United States General Accounting Office

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Report to the Chairman, Subcommittee on Government Information, Justice, and Agriculture, Committee on Government Operations, House of Representatives

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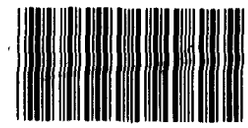
FREEDOM OF INFORMATION

FDA's Program and Regulations Need Improvement



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Office of the General Counsel

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October 11, 1991

The Honorable Bob Wise
Chairman, Subcommittee on Government
Information, Justice, and Agriculture
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

This report responds to your request that we review the Food and Drug Administration's (FDA) implementation of the provisions of the Freedom of Information Act (FOIA). Specifically, we agreed with your office to determine

- the legality of FDA's regulations that provide that (1) the withholding of certain information by FDA is a "minor deletion" rather than a denial, and thus not immediately appealable and (2) when FDA is sued for release of information that it agrees consists of trade secrets, FDA will release the information unless the submitter intervenes to defend against disclosure;
- if FDA properly implemented (1) the 1986 FOIA amendments relating to fees required for processing FOIA requests and (2) a 1987 executive order requiring an agency, before it releases confidential commercial data, to notify the submitter; and
- whether FDA has responded promptly to FOIA requests.

Background

FOIA, as amended (5 U.S.C. 552), makes available to the public all of the records of an executive branch agency unless the records are specifically exempt from disclosure.[1] With a few exceptions, such as national security information, information that is exempt from disclosure under FOIA may be disclosed if the agency waives the exemption. (Laws other than FOIA may create exemptions from disclosure that cannot be waived.)

FOIA requires each federal agency to publish regulations governing how the public can gain access to its records. The regulations must describe how to request information; what types of information can be made

[1]Classes of information exempt from disclosure include: national security information, internal personnel rules, trade secrets, certain agency memoranda, personal information about individuals, law enforcement records, records about financial institutions, and oil well data.

available; fees for processing information requests, including circumstances for waiving fees; and how to appeal from denials.

FOIA requires an agency to determine within 10 working days after receiving a request for information whether to comply. The agency is then to notify the requester immediately of its determination. FOIA does not establish a deadline for releasing records, but says that they should be provided promptly upon a request that complies with the law and regulations.

When a request is denied, the requester may appeal. An appeal begins within the agency—in the case of a denial by FDA, to the Assistant Secretary for Health, Department of Health and Human Services (HHS). Either after an appeal to the agency is turned down, or in some circumstances without first going to the agency, the requester may appeal to the courts.

The 1986 FOIA amendments changed the fee structure for processing FOIA requests and the provisions for waiving fees. Before the amendments, agencies could charge requesters only for costs relating to document search and duplication. The amendments provide that when the records are requested for commercial use, agencies can also charge for costs associated with reviewing records, for example determining whether the records are releasable.

Before and after the amendment, fees could be waived on the basis that disclosure would be in the public interest. However, the explanation of what constitutes the public interest was changed. Before the amendments, agencies could waive fees if they determined that disclosure of the information would primarily benefit the public. Today a waiver is permitted if the information is likely to contribute significantly to the public's understanding of government activities, and is not primarily in the commercial interest of the requester.

Executive Order 12600 (June 23, 1987) requires a federal agency to notify anyone who has submitted confidential commercial information when a FOIA request for the information has been received. Confidential commercial information is defined as information that is arguably exempt from disclosure under exemption 4 of FOIA. This exemption, the so-called trade-secrets exemption, permits withholding of information when "disclosure could reasonably be expected to cause substantial

competitive harm."[2] Disclosure of trade secrets by government officials is prohibited by the Trade Secrets Act (18 U.S.C. 1905). FDA is also specifically prohibited from disclosing trade secrets under section 301(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Under the executive order, before the agency releases such information, it must provide the submitter with an opportunity to object, and must consider any objections by the submitter in deciding whether to release the information.[3]

FDA, a component of HHS, receives about 40,000 FOIA requests annually. FDA's Office of Public Affairs has overall responsibility for administering the agency's freedom of information activities. That office assigns all FOIA requests to the FOIA officer at the appropriate FDA center or field office. FDA centers and field offices determine whether information is available. If so, the office's Freedom of Information staff handles the requests.

FDA's FOIA regulations allow what it calls minor deletions before it releases documents. These are defined by FDA as relatively isolated deletions, from otherwise disclosable documents, of information that FDA considers clearly nondisclosable. These deletions are not considered by FDA to be denials, and, therefore, are not immediately appealable to the Assistant Secretary for Health, as is a denial.

When FDA's denial of a request for trade-secret information is contested in court, FDA will disclose the information, unless the submitter intervenes to defend the exempt status of the information. The submitter's failure or refusal to intervene is considered by FDA to be a waiver of its rights under exemption 4 of FOIA, the trade-secrets exemption.

Results in Brief

Two of FDA's FOIA regulations—one concerning minor deletions and another requiring submitters to intervene in lawsuits—are inconsistent with law. Other FDA FOIA regulations do not accurately reflect the current state of the law, although they have been superseded by HHS regulations that do.

[2]The exemption covers trade secrets as well as confidential commercial or financial information. When referring to exemption 4 in this report, for convenience, we use the term "trade secrets" to include all protected proprietary information, including confidential commercial or financial data.

[3]The order provides that the agency must give notice to the submitter when the agency determines that release of the information could reasonably be expected to cause the submitter substantial competitive harm. Beginning January 1, 1988, the agency also has to give notice, regardless of its own view, if the submitter claims the likelihood of substantial competitive harm as a result of release.

FDA's practice of precluding immediate appeals of minor deletions of information creates a procedure for requesters that is not authorized by FOIA. If the same information had been denied, as the law contemplates, the requester would have been permitted to appeal immediately; when the information is instead the subject of minor deletions, the requester must make a second request for the deleted information, and may not appeal until that second request is denied. FDA argues that this policy benefits requesters: they get a faster answer to their initial request because FDA does not have to make a final determination of the releasability of all the information, and their right to appeal is not lost but only delayed. Although we question this analysis, our objection to the minor-deletions policy is based on its inconsistency with the requirements of FOIA, not on whether it benefits the requester.

The FDA policy of releasing trade secrets unless the submitter intervenes in a lawsuit seeking their release is inconsistent with the laws that expressly prohibit the unauthorized release of such information by government officials in general, and by FDA in particular. It is FDA's, not the submitter's, statutory responsibility to protect information covered by these acts. A submitter's failure to defend against the release in no way changes the responsibility of the agency, the confidentiality of the documents at issue, or the rights of the submitter. As a result, if information held by FDA is covered by the Trade Secrets Act or the Food, Drug, and Cosmetic Act, disclosure would be an abrogation of FDA's statutory responsibilities.

FDA's regulations have not incorporated changes made by FOIA amendments or Executive Order 12600 regarding processing fees and predisclosure notifications. The FDA FOIA regulations have been superseded by HHS regulations that do reflect the changes in the law and the order, but it would be preferable for FDA regulations to be updated as well, so that the public can look in one place for current information.

Generally, FDA has complied with predisclosure notification requirements. However, FDA may not be recovering through its fees all the FOIA costs to which it is entitled under the law.

In about 45 percent of the cases we reviewed, FDA did not meet the 10-day requirement for notifying requesters of the status of their requests. However, while the law does not set a time limit for providing information to a requester, FDA usually provided the information within 30 days.

Objectives, Scope, and Methodology

In response to your request, we reviewed pertinent provisions of FOIA, Executive Order 12600, and HHS and FDA regulations. We reviewed a random sample of 100 FOIA-request files that FDA processed in 1988 and 1989 to determine if FDA appropriately assessed and waived fees for processing requests. Since most requests were from private businesses, we reviewed a separate sample of 133 files from noncommercial requesters. We also reviewed FDA's 1988 and 1989 waiver files and analyzed information on the identity of the requesters, justification for waivers, and amounts involved. From a computer review of the files, we also assessed FDA's compliance with the 10-day notification requirement of FOIA and the predisclosure notification requirement of the executive order.

To develop information on how long FDA took to respond to FOIA requests, we used FDA's freedom of information automated system and analyzed 150,335 requests that were processed between January 1, 1986, through December 31, 1989. Response time represents the number of workdays between the date a request was received and the date a response was provided.

Our work was performed in accordance with generally accepted government auditing standards.

FDA's Minor Deletions Are Not Proper Substitute for Statutory Denials

An agency is required to determine, normally within 10 days, whether to comply with a FOIA request. The agency is then supposed to notify the requester of its determination and, if the decision is to withhold some or all of the information sought, of the requester's right to appeal.

Under FOIA, the general rule is that information must be released unless it falls within one of a set of exemptions specified in the law. FOIA recognizes that a single document may contain both releasable and exempt information, and that an entire document should not be withheld on the basis that some parts of it are exempt from disclosure, if those parts can be separated from the rest. Therefore, any reasonably segregable portion of a record is to be released to a requester "after deletion of the portions which are exempt."

The clear implication is that the requester is entitled to a timely decision whether parts of an otherwise disclosable document are exempt and, therefore, to be withheld. Once notified of a decision, the requester can pursue remedies under the act, first by administrative appeal within the agency and then by judicial review.

FDA's minor-deletions policy appears to add an additional step, not contemplated by the law, before the requester can appeal. The policy and the reason for it are stated in FDA's operating manual:

"The letter accompanying the record sent to the requester must contain the following paragraph:

"'In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the record(s) indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request . . .. Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal.'"

Because a minor deletion of nondisclosable information from disclosable records is not considered by FDA to be a denial of the request, a requester who receives records with minor deletions may not follow the normal appeal route to HHS that would have been available if the same information that was deleted had been denied. Instead, the requester must resubmit a request to FDA for the deleted material. Only when this second request is denied may the requester appeal.[4]

FDA's Freedom of Information Director told us that the policy may benefit requesters because, as the above quote from FDA's operating manual suggests, it gives them releasable information more quickly.[5] FDA also pointed out that by allowing it to make records promptly available, the minor-deletions policy is consistent with FOIA.

We do not agree with either of these assertions. Making records more promptly available does not remedy a process that is clearly inconsistent with FOIA. Further, more timely release may not occur. We see no

[4]Of the approximately 30,000 releases FDA processed with minor deletions from 1986 through 1989, 87 requests were made for the information treated as minor deletions. All were denied. Sixteen were appealed but in each case the original determination was upheld.

[5]Nothing prevents a requester from ignoring the regulation and, instead of submitting a second request for the deleted materials, filing an administrative appeal after minor deletions on the theory that the minor deletions are tantamount to a denial and cannot be used to delay the right to appeal. However, FDA might well contest that procedure.

As a result, the requester may be better off, as a practical matter, to endure the delay. The alternative is to get into a legal battle with FDA over what, from the requester's point of view, is a tangential issue, the legality of the minor-deletions policy. Other factors that could influence the requester's decision whether to challenge the minor-deletions policy are the nature of the document, the inferences that can be made from what is released about what may have been deleted, and the likelihood that FDA's initial determination that the deleted material is exempt will be upheld.

reason why it would take substantially longer for FDA to deny the information that is now the subject of the minor-deletions policy and release the rest. Agencies are required by FOIA, as noted above, to release those parts of a document that are "reasonably segregable" after excising the exempt parts. This requirement can be complied with in the same situations in which minor deletions are made: if material that FDA believes to be exempt can be taken out of a document in the form of minor deletions, it is reasonably segregable.

FDA, instead of applying its minor-deletions policy, should provide the information about which there is no dispute, and allow for an immediate appeal of its decision to exclude certain portions. In doing this, FDA would provide for expeditious disclosure, maintain its discretion to exclude certain kinds of information, and implement FOIA without recourse to a procedure not sanctioned by statute. It is not clear that it would take any longer to get the information to the requester this way.

FDA Regulation Abrogates Its Responsibility to Protect Trade-Secret Information

FDA's policy—that it will not defend in court its determination to withhold information that it has found to fall within the category of trade secrets—is an abrogation of its responsibility under the laws prohibiting public release by government officials in general and FDA officials in particular of trade secrets.

FOIA provides a mechanism for private parties to seek release of information held by government agencies. The mechanism is available whether the information was generated by the government or the private sector. However, agencies may withhold certain classes of information, one of which is trade secrets. This information is protected by exemption 4 of FOIA, the so-called trade-secrets exemption.

Most commonly, trade-secret information comes from a source outside the government. It is afforded special protection under FOIA and other federal law because its release to a competitor could harm the business interests of the submitter.

If a request for information is denied by FDA based on a FOIA exemption, the requester may, after an appeal within the agency, bring suit against the agency. When the basis for its refusal to release the information sought is that the information falls within the trade-secrets exemption, FDA refuses to participate in such suits. Instead, FDA tells the submitter that, unless the submitter intervenes in the suit to defend against release, FDA will release the information. FDA justifies this on the basis

that it deems the submitter's refusal to defend against release to be a waiver by the submitter of the FOIA exemption.

In explaining its waiver theory, FDA told us that companies defend their documents when they believe that disclosure would lead to competitive harm. Those that choose not to defend have determined that disclosure would not cause such harm, the consequence of which is that FDA no longer considers the documents confidential and discloses them. Although FDA may disclose information that is not confidential, its analysis above is overly simplistic and assumes too much. For example, a company may decide not to defend its documents simply because it cannot afford legal representation or believes the responsibility clearly belongs to FDA. FDA should not assume that all companies respond alike under similar circumstances or that they have similar motivations. Nor should it base its regulations on such tenuous assumptions.

FDA's policy of releasing information that it has determined to be covered by the trade-secrets exemption is inconsistent with its statutory responsibilities to the extent that the information is covered by other federal laws that protect trade secrets. Exemption 4 cannot be waived by FDA when the information is protected by the Trade Secrets Act or the Food, Drug, and Cosmetic Act. The Trade Secrets Act makes it a criminal offense for government officials to release to the public "trade-secrets" that become known to them in their official capacities, "to any extent not authorized by law." The Food, Drug, and Cosmetic Act similarly prohibits disclosure by FDA of trade secrets. FDA regulations acknowledge these limitations. Court decisions have held that information that falls under FOIA's trade-secrets exemption is in general also covered by the Trade Secrets Act.[6] FDA has also acknowledged in the past that such material is also covered by the Food, Drug, and Cosmetic Act's prohibition against the release of trade secrets. 39 Fed. Reg. 44,612 (1974).

FDA's policy does not lead to an implied waiver of the rights of a submitter of trade secrets. The relevant right of the submitter is to rely on the government to protect trade secrets turned over to it. As a result, if information held by FDA is in fact covered by the Trade Secrets Act or the Food, Drug, and Cosmetic Act, and there is no other legal authority for its release, it would be a violation of either or both of those statutes and of FDA regulations for FDA to release the information.

[6]For example, General Motors v. Marshall, 654 F.2d 294, 297 (4th Cir. 1981), Westinghouse v. Schlesinger, 542 F.2d 1190, 1203-1204 and n. 38 (4th Cir. 1976).

FDA Regulations on Fees and Predisclosure Notices Should Be Updated

FDA regulations have not been changed to reflect two changes in implementing FOIA: the 1986 amendments to FOIA and the 1987 executive order. HHS issued rules to incorporate these changes, and these HHS rules, by their terms, supersede FDA's regulations to the extent that the regulations are inconsistent with them.

Because the HHS regulations are the operative provisions, FDA's failure to change its regulations has no legal consequence. It does, however, make FDA's regulations misleading for members of the public who want to know the current state of the agency's FOIA policies.

FDA generally has complied with the predisclosure notification requirement in the executive order. The order provides, among other things, that notification of the submitter is not necessary if an agency's regulations specify narrow classes of records that are releasable under FOIA. FDA's regulations do, in fact, identify specific classes of records that are releasable for various products that it regulates. FDA is not required to provide predisclosure notification in those cases.

FDA is required to provide to submitters predisclosure notification of requests relating to "premarket notification" concerning medical devices because its regulations do not identify specific information about medical devices that is disclosable under FOIA. FDA appears to be complying with this requirement. We reviewed 54 requests for information relating to premarket notification and found that FDA had provided predisclosure notification in each case.

While FDA regulations have in effect been modified by the HHS regulations that supersede them, to the extent of any inconsistency, it would be administratively preferable for FDA to update its regulations to reflect changes made by the amendments and executive order. Updated regulations would accurately inform submitters and requesters of information about the requirements of FDA's freedom of information program.

FDA May Not Be Recovering All FOIA Costs to Which It Is Entitled

FOIA authorizes federal agencies to assess reasonable charges for direct costs relating to document search, review, and duplication when records are requested for commercial use. Direct costs include employee salaries for such searches, reviews, and duplication. They do not include overhead expenses, such as costs of space, and of heating or lighting the facility in which the records are stored.

It is not clear whether FDA is recovering all the costs it is entitled to under its FOIA program. We were not able to reconcile from FDA records the difference between total costs incurred and fees charged.

For calendar year 1989, FDA incurred $5.5 million in costs to respond to FOIA requests and charged requesters a total of $659,000. FDA says that the difference is not properly chargeable to requesters, but it was not able to provide a fully documented accounting of the difference. Moreover, FDA has not collected all fees that are owed.

FDA does not maintain records that show a detailed accounting of the costs that are incurred for the FOIA program. FDA's 1989 reported costs of $5.5 million are based on data provided by the various FDA centers and field offices. Those data show the number of hours clerical and professional staff spent on FOIA activities. However, the data do not distinguish between recoverable and nonrecoverable costs, and center officials told us they represent estimates rather than supportable time charges.

The 1989 charges by FDA of about $659,000 for processing FOIA requests may not represent all of the recoverable charges. FDA does not maintain an accurate system to account for direct and indirect costs of implementing FOIA. FDA contends that the difference between the total staff costs incurred and the amount billed represents indirect expenses and certain other nonrecoverable direct costs, such as supervisory time and costs for preparing correspondence and maintaining a computer data system for FOIA requests. However, FDA has no documentation to support its contention.

In addition to this uncertainty about the adequacy of fees charged, FDA has not collected all the fees it has billed to requesters. From 1986 through 1989, FDA charged requesters a total of $1,925,260 for processing their FOIA requests. As of March 1990, about 6.5 percent of these charges each year have gone uncollected. Annually the uncollected amounts ranged from about $26,000 to more than $43,000 from 1986 to 1989. FDA has not aggressively pursued nonpayers, and it does not have a management information system to alert it when a requester has not paid a bill.

In December 1989, FDA hired a private firm to send follow-up letters requesting payment of overdue FOIA bills. Information provided by FDA indicates that, since then, it has collected over $58,000 from overdue 1988 and 1989 accounts.

FDA's 10-Day Notifications Were Often Late, but Responses to Requests Were Fairly Prompt

FDA often did not comply with FOIA's requirement to inform requesters within 10 days whether their request would be granted. However, although the law does not set a time limit for providing information to a requester, in most cases FDA provided the information within 30 days.

We analyzed more than 150,000 of the 165,768 requests for information received by FDA from 1986 through 1989. We found that, in about 45 percent of the cases, FDA did not provide the requested information or the required notification within 10 days. However, for about 71 percent of the requests, FDA provided the requested information within 30 days. Information sought in most of the remaining requests was provided within 90 days. Table 1 shows the overall FDA processing time for the FOIA requests we analyzed.

Table 1: FDA Processing Time for Closed FOIA Requests 1986-89

Number of workdays	Requests processed	
	Number	Percent
0-30	106,129	70.6
31-60	20,882	13.9
61-90	6,721	4.5
91-180	7,784	5.2
181-365	6,073	4.0
366-730	2,547	1.7
731-1095	199	0.0
Total	**150,335**	**100.0[a]**

[a]Figures do not add to total due to rounding.

Although FDA responded to most requests within 30 days, response times varied among the FDA centers and offices, as shown in table 2.

Table 2: FOIA Requests Closed Within 30 Days by Selected FDA Centers and Offices (1986-89)

	Total number of FOIA requests received	Number closed	Closed in 30 days or less	
			Number	Percent
FDA Freedom of Information Office	35,610	35,516	24,982	70
Center for Drug Evaluation and Research	21,100	20,489	16,947	83
Center for Devices and Radiological Health	17,354	14,077	7,598	54
Center for Food Safety and Applied Nutrition	3,710	3,477	2,962	85
Center for Biologics Evaluation and Research	2,848	2,785	1,694	61
Office of Regulatory Affairs	1,663	1,470	924	63
Center for Veterinary Medicine	1,030	1,021	886	87
Los Angeles District Office	2,184	2,060	1,593	77
Orlando District Office	1,259	1,215	889	74
New Orleans District Office	347	339	326	96

Note: District offices were selected on the basis of high, medium, and low volume of FOIA requests.

While our analysis showed that some offices with smaller volumes of requests processed a higher rate of responses within 30 days, there was not a consistent relationship between response time and volume. For example, the Center for Drug Evaluation and Research processed 83 percent of its nearly 20,500 closed cases in 30 days or less. By contrast, the Center for Biologics Evaluation and Research processed 61 percent of its approximately 2,800 closed cases within 30 days.

However, we did find that requests that were processed by a single office took less time than requests whose processing had to be coordinated within two or more offices. As table 3 shows, about 75 percent of requests requiring action by a single office were processed within 30 days whereas about 47 percent of requests requiring action by multiple offices were processed within 30 days.

Table 3: Comparison Between Single Office and Multiple Office Closure of FOIA Requests Processed Within 30 Days

	FDA		Single office requests		Multiple office requests	
Calendar year	Number	Percent	Number	Percent	Number	Percent
1986	26,875	67.4	24,453	70.9	2,422	46.5
1987	28,280	68.6	25,979	71.4	2,301	47.3
1988	24,462	66.8	21,393	75.5	3,069	37.0
1989	26,512	81.3	22,955	85.6	3,557	61.1
Total	**106,129**	**70.6**	**94,780**	**75.2**	**11,349**	**46.5**

FDA officials told us that they believe a key element affecting response time is the priority given to FOIA activities by each center or office.

Conclusions

While FDA has provided information on FOIA requests in a fairly timely manner, it needs to improve compliance. To be fully consistent with the law, FDA also needs to rescind its policies regarding minor deletions and private intervention in lawsuits. These policies lack a basis in law.

Also, even though FDA's regulations have in effect been modified by superseding HHS regulations, with respect to fee charges and predisclosure notifications, it would be administratively preferable for FDA to update its regulations to reflect changes made by FOIA. In this way, those reading the regulations would know which parts remain in effect.

FDA needs to (1) better account for costs under its FOIA program so that it can recover through its fee structure all allowable costs and (2) do better in providing 10-day notices to requesters to advise them of the status of their requests as contemplated by the law.

Recommendations

To strengthen FDA's administration of its FOIA program, we recommend that the Secretary of HHS direct FDA to (1) rescind its FOIA regulations concerning minor deletions and private-party interventions, (2) update its regulations regarding fees and predisclosure notifications to reflect the requirements of the law and executive order, (3) better account for costs related to its FOIA activities so that FDA has greater assurance that it is recovering through its fee charges all allowable costs, and (4) take measures that would better assure that it complies with the statutory 10-day notification requirement.

As agreed with your office, we did not request written comments from FDA, but we discussed the matters in this report with FDA officials and incorporated their comments where appropriate. Unless its contents are announced earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies to the Secretary of HHS and interested parties and will make copies available to others on request. If you have any questions about this report, please call me at (202) 275-5881. Other major contributors are listed in appendix I.

Sincerely yours,

Barry R. Bedrick
Associate General Counsel

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