



AMERICANS FOR LIMITED GOVERNMENT

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March 6, 2012

Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Via fax to: 301.827.9267

Re: Freedom of Information Act (FOIA) Request

Dear FOIA Officer:

Pursuant to the federal Freedom of Information Act, 5 U.S.C. § 552 *et seq.*, I request on behalf of Americans for Limited Government (ALG) copies of the federal records described below. This request is for records of the Center for Tobacco Products (CTP).

Please provide copies of any records that exist in any of the following categories that were created on or after January 1, 2011:

1. Records indicating the number of Substantial Equivalence reports submitted to CTP dealing with existing, modified or new tobacco products;
2. Records indicating the number of these submitted Substantial Equivalence reports that CTP has acted upon; and
3. Records regarding the backlog of Substantial Equivalence reports and CTP's plan of action to address the backlog.

If reasonably possible I request that responsive records be provided in electronic form on either unencrypted CDs or DVDs.

Further Definition of Records Sought

The term "record" should be construed to mean any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail

(e-mail), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voicemails, microfiche, microfilm, videotape, recordings and motion pictures), and electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind of nature. A record bearing any notation not a part of the original text is to be considered a separate record. A draft of a non-identical copy is to be construed as a separate record.

The term “relating” and “regarding” with respect to any given subject, should be construed to mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is in any manner whatsoever pertinent to that subject.

The inclusion and description of particular records in this request should not be construed to eliminate other records that are not described in particular detail if they should exist in another format.

Procedure Regarding Records Exempt from Disclosure

Given the nature of the records requested I anticipate that the vast majority of any responsive records will be of the type required to be released under FOIA. However, in the event that records exist that FOIA does not require to be released I request that they be released regardless unless the failure to release such records can be justified based upon sound reasoning related to one of the statutory exemptions or exceptions in FOIA and there is a patently manifest danger of significant harm that would occur from release of such records, *e.g.*, danger to health or safety of an individual.

Further, the Food & Drug Administration should be reminded of the policy in favor of disclosure mandated by President Barack Obama on January 26, 2009. President Obama instructed the executive departments and agencies to operate with a presumption towards disclosure. On this point the President stated as follows:

A democracy requires accountability, and accountability requires transparency. As Justice Louis Brandeis wrote, “sun-light is said to be the best of disinfectants.” In our democracy, the Freedom of Information Act (FOIA), which encourages accountability through transparency, is the

most prominent expression of a profound national commitment to ensuring an open Government. At the heart of that commitment is the idea that accountability is in the interest of the Government and the citizenry alike.

The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails. The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears. Nondisclosure should never be based on an effort to protect the personal interests of Government officials at the expense of those they are supposed to serve. In responding to requests under the FOIA, executive branch agencies (agencies) should act promptly and in a spirit of cooperation, recognizing that such agencies are servants of the public. Freedom of Information Act, Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 4683 (January 26, 2009.)

These instructions from the President were followed up by further instructions from Attorney General Eric Holder on March 19, 2009. The Attorney General stated as follows:

First, an agency should not withhold information simply because it may do so legally. I strongly encourage agencies to make discretionary disclosures of information. An agency should not withhold records merely because it can demonstrate, as a technical matter, that the records fall within the scope of a FOIA exemption.

Second, whenever an agency determines that it cannot make full disclosure of a requested record, it must consider whether it can make partial disclosure. Agencies should always be mindful that the FOIA requires them to take reasonable steps to segregate and release nonexempt information. Even if some parts of a record must be withheld, other parts either may not be covered by a statutory exemption, or may be covered only in a technical sense unrelated to the actual impact of disclosure. The Freedom of Information Act (FOIA), Attorney General Memorandum for Heads of Executive Departments and Agencies, March 19, 2009.

Based on this policy I believe that there will be no records sought that the Food & Drug Administration will withhold. However, in the event that records are withheld I request to be provided with the following information:

1. Reason each record is not being produced;
2. Type of record withheld;

3. Subject matter of record withheld; and
4. Date, author, and addressee, if applicable of the record.

Further, I request that the above information be indexed by individual record and comply with *Vaugh v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), by providing information sufficient for a reasonable person to be able to ascertain whether the record sought is actually exempt from disclosure.

Request for Waiver of Fees

The information sought by ALG in this FOIA request will be used to better the public's understanding of how the Food & Drug Administration is spending the taxpayers' money. As such the public good that will occur in disclosing the information sought in and of itself weighs strongly in favor of a fee waiver. Further, the information sought is "in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). ALG regularly publishes information on the activities, structure, and operations of the federal government. This information is distributed to a large number of diverse individuals across the entire nation. The records sought are of the type which ALG regularly provides to the public through its publications and website, www.getliberty.org. As such granting the request to waive fees is in the public interest. Further, "Congress intended that the **public interest standard be liberally construed** and that fees not be used as an obstacle to disclosure of requested information." (*Emphasis added.*) *Eudey v. Central Intelligence Agency*, 478 F.Supp. 1175 (D.D.C. 1979). (*Internal citations omitted.*) The central focus of the analysis in determining whether the fee waiver is in the public interest is whether the public rather than the requestor is the primary beneficiary of the release of the information. "The statute indicates that the issue to be considered by the agency is whether furnishing the information will primarily benefit the public at large or whether any benefit will inure primarily to the specific individual requesting the documents." *Id.* In the instant case the records sought will be used to further the public's understanding of the operations of the Food & Drug Administration. The records sought will be disseminated widely to parties interested in the workings of the government and as such will not inure primarily to the benefit of the requestor. Therefore the request for waiver of fees should be granted pursuant to 5 U.S.C. § 552(a)(4)(A)(iii).

In the event that a fee waiver is not granted, please inform me before taking any action that would result in the incurrence of fees by ALG.

Conclusion

Pursuant to 5 U.S.C. § 552(a)(6)(A)(i) please provide the requested documents within 20 days. If for some reason all of the requested documents cannot be provided within 20

days I request that documents that are available within the 20 day time period be provided first and that when the remaining documents subsequently become available that they be provided at that time.

I request that any records disclosed pursuant to this request be indexed, to the extent feasible, in such a way as to enable the reader to readily ascertain to which number listed above the responsive records relate. **If reasonably possible I request that responsive records be provided in electronic form on either unencrypted CDs or DVDs.** If you have any questions as to the medium on which responsive records are to be provided please contact me in advance to sending the medium.

If my request is denied in whole or part, I ask that you justify all deletions by reference to specific exemptions of the act. I will also expect you to release all segregable portions of otherwise exempt material. I, of course, reserve the right to appeal your decision to withhold any information or to deny a waiver of fees.

Please send the requested records to the following address:

Nathan Paul Mehrens
General Counsel
Americans for Limited Government
9900 Main Street
Suite 303
Fairfax, VA 22031

If you have any questions regarding this FOIA request please contact Nathan Paul Mehrens at 703.383.0880 or nathan@getliberty.org. I look forward to your reply within 20 business days, as the statute requires. In the event that processing this request will take longer than 10 business days I request that you immediately provide me with an individualized tracking number for my request.

Thank you in advance for your assistance.

Sincerely,



William Wilson
President