

Freedom of Information Act Requests: A Primer

Knowing how to submit an FOIA request can be a tremendous tool that provides a competitive edge.

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REGULATORY OUTLOOK

When device manufacturers add revealing FDA documents to their arsenals of information, it can make it easier for them to bring products to the marketplace and to keep them in compliance. That is why understanding the intricacies of the Freedom of Information Act (FOIA)—including learning how to submit a request and knowing where to turn when the wait for requested documents proves excruciatingly long—is extremely important.

FOIA allows companies to peruse minutes of a closed-door meeting between FDA and a competitor and to study FDA-483 notes written by an agency investigator. They may also browse the resumes of potential product reviewers or learn about the precise deficiencies a firm encountered during its most recent FDA inspection.



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Of course, a request under FOIA does not ensure that companies will receive everything they want, whenever they want it. However, the act—passed in 1966 to encourage transparency in government—does provide an avenue by which manufacturers and other interested parties can view information that might otherwise never be seen outside a government employee's desk drawers.

What Are the First Steps?

Before spending time and effort on an FOIA request, it is necessary to determine whether the type of information requested does indeed exist. Contact FDA officials to learn the status of specific documents by using agency phone numbers and e-mail addresses listed online at <http://directory.psc.gov> [3].

Keep in mind that the FOI office at FDA is not a personal reference library, and officials there are not obligated to create any original documents. If a report was not prepared, a firm may never receive the information it is looking for. However, if you are reasonably sure that the information exists, you should first visit FDA's Web site to see whether the documents are already listed there.

The FOIA currently requires that releasable documents that are requested three or more times be placed online. Every so often, FDA places high-profile documents on its Web site because it knows that they will most likely be requested by more than three interested parties. For example, an FDA-483 issued to Guidant Corp. on February 9, 2006, was placed online immediately. The intense public and media



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interest over the firm's recent troubles with its implantable cardioverter-defibrillators and pacemakers warranted this action.

Other documents that are quickly posted online include documents of interest to a wide audience, such as guidelines and warning letters. However, if a particular document is sought, it may not be wise to wait for it to be posted online. There is a distinct possibility that FDA may not receive three or more requests for it. If the information exists but isn't available online, then FOIA requests can be fruitful. Remember, though, that documents dealing with personal information (such as patient records), confidential business information (trade secrets or customer lists, for example), and ongoing legal action may be held back or redacted by FDA. (There are also six other FOI exemptions that are not commonly applicable to FDA documentation.) Redaction, or censoring those parts of a document withheld because of the exemptions to FOIA, is done by designated FDA staff within a particular office or district. Occasionally, agency staffers may inadvertently release confidential information. Although they usually are disciplined for this type of error, no FDA staffer has ever been criminally charged for such a transgression.

In addition, even though a document may exist, it doesn't mean FOI staff will be able to find it. Once records have been retired, they are extremely difficult to find, and many older preelectronic documents may be damaged or unreadable. Bear in mind that despite all of these potential drawbacks, documents received via an FOIA request are valuable and may include information not available elsewhere. These documents can give manufacturers unique insight into what FDA is thinking and how the agency handles particular situations, notably those that may arise during the approval process or facility inspections.

What Information Should a Request Letter Include?

Write FOIA request letters clearly and concisely, and be as specific as possible to ensure the fastest possible reply by FDA. Identify a contact name, company affiliation, mailing address, e-mail address, and phone and fax numbers. Providing a phone number is important because FOI office staff will most likely attempt to call if they have a question about the documents that are being sought.

Next, invoke FOIA by informing FDA that the letter serves as a Freedom of Information Act request, and explain exactly what you are looking for. The more specific the request, the better the chance is of quickly receiving accurate documents. The letter also should inform the FOI office of how much the firm is willing to spend to receive a copy of the requested information. Such a statement could read, "If the cost of providing these documents will exceed \$150, please call us first for authorization of the charges."

Commercial-use requesters are charged search and review fees of \$20, \$40, or \$72, depending on the grade level of the FDA employee who fulfills the request. Duplications cost \$0.10 per page and \$0.50 for a sheet of microfiche; certifications are \$10 each. Computer charges are the actual cost for time involved in retrieving the information. Charges for electronic forms and formats are the actual cost of the



form and format requested. Non-commercial-use requesters, such as students, journalists, educators, and public interest groups, only pay duplication fees, with no charge for the first 100 pages that are duplicated. Other requesters, including consumers, pay the same search and duplication costs as commercial-use requesters. However, consumers are not charged for the first two hours of the search or for the first 100 pages of duplication.

It is also important to specify in a request letter whether the firm would like to receive all of the information that is available on a certain subject—which usually takes a much longer time to process—or just the material that can be disclosed, which means portions of the document will most likely be redacted when it is received.

Once the letter is completed, it should be mailed to: Food & Drug Administration, Office of Management Programs, Division of Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. (For addresses of agencies other than FDA, visit www.usdoj.gov/oip/index.html[4].)

When the request is received by FOI office staff, it is registered in the FOIA log (see the sidebar, "[Effectively Using an FOIA Log](#) [5]"). If the request is for a document that is in their control, such as copies of previously released FOIA documents that already have assigned FOIA control numbers, then they usually fulfill the request. If not, the staffers pass the request along to the proper center, regional office, or district office where the document is maintained. Center or office staff then are responsible for locating the document and determining whether it can be fully disclosed or whether it needs to be redacted. The document is then sent to the requester.

What Factors Slow Down FOIA Requests?

Although FOIA specifies that the requester will receive a response to an FOIA request within 20 days, this reply is only an acknowledgement that the request has been received by the FOI office. The time it takes for the document to actually follow can take much longer and, in some cases, it may take years.

The wait for documents depends in large part on the type of information that is requested. FDA places FOIA requests into one of two categories: simple requests and complex requests. Simple requests are documents that the FOI office can process relatively quickly. They generally involve receiving information from only one particular FDA office. Conversely, complex requests are more likely to be released at a slower pace, because more than one agency office must typically become involved.

For example, if a requester asks for all of the Inspection Reports and FDA-483s for a particular competitor with multiple sites, the request would be considered complex because it would involve requesting documents from all relevant FDA district offices. One way to avoid such a complex request would be to file separate FOIA requests for FDA-483s at each of the competitor's facilities. Those requests would be considered simple and, theoretically, they would be processed faster.

What Information Can Be Gained through FOIA?

Several important documents can be obtained through an FOIA request, including establishment inspection reports (EIRs) and FDA investigator notes and diaries, as well as FDA-483s and responses.

Device companies can learn a lot from reviewing EIRs that are issued to competitors. This includes learning what happened during an inspection, who at the firm was in charge at the time, and which employees were interviewed by the FDA investigator. The EIR also may include information about the inspected firm's various programs that the agency found acceptable. This could be helpful information for a manufacturer wondering whether a comparable program it employs at its own company would be deemed satisfactory by FDA.

EIRs do not only include information on observations made by the FDA investigator. They also provide a detailed account of any discussions the investigator had with management. An FDA-483 also may be attached to the EIR, along with a response by the manufacturer.

When constructing an FOIA request for an EIR, specify the name of the company that received the EIR, as well as the firm's location and a rough time frame when the inspection occurred. The time frame does not have to be the exact date of the inspection; rather, you could request the most recent EIR that the manufacturer received. It is a good idea to request the FDA-483 in addition to the EIR.

Diaries and notes that were compiled by an investigator who was assigned to a specific facility inspection may also be requested. Diaries provide an insight into an investigator's thought process when inspecting a firm and may contain valuable information that could reveal what the investigator thought of certain manufacturing processes. Do not send that request to the FDA district office that conducted the investigation; rather, send it to the FOI office in Rockville, MD.

Having this information gives manufacturers an edge because it allows them to build up information about FDA investigators who may inspect their facilities. It also provides insight into how companies that manufacture competing products and use similar manufacturing processes fared during inspections. This can help companies be more prepared for the next agency inspection and help them avoid errors that other firms have made.

In addition, it makes sense for manufacturers to use this information when creating standard operating procedures. By reading other firms' inspection reports, a company can learn what FDA did and didn't like, and therefore bolster its procedures to fit agency expectations.

Can 510(k)s Be Requested?

Through the FOIA process, manufacturers also may review 510(k) submissions. Although 510(k) summaries often are posted on FDA's Web site, those small bits of

information don't provide the level of detail that full 510(k)s do. In addition, more-complicated 510(k)s can provide valuable preclinical and clinical trial results and other useful information.

Full 510(k)s can be used in different ways. For example, if a particular device is similar to a firm's product, that firm could use the device's 510(k) as a template. And, because that marketed device's 510(k) has been approved, the firm also may consider plugging its own numbers into the document and submitting essentially the same form. However, bear in mind that requesting a 510(k) through the FOIA process could take 18 months to three years, which is among the longest response times for FOIA documents. Although FDA does allow the 510(k) submitter to mark trade secret and confidential commercial information as exempt from disclosure, the FOI office will review these redactions for adherence to the strictures of FOIA.

What Other Documents Can Be Requested?

Other interesting documents that can be requested include résumés, curricula vitae, and government employment forms (SF-171s) for FDA investigators, as well as training modules investigators follow when learning how to inspect device manufacturers. These documents may provide insight into the investigators' education, background, and experience, and show what they are being taught by FDA when it comes to facility inspections.

Correspondence, minutes, and transcripts between FDA and manufacturers also may be of use. For example, if you are aware that a particular manufacturer is meeting with FDA, you can submit an FOIA request for the minutes of the meeting in an effort to learn about issues affecting devices currently in the marketplace that the competitor manufactures. In addition, correspondence between the company and the agency may reveal other product issues. However, you should be aware that FDA will redact any information in these records that is exempt from public disclosure.

Finally, reviewing inspection reports, warning letters, and correspondence is a good way to research a private company that your firm may be considering buying, entering into a joint venture with, or using as a subcontractor.

What if an FOIA Request Is Denied?

Although some information may be redacted before documents are released, FDA does in fact approve a majority of FOIA requests. In 2005, the agency denied only 37 out of a total of 17,528 requests; another 39 requests were granted only in part. Once FDA decides a document should be denied, it is unlikely that it would overturn that position on appeal. However, should you decide to appeal an FOIA denial, you must send the appeal in writing within 60 days of receiving the initial denial letter. FDA recommends that the letter be clearly marked "Freedom of Information Act Appeal" and sent to the FDA's FOIA staff at the aforementioned address. According to the agency, the letter will then be hand-carried to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services.

Make sure to write "Freedom of Information Act Appeal" in the text of the letter and on the front of the envelope. It is also important to include in the appeal letter the initial request number and the name of the FOI office staffer who handled the request. No specific language is required to be written in the appeal letter, although you may choose to explain why you believe the document you requested should be released.

Conclusion

Although the FOIA process can at times prove somewhat tricky and time-consuming, the benefits of requesting and receiving unpublished documents are extraordinary. With just a little patience and perseverance, you can open doors of information that could help your company more effectively ensure FDA compliance, create world-class standard operating procedures, or more easily release a new product. This service is open to anyone, anywhere, at any time. Take the initiative and exercise your right to request information under FOIA.

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