



September 19, 2012

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

### **CITIZEN PETITION**

Public Citizen, a consumer organization with members and supporters nationwide, submits this citizen petition under 21 C.F.R. § 10.30 to request that the Food and Drug Administration (FDA) (1) revoke 21 C.F.R. § 20.49(d), which provides that “minor deletions” from records disclosable under the Freedom of Information Act (FOIA) do not constitute a denial of a FOIA request, and (2) rescind portions of its Staff Manual Guide providing that “minor deletions” do not constitute a partial FOIA denial in the first instance and do not trigger a requester’s right to an administrative appeal. This regulation and the Staff Manual Guide portions that implement it (collectively, the deletions policy) are inconsistent with FOIA and the FOIA regulations of the Department of Health and Human Services (HHS), of which FDA is a component. Moreover, the deletions policy cannot be justified as necessary to serve FOIA requesters promptly; in fact, it negatively affects requesters and the public.

#### **I. ACTIONS REQUESTED**

Public Citizen requests that FDA revoke 21 C.F.R. § 20.49(d), which provides:

Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

Public Citizen also asks that FDA promptly revise its Staff Manual Guide to rescind or revise several portions of §§ 3297.1 and 3297.2 that address FDA’s handling of FOIA requests and implement 21 C.F.R. § 20.49(d). First and foremost, FDA should revoke Part 8(E) of Staff Manual § 3297.1, which states in full:

FDA does not treat “minor deletions” made to otherwise releasable records as formal denials in the first instance. The overwhelming majority of requesters who receive documents with minor deletions are satisfied with the material they receive and do not request the withheld material. When making minor deletions, the [Freedom of Information (FOI)] component office response letter should include the following paragraph:

**“Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA’s preliminary determination and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.”**

If, after reviewing and redacting the requested records, the FOI officer determines that a significant amount of material must be withheld, the FOI officer should prepare a partial denial recommendation, and submit the recommendation to [FDA’s Division of Freedom of Information (DFOI)].

In addition, Public Citizen requests that FDA revise Staff Manual §§ 3297.1 and 3297.2 to omit all other references to “minor deletions” or corresponding procedures to accommodate them and to make clear that the deletion of *any* material from a record otherwise responsive to a FOIA request is a partial denial under FOIA. These other references are contained in Parts 8(D) and 8(F) of § 3297.1 and Parts 6(A)(1)(b), 7(B)(5), and 7(B)(6)(c) of § 3297.2.

Public Citizen also requests, in the interim, that FDA immediately stop applying the deletions policy to pending and new requests.

## **II. STATEMENT OF GROUNDS**

### **A. Introduction**

Under 21 C.F.R. § 20.49(d) (the deletions regulation), FDA does not consider “minor deletions” from otherwise disclosable records to constitute a partial denial of a FOIA request. Instead, FDA’s current Staff Manual, which implements the regulation, instructs that a requester who receives documents with redactions that FDA deems “minor deletions” should receive only a preliminary determination letter that does not advise the requester of his right to immediate administrative appeal. The requester may receive a formal denial of the request and notice of appeal rights only after making a written request to FDA for reconsideration of a deletion. If the agency continues to withhold the information, it then issues a denial letter that advises the requester of the right to appeal. A requester who does not send a letter asking for reconsideration is never apprised of the right to appeal the withholding.

Public Citizen is not aware of any current, publicly available information that quantifies FDA’s use of the deletions policy. But based on Public Citizen’s experience as a frequent FDA FOIA requester and discussions with FDA, Public Citizen believes that FDA relies heavily on the policy. Public Citizen includes, as Appendix I, a sample of FDA FOIA responses citing the

agency's deletions policy and directing Public Citizen to mail a written request for reconsideration to challenge deletions.

Moreover, in practice, FDA relies on the "minor deletions" policy to make significant redactions from documents. FDA staff indicated in discussions with Public Citizen that the policy permits withholdings of up to twenty percent. We are not certain whether this "twenty percent" rule, as described by FDA staff, is supposed to be applied per document or per page, but in practice, Public Citizen has seen FDA FOIA responses that rely on the deletions policy to delete *full pages* of documents. An excerpt of a response subject to the deletions policy from which half of a page has been deleted is attached as Appendix II.

More than two decades ago, the U.S. General Accounting Office (now, the Government Accountability Office, or GAO) urged FDA to rescind its deletions regulation and a similar policy on "minor deletions." See GAO, Freedom of Information: FDA's Program and Regulations Need Improvement 1 (1991) (hereinafter, the GAO Report), *available at* <http://archive.gao.gov/d18t9/145264.pdf>, attached as Appendix III. GAO concluded that the deletions policy ran counter to FOIA. Despite GAO's rebuke, FDA maintains its deletions policy in substantially similar form today.

FDA's deletions policy should be rescinded because it authorizes a process for responding to FOIA requests that violates FOIA. FOIA establishes the exclusive mechanism for consideration of FOIA requests. Under the statute, any withholding of information constitutes a partial denial, and a requester must be advised of his right to an immediate administrative appeal. The deletions policy is also inconsistent with HHS's FOIA regulations, from which FDA, a component of HHS, may not diverge.

Not only is the deletions policy inconsistent with the governing statute and HHS regulations, it is not necessary to serve FOIA requesters promptly. It creates an incentive for FDA staff to over-redact documents, in stark contrast to FOIA's presumption in favor of disclosure. And FDA's use of the policy calls into question the integrity of its annual statutorily-required FOIA performance report.

In 2010, Public Citizen informally asked FDA to rescind its deletions policy on the ground that the policy was inconsistent with FOIA. In February 2011, it participated in a meeting with FDA staff, who indicated their belief that the policy benefits requesters by expediting requests. Public Citizen now formally requests that FDA rescind the policy by revoking 21 C.F.R. § 20.49(d) and revising or revoking portions of the Staff Manual that implement the regulation.

## **B. Factual Background**

### ***1. The deletions regulation***

The deletions regulation, 21 C.F.R. § 20.49(d), is contained in a section entitled "Denial of a request for records," which states in full:

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

FDA adopted the deletions regulation in 1974, but the regulation's underpinnings date to 1972, when FDA issued a notice for public comment on rules to implement FOIA. *See* FDA, Notice of Proposed Rule Making, 37 Fed. Reg. 9128 (May 5, 1972). The notice addressed only briefly the general processing of FOIA requests. *See, e.g., id.* at 9134. Although it stated that information “not available for . . . disclosure” should be deleted from otherwise releasable records, it did not propose the deletions regulation. *Id.* In 1974, before FDA had issued its final rule, Congress amended FOIA to require, among other things, that “[a]ny notification of denial of any request for records . . . shall set forth the names and titles or positions of each person responsible for the denial of such request.” Freedom of Information Act Amendments of 1974, Pub. L. No. 93–502, 88 Stat. 1561, 1563, *codified at* 5 U.S.C. § 552(a)(6)(C)(i).

When FDA issued the final rule, the deletions regulation appeared for the first time, contained in a section entitled “Denial of request for records.” FDA, Public Information, 39 Fed. Reg. 44,602, 44,646 (Dec. 24, 1974). In the Federal Register commentary accompanying the rule, FDA stated that the “Denial of request for records” section was intended to provide a procedure for denying a request and to implement the 1974 FOIA amendments, which “provide[d] that the names and titles or positions of each person responsible for the denial of a request for information shall be set forth in the letter denying the request.” *Id.* at 44,610. The commentary did not address subsection (d), the “minor deletions” provision. FDA has not specifically addressed the deletions regulation in a rulemaking since 1974.<sup>1</sup>

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<sup>1</sup> The agency twice recodified the deletions regulation and its surrounding subsections. *See* FDA, Reorganization and Republication, 42 Fed. Reg. 15,553, 15,553, 15,620 (Mar. 22, 1977) (recodifying 21 C.F.R. § 4.47 as 21 C.F.R. § 20.47); FDA, Public Information Regulations, 68 Fed. Reg. 25,283-01, 25,287 (May 12, 2003) (2003 Final Rule) (recodifying 21 C.F.R. § 20.47 as

## 2. *The Staff Manual's provisions regarding "minor deletions"*

FDA's Staff Manual implements the deletions regulation. The Staff Manual provides that "minor deletions" do not constitute an appealable denial under FOIA "in the first instance." FDA, Staff Manual § 3297.1, Part 8(E), *available at* <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm138408.htm>. The Staff Manual instructs FDA staff to tell a requester that, to ask for "reconsider[ation]" of a "minor deletion," the requester must make a second, written request to FDA, within thirty days, by mail. *Id.* If on reconsideration the agency continues to withhold the information, the agency then issues a formal denial that advises the requester of the right to appeal. *Id.*; *see also id.* § 3297.2, Part 6(D), *available at* <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm138410.htm>.

This procedure is set forth in the Staff Manual through the following language, which the Staff Manual directs FDA offices responding to an initial request with minor deletions to include in response letters:

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

*Id.* § 3297.1, Part 8(E).

Other portions of the Staff Manual make clear that FDA's internal process for making "minor deletions" is different from the process for withholding a "significant amount of material." *Id.* FDA components may issue "preliminary determination" letters with "minor deletions" without first obtaining approval from the FDA Division of Freedom of Information (DFOI). *Id.* In contrast, when they make other deletions not deemed "minor," FDA components must "prepare a partial denial recommendation," which they then forward to DFOI. *Id.* Only DFOI can issue an appealable denial, *see id.* § 3297.2, Part 6(D)(2)(a), which must be signed by

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21 C.F.R. § 20.49). And it made limited changes to other subsections now codified at 21 C.F.R. § 20.49. *See* FDA, Reorganization/Location Changes, 46 Fed. Reg. 8454-03, 8457 (Jan. 27, 1981); FDA, Public Hearing Before a Public Advisory Committee; Standards of Conduct and Conflicts of Interest; Public Information; Editorial Amendments, 55 Fed. Reg. 1404-02, 1405 (Jan. 16, 1990); 2003 Final Rule, 68 Fed. Reg. at 25,287. For the purpose of this petition, those changes are not relevant.

the FDA Assistant Commissioner for Public Affairs or his or her designee and provide a requester with notice of his right to administrative appeal, *id.*, Part 6(D)(1).

### 3. *The GAO Report on FDA's deletions policy*

FDA has long been aware that the deletions policy is, at a minimum, legally questionable. More than two decades ago, GAO responded to a congressional request from Rep. Bob Wise, Chairman of the House Subcommittee on Government Information, Justice, and Agriculture, to analyze FDA's implementation of FOIA. GAO agreed to determine, among other things, "the legality of FDA's regulations that provide that . . . the withholding of certain information by FDA is a 'minor deletion' rather than a denial, and thus not immediately appealable." GAO Report at 1. The agency's operating manual at the time, much like today's Staff Manual, provided that requesters could take a second step to obtain a final, appealable decision. The manual instructed the agency to respond to requests subject to "minor deletions" by directing requesters wishing to challenge deletions to "make an additional request" and that, "[s]hould the [a]gency then deny this information, [the requester] would have the right to appeal such denial." *Id.* at 6.

GAO concluded in a public report, attached as Appendix III, that the FDA's deletions policy was unlawful, and it recommended that FDA rescind the policy. GAO summarized its findings as follows:

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.

*Id.* at 4. GAO rejected FDA's assertion that the deletions policy was consistent with FOIA because it "allow[ed] [the agency] to make records promptly available." *Id.* at 6. GAO concluded that "[m]aking records more promptly available does not remedy a process that is clearly inconsistent with FOIA." *Id.* GAO also concluded that FDA's use of "minor deletions" provided no obvious benefit to requesters, stating that it saw "no 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." *Id.* at 6-7.

Accordingly, GAO urged FDA to rescind its deletions policy, which FDA had applied to approximately 30,000 releases from 1986 through 1989. *Id.* at 6 n.4, 13. It encouraged FDA instead to "provide the information about which there is no dispute, and allow for an immediate

appeal of [the] decision to exclude certain portions,” as doing so “would provide for expeditious disclosure, maintain [FDA’s] discretion to exclude certain kinds of information, and implement FOIA without recourse to a procedure not sanctioned by statute.” *Id.* at 7.

Despite GAO’s strong disapproval of FDA’s deletions policy, FDA has not rescinded its deletions regulation, and its current Staff Manual authorizes a “minor deletions” policy substantially similar to the one in place in 1991.

### **C. The Deletions Policy Is Inconsistent with FOIA and HHS’s FOIA Regulations.**

#### ***1. The deletions policy is at odds with FOIA.***

The deletions policy is inconsistent with FOIA’s plain terms, which establish the exclusive scheme for agency consideration of FOIA requests. Under FOIA, within 20 working days after receipt of a request, an agency must “determine . . . whether to comply with [a] request and . . . immediately notify the [requester] of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination.” 5 U.S.C. § 552(a)(6)(A)(i); *see also Oglesby v. U.S. Dep’t of Army*, 920 F.2d 57, 65 (D.C. Cir. 1990). If the agency upholds the denial of a request “in whole or in part” on appeal, it must then “notify the [requester] of the provisions for judicial review of that determination.” 5 U.S.C. § 552(a)(6)(A)(ii). The statute’s plain terms make this two-step process for the withholding of material the exclusive mechanism for denying FOIA requests. FOIA “does not authorize withholding of information or limit the availability of records to the public, *except as specifically stated in [the statute].*” *Id.* § 552(d) (emphasis added); *see also U.S. Dep’t of Justice v. Tax Analysts*, 492 U.S. 136, 151 (1989) (holding that an agency’s withholding of information is improper when it is not covered by one of FOIA’s “explicitly exclusive” exemptions).

Nowhere does FOIA’s exclusive scheme suggest an exception under which redactions from responsive records—so long as they are “minor”—do not constitute a partial denial, and thus do not trigger an immediate right to administrative appeal. Nor does FOIA countenance “preliminary determination” letters for “minor deletions” that add a layer of agency “reconsideration” before a requester has a right to administrative appeal. And nothing in the text of the statute allows an agency to close an otherwise proper request after releasing only a portion of requested records and without making a final determination whether or not to release the rest.

The deletions policy is thus at odds with FOIA. The deletions regulation states that “minor deletions” do not constitute a denial, even though a deletion “obviously, as well as literally, . . . is a denial of access.” James T. O’Reilly, *Food & Drug Administration* (3d ed. 2007), § 22.4 n.28. Likewise, despite the statutory requirements, the Staff Manual makes clear that “minor deletions” should not be accompanied by a final determination and notice of a requester’s immediate right to administrative appeal. Rather, to receive such a determination, a requester must file another request seeking reconsideration of “minor deletions” before he is advised of a right to appeal. If the requester does not do so, the agency closes his request without ever making a final determination. As GAO noted in 1991, “[i]f the same information [withheld by “minor deletions”] 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.” GAO Report at 4. GAO concluded that “FDA’s practice of precluding immediate appeals of minor deletions of information creates a procedure for requesters that is not authorized by FOIA.” *Id.* The same is true today.

**2. *The deletions policy is inconsistent with HHS’s own FOIA regulations.***

The FDA deletions policy is also inconsistent with HHS regulations. HHS’s FOIA regulations apply to all components of the agency. 45 C.F.R. § 5.3. Although some components, including FDA, “may establish additional rules because of unique program requirements,” those rules cannot conflict with HHS’s own regulations. *Id.*

HHS’s FOIA regulations provide that a denial includes a “withholding” or “deletion” and that either type of denial triggers a requester’s immediate right to appeal. Under 45 C.F.R. § 5.33(a), “[a]ll denials are in writing and describe in general terms the material withheld; state the reasons for the denial, including, as applicable, a reference to the specific exemption of the FOIA authorizing the withholding or deletion; explain your right to appeal the decision and identify the official to whom you should send the appeal; and are signed by the person who made the decision to deny all or part of the request.” FDA’s deletions policy thus reads an exception into 45 C.F.R. § 5.33 for “minor deletions” that is not countenanced by the HHS regulation. The deletions policy should, therefore, be rescinded on this ground as well.

**D. *The Deletions Policy Is Not Only Unlawful, It Is Also Unnecessary to Respond to Requesters Promptly and Disserves Requesters and the Public.***

**1. *The deletions policy is not necessary to serve FOIA requesters promptly.***

As noted in Part II.B.1, FDA has never provided a legal basis for its deletions policy in a rulemaking, nor did FDA explain the legality of its policy in its 2011 meeting with Public Citizen. In response to GAO’s inquiry in 1991, however, FDA justified the policy on the ground that it allowed the agency to respond more quickly to requests. Agency staff made the same assertion in the 2011 meeting. They added that only one agency staff person has authority to issue formal denials, and, therefore, without the deletions policy, that single person would have to review thousands of requests each year, resulting in substantial backlogs.

In fact, the deletions policy is not necessary to ensure that FDA can respond to FOIA requesters promptly. As the GAO observed in its report, there is seemingly “no 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.” GAO Report at 6-7. Moreover, the dilemma created by FDA having only one person with authority to issue final determinations on FOIA requests appears to be a problem of the agency’s own making. FDA could seek advice from other agencies or agency components that receive a similar or greater number of FOIA requests about ways to restructure FDA’s process for responding to requests. In any event, as is true for all agencies, bureaucratic hurdles do not justify systematic violation of FOIA.



**2. *The deletions policy lends itself to abuse by FDA staff.***

FDA should also rescind the deletions policy because the policy creates perverse incentives for FDA to withhold more information than is permissible by law. “[D]isclosure, not secrecy, is the dominant objective of” FOIA. *Dep’t of Air Force v. Rose*, 425 U.S. 352, 361 (1976). Yet the deletions policy encourages FDA staff to redact more information from records than is justifiable under FOIA, confident that more difficult decisions to withhold information will be resolved only if a requester disputes the initial deletions and the agency is forced to issue a formal denial. *Cf. Vaughn v. Rosen*, 484 F.2d 820, 826-28 (D.C. Cir. 1973) (recognizing that without a requirement for agencies to provide detailed, itemized justifications for withholding records, agencies have an incentive to over-withhold records). In other words, FDA’s deletions policy encourages staff to disclose the least amount of information acceptable to requesters, rather than the maximum amount of information required by law.

The deletions policy also allows, if not encourages, FDA staff to withhold portions of documents that are obviously not minor, rendering the term “minor deletions” a misnomer and the policy a significant problem. As described in Part II.B.2, the deletions policy permits FDA staff to make “minor deletions” without DFOI approval and without preparing a partial denial recommendation, as would be required for a denial not subject to the deletions policy. And under the guise of the deletions policy, FDA staff may partially disclose records without facing an immediate appeal from requesters. FDA staff, therefore, have incentives to label even non-minor withholdings as “minor deletions.” Accordingly, it is unsurprising that FDA interprets the deletions policy to permit a withholding of twenty percent, as described in Part II.A, and that Public Citizen has seen substantial redactions from documents denominated as “minor deletions,” *see, e.g.*, Appendix II. Thus, the deletions policy lends itself to abuse by FDA staff in a way that regular FOIA consideration practices do not.

**3. *The deletions policy overstates FDA’s and HHS’s FOIA performance in public data used to measure FOIA compliance.***

The deletions policy also undermines the integrity of FOIA performance data that FDA and HHS provide to the public to satisfy statutory reporting requirements. FOIA requires that each agency, including HHS, and its major subcomponents, such as FDA, report annually on a variety of indicators used to measure FOIA compliance. *See* 5 U.S.C. § 552(e)(1), (e)(2). Specifically, the statute directs each agency and major subcomponent to disclose annually the number of determinations that they make not to comply with FOIA requests and their reasons for not complying. *Id.* § 552(e)(1)(A). FOIA requires that this information be affirmatively available to the public through electronic and other means, *id.* § 552(e)(3), an obligation that agencies and their components meet by issuing annual FOIA reports.

FDA does not disclose the use of its deletions policy when it issues annual FOIA reports, nor does it publicly explain how it accounts for the policy in its reported statistics. *See generally* FDA, Freedom of Information Annual Report 2011, *available at* <http://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/ucm295118.htm>. But based on FDA’s treatment of “minor deletions” as non-denials, we assume that FDA classifies its “preliminary determinations” relying on the deletions policy as if those determinations had granted FOIA

requests in full. If so, the deletions policy artificially inflates FDA's record of responding to FOIA requests through full disclosure. Because FDA data compose a part of HHS's annual FOIA reports, the deletions policy presumably distorts HHS's annual FOIA reporting as well.

FDA data confirm the likelihood of this effect. In 2011, for example, among those FOIA requests for which FDA either released documents in full, released documents in part, or denied release in full, nearly 97 percent were deemed full releases—the highest share among any of HHS's components for which information is available. Only 2.2 percent of those same FOIA requests were resolved through a partial grant / partial denial—the second lowest share among reported HHS components. *See* Appendix IV (advanced report produced using [www.FOIA.gov](http://www.FOIA.gov) and based on 2011 HHS data reported as ratios). As noted above, we believe that FDA relies heavily on the deletions policy. As a result, had FDA counted responses with “minor deletions” as partial grants / partial denials—as it should have—the share of FOIA requests listed as resolved through a partial grant / partial denial would presumably be much higher and the share of full grants much lower than FDA's current data indicate.

In sum, if FDA counts responses with “minor deletions” as “full grants” of requests, it overstates its “full release” statistics because records released with minor deletions are not, in fact, released in full. Consequently, the deletions policy is at odds with Congress's clear intent to provide the public with useful, reliable data on agencies' FOIA compliance.

#### **E. Conclusion**

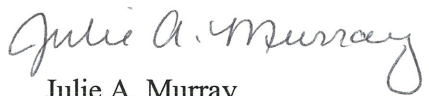
For the foregoing reasons, FDA should immediately stop applying the deletions policy, revoke 21 C.F.R. § 20.49(d), and rescind or revise the portions of the Staff Manual instructing that “minor deletions” do not constitute a partial FOIA denial in the first instance and do not trigger a requester's immediate right to administrative appeal. FDA's deletions policy is contrary to law, unnecessary to serve FOIA requesters promptly, and a disservice to FOIA requesters, the public, and FOIA's commitment to transparency.


### **III. ENVIRONMENTAL IMPACT**

The actions requested in this petition will have no significant effect on the human environment.

### **IV. CERTIFICATION**

To the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and includes representative data and information known to the petitioner that are unfavorable to the petition.

  
Julie A. Murray  
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Public Citizen Litigation Group

  
Adina H. Rosenbaum  
Attorney  
Public Citizen Litigation Group

**cc:** Dr. Margaret Hamburg, Commissioner, Food and Drug Administration

Ms. Elizabeth H. Dickinson, Chief Counsel, Office of Chief Counsel, Food and Drug Administration

Mr. William B. Schultz, Acting General Counsel, Office of the General Counsel, U.S. Department of Health and Human Services

Ms. Melanie Ann Pustay, Director, Office of Information Policy, Department of Justice

# Appendix I



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

Food and Drug Administration  
Division of Freedom of Information  
12420 Parklawn Drive, Room 1050  
Rockville, MD 20857

December 6, 2011

In Response Refer to File: 2011-8381

Public Citizen  
ATTN: Elizabeth Barbehenn, Ph.D.  
1600 20<sup>th</sup> St., NW  
Washington, DC 20009

Dear Dr. Barbehenn,

This is in response to your letter dated 11/15/11, in which you requested adverse events associated with the use of Liraglutide, Exenatide, Metformin and Glipizide. Your request was received in the Center for Drug Evaluation and Research on 11/16/11.

Please find the enclosed case reports. **Please note, all the redactions in the following documents have been made under the (b)(4) and (b6) exemptions.** Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed above within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you will have the right to appeal that decision. Any letter of denial will explain how to make this appeal. Responses can be mailed to the address above.

**Your request for a waiver of fees has been granted by the Associate Commissioner for Public Affairs.**

**If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.**

If I can be of further assistance, please contact me.

This concludes the response from the Center for Drug Evaluation and Research.

Sincerely,

***Harold D. Stepper***

Paralegal Specialist  
Office of Regulatory Policy  
Division of Information Disclosure Policy  
301-796-3461



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

Food and Drug Administration  
Division of Information Disclosure Policy  
10903 New Hampshire Avenue, Rm. 6269  
Silver Spring, Maryland 20993-0002

December 7, 2010

In Response Refer to File: 2010-8639

Public Citizen  
ATTN: Elizabeth K. Barbehenn, PhD  
1600 20<sup>th</sup> St., NW  
Washington, DC 20009

Dear Dr. Barbehenn,

This is in response to your letter of 11/16/10, in which you requested adverse events associated with the use of Orlistat, Alli and Sibutramine. Your request was received in the Center for Drug Evaluation and Research on 11/18/10.

Please find the enclosed case reports. **Please note, all the redactions in the following documents have been made under the (b)(6) and (b)(4) exemptions.** Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed above within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you will have the right to appeal that decision. Any letter of denial will explain how to make this appeal. Responses can be mailed to the address above.

**Your request for a waiver of fees has been granted by the Associate Commissioner for Public Affairs.**

**If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.**

If I can be of further assistance, please contact me.

This concludes the response from the Center for Drug Evaluation and Research.

Sincerely,  
**Harold D. Stepper**  
Paralegal Specialist  
Office of Regulatory Policy  
Division of Information Disclosure Policy  
301-796-3461

10008639\_ltr\_400.pdf

10008639\_enc\_400.pdf (Medwatch Reports)



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

PublicCitizen Health Research Group  
Attn: Michael A. Carome  
1800 20<sup>th</sup> Street NW  
Washington, D.C.  
20009

March 16, 2011

In response refer to: 2011-1493

Dear Michael A. Carome

In response to your request (copy enclosed) for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act:

After searching our files, we did not find the requested records.

We have no disclosable information as requested.

We are enclosing the requested record(s). Adverse Event Reports and cases for Anaplastic large cell lymphoma in women with breast implants.

This is a partial response.

*Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.*

Food and Drug Administration  
Freedom of Information Staff, HFI-35  
5600 Fishers Lane  
Rockville, Maryland 20857

"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."

The following charges **will not** be included in a monthly invoice. A waiver of fees was granted on February 25, 2011:

**Reproduction: 1.00 Search: 92.00 Review: 46.00 Other: 0.00 Total: \$ 139.00**

See addendum for comment(s).

The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you secure an invoice for the total monthly fee.



If I can be of further assistance please contact me at (301)796-6812 or kimberly.mcintosh@fda.hhs.gov.

Sincerely yours,

Handwritten signature of Kimberly McIntosh-Little in black ink.

Kimberly McIntosh-Little, CDR, USPHS  
Senior Regulatory Research Officer  
Freedom of Information Branch  
Office of Management Operations  
Center for Devices and Radiological Health  
Food and Drug Administration

Addendum

The data has been sanitized to remove personal identifiers in accordance to b(6) of the Freedom of Information Act.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville MD 20850-3229

April 1, 2011

In Response Refer to File: 2011-2519

Allison Zieve  
Public Citizen  
1600 20<sup>th</sup> Street, NW  
Washington, DC 20009

Dear Ms. Zieve,

This is in response to your request for copies from the Food and Drug Administration pursuant to the Freedom of Information Act regarding a copy of the March 2011 letter from the FDA to Star Scientific regarding dissolvable tobacco lozenges. Your request was received in the Center for Tobacco Products on April 1, 2011.

The documents you have requested were previously requested and are enclosed.

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges may be included in a monthly invoice:

*Reproduction: \$0.40 Search: \$0.00 Review: \$0.00 Certification: \$0.00 CD: \$0.00  
TOTAL: \$0.40.*

**DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration  
Division of Freedom of Information  
12420 Parklawn Drive, Room 1050  
Rockville, MD 20857

This concludes the response for the Center for Tobacco Products.

If I can be of further assistance, please let me know by referencing the above file number. You can reach me by phone at 301-796-8880.

Sincerely yours,

A handwritten signature in black ink that reads "Katherine Uhl". The signature is written in a cursive, slightly slanted style.

Katherine Uhl  
Senior FOIA Specialist  
Food and Drug Administration  
Center for Tobacco Products

Enclosures

## Appendix II



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

April, 12, 2010

Public Citizen  
1600 20<sup>th</sup> St  
Washington, D.C. 20009

In reply refers to:  
File No. F-2008-8865

Dear Requestor

This is in response to your Freedom of Information Act (FOIA) request received by the Food and Drug Administration (FDA) on December 9, 2008, in which you ask for FDA reviews (Medical, Pharmacologist, Statistical and Biopharm) and memos of communications regarding Slentrol. NADA 141-260.

Enclosed you will find the records you requested.

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges will be included in a monthly invoice:

Reproduction	Pages	\$0
Search	hour	\$0.
Review	Hour	\$0
Total		\$ 0

The above charges may not reflect final charges for this request. Please **DO NOT** send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

Sincerely yours,

Sandy McGeehan  
Paralegal Specialist  
Communications Staff  
Center for Veterinary Medicine  
Food and Drug Administration

includes the same studies described in this document and previous submissions. However, the data includes summaries from 3 rodent studies and 1 *in vitro* study not previously submitted to CVM. The human data represents phase 1 and early phase 2 studies evaluating dirlozapide for weight loss in humans under IND 68383.

The sponsor performed 2 studies that evaluated the ability of dirlozapide to inhibit intestinal MTP compared to liver MTP *in vivo*. In these studies in mice they determined that dirlozapide, when administered orally, was an effective inhibitor of intestinal MTP with an ED<sub>25</sub> of 0.16 mg/kg. In regard to the inhibition of liver MTP, the ED<sub>25</sub> for dirlozapide, when administered orally, was 6 mg/kg. The summary states that the difference in ED<sub>25</sub> values in the intestinal versus liver MTP is most likely due to the route of administration and low systemic drug absorption. There is no data to support that the drug preferentially inhibits intestinal MTP compared to liver MTP, the difference appears related to the exposure of the enzymes to the drug.

Whole body autoradioluminology studies in rats assessed the tissue distribution of [<sup>14</sup>C] dirlozapide from 2.5 to 168 hours after an oral dose. The majority of the radioactivity was in the gastrointestinal tract followed by the liver. The drug did not appear to penetrate into the CNS or ocular tissue.

The sponsor used *in vitro* assays to evaluate the affinity of dirlozapide for 59 receptors, ion channels, and uptake sites. The report states that there were no interactions.

(b) (4)



(b) (4)



### ***Reviewer's Discussion***

The submission provides information that reveals the relative safety of SLENTROL in regard to accidental exposures in humans treating their pets and the potential adverse

## Appendix III

GAO

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

October 1991

# FREEDOM OF INFORMATION

## FDA's Program and Regulations Need Improvement



145264



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Office of the General Counsel

B-238342

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.

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## 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.<sup>1</sup> 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

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<sup>1</sup>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.

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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

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competitive harm.”<sup>2</sup> 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.<sup>3</sup>

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.

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## 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.

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<sup>2</sup>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.

<sup>3</sup>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.

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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.<sup>4</sup>

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.<sup>5</sup> 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

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<sup>4</sup>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.

<sup>5</sup>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.

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## 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



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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.<sup>6</sup> 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.

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<sup>6</sup>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).

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## 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.

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## 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.

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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
<b>Total</b>	<b>150,335</b>	<b>100.0<sup>a</sup></b>

<sup>a</sup>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**

Calendar year	FDA		Single office requests		Multiple office requests	
	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
<b>Total</b>	<b>106,129</b>	<b>70.6</b>	<b>94,780</b>	<b>75.2</b>	<b>11,349</b>	<b>46.5</b>

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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.

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## 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.

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## 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.

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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,

A handwritten signature in black ink that reads "Barry R. Bedrick". The signature is written in a cursive style with a large, stylized "B" and "R".

Barry R. Bedrick  
Associate General Counsel

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## Appendix IV

# FOIA Requests During Fiscal Year 2011

## Department of Health and Human Services, All Components

Source: [www.FOIA.gov](http://www.FOIA.gov), using “Advanced Report” option



**COMPARE**

(18) Total Active Results

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Agency	Component	Year	Request Pending on Start	Request Received in FY	Request Processed in FY	Request Pending for Next	Released in Full ratio	Released in Part ratio	Denied in Full ratio	
HHS	CMS	2011	5233	52116	53328	4021	0.8249	0.0192	0.1559	
HHS	FDA	2011	4691	9301	10602	3390	0.9680	0.0220	0.0100	
HHS	OS	2011	560	1396	1592	364	0.3626	0.5348	0.1026	
HHS	CDC	2011	323	1128	1088	363	0.4365	0.5061	0.0574	
HHS	ACF	2011	317	296	416	197	0.3690	0.5830	0.0480	
HHS	OASH	2011	158	576	529	205	0.4549	0.4792	0.0660	
HHS	SAMHSA	2011	154	166	152	168	0.4384	0.5616	0.0000	
HHS	NIH	2011	85	1198	1204	79	0.8727	0.1149	0.0124	
HHS	IHS	2011	35	100	104	31	0.7037	0.1481	0.1481	
HHS	HRSA	2011	31	332	330	33	0.8792	0.1107	0.0101	
HHS	OIG	2011	18	729	737	10	0.4380	0.4749	0.0871	
HHS	AHRQ	2011	7	77	81	3	0.3125	0.6875	0.0000	
HHS	AOA	2011	0	16	16	0	0.0000	1.0000	0.0000	
HHS	PHS	2011								
HHS	ASPA	2011								
HHS	ATSDR	2011								
HHS	PSC	2011								
Total			11612	67431	70179	8864	N/A	N/A	N/A	

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