



FREEDOM OF INFORMATION ACT AND THE FDA

In June 2009, President Obama signed the Family Smoking and Tobacco Control Act¹ into law, authorizing the U.S. Food and Drug Administration (FDA) to regulate tobacco products for the first time.² In the three years since the law was enacted, the FDA has established the Center for Tobacco Products and begun developing regulations and guidance concerning tobacco products. In the course of this work, the Center has generated and collected thousands of pages of correspondence, reports, and other documents of interest to the public health community. Much of the written information created or received by the Center is available to the public. The tool to get access to this information is found in the Freedom of Information Act (FOIA), a law designed to protect public access to government information.

FOIA, enacted in 1966, establishes a statutory right of access for individuals to many federal agency records.³ In addition, FOIA compels agencies to automatically disclose certain information, including frequently requested records.⁴ The law also establishes nine exemptions protecting specific documents from disclosure.⁵ 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 for the public health community to maximize its impact on the federal regulation of tobacco. Many of the FDA's written communications with tobacco companies and documents exchanged between the FDA and the industry may be available under FOIA. Access to this information may 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 the FDA will allow public health professionals to counter industry arguments and rebut false or misleading information provided to the FDA. To date, the Center has received more than 140 FOIA requests, the vast majority of which are from the tobacco industry.

I. What is the process for requesting documents from the FDA Center for Tobacco Products?

The process for requesting records under FOIA is simple and informal. Requests must be in writing and submitted directly to the FDA. Requests must include a description of the records being sought. Identifying the records as specifically as possible may reduce copying costs and increase accuracy of the results, and will avoid bogging down FDA 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 requestor's name, address, and telephone number; (2) a description of the records being sought, identified as specifically as possible; and (3) a statement concerning willingness to pay fees, including any limitations. The FDA will accept FOIA requests three ways:

- Faxed to (301) 827-9267
- Submitted online at:
<http://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>
- Sent via U.S. Mail to:

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

II. What kind of information can be requested?

A FOIA request can be made for any agency record.⁶ The person making the request may also specify the format in which he or she wishes to receive the records.⁷ However, FOIA does not require agencies to do research, analyze data, answer written questions, or create records in response to a request.

III. Can the FDA refuse to disclose the requested information?

As mentioned above, FOIA does not mandate that an agency release all requested records. Instead, Congress 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.⁸ To qualify for this exemption the material must be properly classified under an Executive Order.⁹
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 which are protected by legal privileges.¹³ Such legal privileges include attorney work product privilege, attorney-client privilege, and presidential communications privilege.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.¹⁷
8. Information that concerns the supervision of financial institutions.¹⁸
9. Geological information on wells.¹⁹

The U.S. Supreme Court has concluded that "[t]hese exemptions are specifically made exclusive . . . and must be narrowly construed."²⁰ This interpretation means that the FDA 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. That is, 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.²¹ Consequently, even if a requested document falls within one of the nine exemptions, you can ask the FDA to release it anyway as an exercise of its discretionary powers.

When a requested document contains some information which falls under one of the exemptions, FOIA requires that all non-exempt portions of the record must still be released. FOIA specifically provides that any "reasonably segregable portion" of a record must be disclosed to a requester after the redaction of any parts which are exempt.²² This is an important aspect of FOIA because it prohibits the FDA from withholding an entire document merely because some small portion of it is exempt.

Generally, the exemption most likely related to FOIA requests of information from the Center for Tobacco Products is the exemption for business trade secrets or confidential commercial information. The trade secret exemption protects from public disclosure two types of information: (1) trade secrets; and (2) information that is (a) commercial or financial, and (b) obtained from a person, and (c) privileged or confidential. 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 the FDA charge any fees to provide the requested information?

While there is no initial fee required to submit a FOIA request, the law does allow the FDA to charge fees in some instances. The FDA Center for Tobacco Products can charge for the time it takes to search for records and for duplication of those records, but rates vary depending on the entity making the request. For commercial requestors, the Center will charge between \$46 and \$83 per hour for the time spent compiling the requested records, depending on the pay rate of the staff necessary to locate the records. Commercial requestors must also pay 10 cents per page for copies (or \$1.00 for a compact disc containing all of the requested documents). Requests from educational institutions, nonprofit organizations, and members of the media will not include charges for time but instead will only result in charges for the copies made.

If you are unwilling or unable to pay these fees, you may always include in your request letter a specific statement limiting the amount that you are willing to pay in fees. If the Center 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 records are located, even if they are determined to be wholly exempt from disclosure.

You may also request a waiver of fees. Under FOIA, fee waivers are limited to situations in which a requester can show that: (1) the disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations and activities of the government and is not primarily in the commercial interest of the requester; and (2) that the requestor will disseminate the disclosed information to the public. Unfortunately, a requester's inability to pay fees is not a legal basis for granting a fee waiver. In other words, the fee waiver is not available as a hardship exemption for those individuals and organizations that are not able to pay for the requested documents. Fee waivers are only available where the two criteria described above are met.

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

FOIA allows federal agencies twenty days to respond to FOIA requests, but backlogs at many agencies result in much longer waits. Fortunately, there is not typically a FOIA backlog at the Center and, where records exist, the response time has been about two weeks. If you are concerned, you may contact the Center's FOIA Chief, Candace Boston, at (240) 402-3736 to check on the status of your request, to see if additional information is needed to expedite processing, or to clarify what documents you want.

VI. What if the FDA refuses to produce the requested information?

Don't be discouraged if the FDA is less than fully responsive to your request. Keep copies of all your correspondence and notes of all phone calls. Once you have requested information, if you are not satisfied with the FDA's initial response to a request, you may contact the Center's FOIA Chief, Candace Boston (see above). Ms. Boston will be able to explain the process, assist in reducing delays, and help resolve disputes. In some cases, a discussion between the requester and the agency may provide resolution.

If the requester is unable to resolve the denial through informal means, the next step is to file an administrative appeal. To do so, you may send a letter to the FDA stating that you are appealing the initial decision made on the request. There is no fee or cost involved for initiating an administrative appeal. After an independent review, the appellate authority will send a letter advising the requester of its decision. 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.

It is worthwhile to file an administrative appeal if the agency's response is unsatisfactory. 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. 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. An appeal letter should state the grounds for appeal and reasons why the FDA's response to the request was improper, request a more precise explanation of the FDA's decision (if the reasons for the initial determination were unclear), and say that you expect a final ruling on the appeal within the 20-day statutory time limit.

If the FDA 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. 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. Litigation is a drastic and expensive option, of course, and should only be undertaken if the benefits of obtaining the requested information outweigh the significant costs of litigation.

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Notes

¹ Family Smoking Prevention and Tobacco Control Act, 21 U.S.C.A. §§ 387–387u (West 2009); Pub. L. No. 111-31, 123 Stat. 1776 (2009); 21 C.F.R. §§ 1140.30, 1140.32 (2010).

² The Tobacco Control Legal Consortium has produced several publications which describe the provisions of this law in greater detail. Please see our [website](http://www.publichealthlawcenter.org) for more information, located at www.publichealthlawcenter.org.

³ 5 U.S.C. § 552(a).

⁴ *Id.*

⁵ 5 U.S.C. § 552(b).

⁶ 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).

⁷ 5 U.S.C. § 552(a)(3)(B).

⁸ 5 U.S.C. § 552(b)(1)(A).

⁹ 5 U.S.C. § 552(b)(1)(B).

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 *Id.*

¹⁵ 5 U.S.C. § 552(b)(6).

¹⁶ 5 U.S.C. § 552(b)(7).

¹⁷ 5 U.S.C. § 552(b)(7)(B).

¹⁸ 5 U.S.C. § 552(b)(8).

¹⁹ 5 U.S.C. § 552(b)(9).

²⁰ *Dept. of the Air Force v. Rose*, 425 U.S. 352, 361 (1976).

²¹ *Chrysler Corp. v. Brown*, 441 U.S. 281, 293 (1979).

²² 5 U.S.C. § 552(b).