulfill the request in that time period, the agency must notify the requester.²⁶ Despite the requirement to respond in 20 days, it often takes far longer to receive responsive records. For instance, most FOIA requests processed by the FDA take months — some over a year — to complete.²⁷

VI. What if an agency refuses to produce the requested information?

Do not be discouraged if the agency is less than fully responsive to your request. Keep copies of all your correspondence and notes of all phone calls.

1. Informal resolution

Once you have requested information, if you are not satisfied with the agency's initial response to a request, you may contact the agency's FOIA contact, who will be able to explain the process, assist in reducing delays, and help resolve disputes.

2. Administrative appeal

If the requester is unable to resolve a FOIA dispute through informal means, the next step is to file an administrative appeal. Appeals can be an effective tool to successfully challenge excessive processing delays, fee waiver denials, and the improper full or partial withholdings of responsive documents. There is no fee or cost involved for initiating an administrative appeal.

Agency regulations governing appeals vary; take careful note of the instructions for filing an appeal in the agency's response to ensure that your appeal is timely.²⁸ An appeal letter should 1) state the grounds for appeal and reasons why the agency's response to the request was improper; 2) request a more precise explanation of the agency's decision (if the reasons for the initial determination were unclear); and 3) state that the agency's final ruling on the appeal is expected within the 20-day statutory time limit.²⁹ After an independent review, the appellate authority will send a letter advising the requester of its decision.

3. Mediation

Once the administrative appeal process is complete, the requester also has the option to seek mediation services from the Office of Government Information Services at the National Archives and Records Administration.³⁰

4. Outside Advocacy

If the agency fails to respond satisfactorily, you could also enlist the assistance of a member of Congress to contact the agency on your behalf. Although such a contact would not typically constitute lobbying, before contacting a member of Congress it is always useful to consider any restrictions on your organization's activities under law or pursuant to your funding agreements.

5. Litigation

If all else fails, you may consult with legal counsel regarding the possibility of going to court to force the agency to release the documents.³¹ Litigation is a drastic and expensive option, and should only be undertaken if the benefits of obtaining the requested information outweigh the significant costs of litigation.³²

This publication was prepared by the Public Health Law Center at Mitchell Hamline School of Law, St. Paul, Minnesota, and made possible with funding from Robert Wood Johnson Foundation. The Public Health Law Center provides information and legal technical assistance on issues related to public health. The Center does not provide legal representation or advice. This document should not be considered legal advice.

Endnotes

- 1 5 U.S.C. §§ 552 et seq.; see generally U.S. Dep't of Justice, United States Department of Justice Guide to the Freedom of Information Act, at Exemption 5 (updated 2019), <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.
- 2 *Id.* FOIA applies to any "agency records" that are documents (1) either created or obtained by an agency, and (2) under agency control at the time of the FOIA request. U.S. Dep't of Justice v. Tax Analysts, 492 U.S. 136, 144-45 (1989). The 1996 amendments to FOIA explicitly indicate that the term "record" and any other term used in FOIA in reference to information includes "any information that would be an agency record subject to the requirements of this section when maintained by an agency in any format, including an electronic format." 5 U.S.C. § 552(f)(2).
- 3 5 U.S.C. § 552(b).
- 4 5 U.S.C. § 552(a)(3)(A).
- 5 5 U.S.C. § 552(a)(3)(B).

- 6 The organization found industry group representatives were present at 78 percent of these meetings while consumer group representatives were present at only 18 percent. Nancy Watzman, *Rulemaking in the Dark: Little Disclosure When Big Food Lobbies the FDA*, Sunlight Foundation (Sep. 26, 2013), https://sunlightfoundation.com/2013/09/26/rulemaking_in_the_dark_fda.
- 7 5 U.S.C. § 552(a)(3)(A).
- 8 45 C.F.R. §§ 5 et seq. (HHS implementing regulations); 21 C.F.R. §§ 20 et seq. (FDA regulations).
- 9 5 U.S.C. § 552(b)(1)(A).
- 10 5 U.S.C. § 552(b)(2).
- 11 5 U.S.C. § 552(b)(3).
- 12 5 U.S.C. § 552(b)(4).
- 13 5 U.S.C. § 552(b)(5).
- 14 For more information on the specific privileges included in this FOIA exemption, see U.S. Dep't of Justice, *supra* note 1, at Exemption 5.
- 15 5 U.S.C. § 552(b)(6).
- 16 5 U.S.C. § 552(b)(7).
- 17 5 U.S.C. § 552(b)(8).
- 18 5 U.S.C. § 552(b)(9).
- 19 *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976) (quoting *EPA v. Mink*, 410 U. S. 73, 79 (1973)).
- 20 *Chrysler Corp. v. Brown*, 441 U.S. 281, 293 (1979).
- 21 5 U.S.C. § 552(b).
- 22 See "The Freedom of Information Act: Protecting Citizens' Right to Know' by Fostering CTP Transparency," U.S. Food & Drug Admin., <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/freedom-information-act>.
- 23 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61 (defining trade secrets and commercial or financial information which is privileged or confidential under FDA FOIA implementing regulations).
- 24 5 U.S.C. § 552(a)(4)(A).
- 25 21 C.F.R. § 20.46.
- 26 5 U.S.C. § 552(a)(6)(A).
- 27 Dep't of Health & Human Services, HHS Fiscal Year 2019 Freedom of Information Annual Report, Tables VII.A., VII.B. & VII.C. (2020), <https://www.hhs.gov/foia/reports/annual-reports/2019/index.html>.
- 28 For example, an adverse determination by the FDA must be appealed to the Department of Health and Human Services in accordance with its regulations regarding the appeal process. 21 C.F.R. § 20.49; 45 C.F.R. §§ 5.61-.63.
- 29 5 U.S.C. § 552(a)(6)(A)(ii).
- 30 5 U.S.C. § 552(h)(3).
- 31 5 U.S.C. § 552(a)(4)(B) ("the district court ... has jurisdiction to ... order the production of any agency records improperly withheld from the complainant"); 45 C.F.R. § 5.64 ("Before seeking review by a court of an adverse determination, you generally must first submit a timely administrative appeal.").
- 32 A requester who substantially prevails in their suit may be awarded reasonable attorney fees and litigation costs. 5 U.S.C. § 552(a)(4)(E).