June 30, 2022

Via Electronic Submission
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

Re: Citizen Petition- Asking FDA-CVM To Provide Clarification For Questions In Association With FDA-2022-P-0119.

To whom it may concern:
The undersigned submits this petition under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and in accordance with 21 C.F.R. § 10.30(b), requesting both the FDA-CVM and FDA FOIA Department answer questions in relation to FDA-2022-P-0119 and FOIA law.

A. Action Requested

Petition requests FDA-CVM to clarify question in relation to FDA-CVM's compliance under FOIA.

B. Statement of Grounds

FDA-CVM is a subagency of the FDA. The FDA is an agency within the Department of Health and Human Services, and is subject to FOIA laws.

The FOIA requires each agency to make available for public inspection, in electronic format, copies of all records that have previously been released under FOIA and "(I) that because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; or (II) that have been requested 3 or more times." 5 U.S.C. § 552(a)(2)(D).

FDA-CVM is consistently violating FOIA law, burdening citizens in the process and forcing them to wait 3+ years for FOIA requests to be fulfilled. This is on top of FDA-CVM employees engaging in regulatory rulemaking work via a private corporation, refusing to hold regular public meetings, and on top of the agency regulating by their opinion. As a citizen questioning and challenging this agency on these issues, FDA-CVM is using FOIA to try and slow as much information to the public as they possibly can.

On February 3, 2022, I submitted a citizen petition to FDA-CVM which FDA assigned tracking number FDA-2022-P-0119. This petition requested "FDA-CVM to hire 2 more FOIA employees, bringing FDA-CVM into compliance with the freedom of information act, 5 U.S.C. § 552." My petition stated that "FDA-CVM continues to violate FOIA law, and provide records in 2, 3, or even 4 or more years" after records are requested. I also stated that FDA points to limited staff as the primary reason for not complying with FOIA.

FDA-CVM denied my petition. As a note, FDA-CVM continues to violate FOIA law, estimating they may begin searching for requestors records in a whopping 18-24 months from the date in which the request is received by the agency. As justification for their denial to my citizen petition FDA-2022-P-0119, FDA-CVM stated things such as “as you know, CVM is one of the smallest centers in FDA” and “Our budget is comprised of money specifically earmarked by Congress for certain programs, user fees for certain program areas (not including FOIA), and discretionary funds. Currently, FDA-CVM does not receive specific appropriations for FOIA work.” CVM also stated “we must budget for FOIA work along with all our other responsibilities that do not have specific appropriations.”

Evasively, FDA-CVM stated, “we are working to hire additional CVM FOIA reviewers. We hope to have additional staff on board in the next few months. Thus, to the extent you are petitioning CVM to request that the agency hire two additional staff, these efforts are already under way and we are denying your petition in accordance with 21 CFR 10.30(e)(3).” My petition was to hire 2 additional employees. FDA-CVM did not confirm in their citizen petition response if they are hiring “two additional staff” as part of these efforts CVM claims is “already under way.”

On May 19, 2022, I emailed Sandra Cepeda at FDA-CVM, cc’ing Steven Solomon of FDA-CVM. My email stated:

> I have marked in my notes that for an email sent for Sandra at cvmfoia@fda.hhs.gov on May 18th, asking for clarification on a question I have been asking since September 2020, Sarah Kotler responded. Sarah Kotler cites a May 9th email she sent to me, yet Sarah Kotler did not state via her May 9th email that her response was intended to be an official response on behalf of FDA-CVM FOIA for this specific question that remained unanswered since September 2020. In fact, Sarah stated to me, "I don’t work for CVM and their FOIA staff doesn’t report to me." She also stated, "You will have to address your questions about CVM hiring and funding to CVM management."
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> I note that on May 9, 2022, Sarah Kotler did not answer various important questions relating to CVM FOIA operations. She stated, "If you’d like to see FDA get more resources to handle the increased workload at CVM, please contact your member of Congress." However, my question to her was not concerning my reaching out to my member of congress. My question was specifically about you and what you and FDA-CVM FOIA is doing to comply with FOIA law, given that FDA takes its obligations under FOIA law "seriously". How many employees has FDA-CVM attempted to hire over the past few years? Zero? One, two, three? How many additional staff is FDA-CVM attempting to hire going forward? Zero? One, two, three? More?
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> I am aware FDA-CVM just asked for $48 million in additional funding from congress in their 2023 budget. I don't see additional FOIA listed as part of the $48 million in FDA-CVM's funding request. Why aren't you attempting to improve this in regards to FOIA funding requests FDA makes themselves?

Have you requested FDA-CVM hire additional staff?

Those are all additional questions that remain, of which Sarah did not answer via her May 18, 2022 response to me. She also didn't disclose via her May 18th email that I had asked those questions, and she hadn't provided any response to them. I would appreciate you answering these outstanding questions, or directing me to the appropriate person in CVM management over this issue.

Harry

On May 23, 2022, I received an email from an anonymous ASKCVM email address, with no human being or employee of FDA-CVM signing the email. The email response from FDA-CVM stated, "Thank you for your email. The issues you raise in your email are related to those you raised in your February 3, 2022, Citizen Petition (FDA-2022-P-0119). As we stated in our response to that Petition, we are working to hire additional FOIA reviewers and we hope to have additional staff on board in the next few months. We have no additional information to share with you at this time. For your convenience, we are attaching a copy of our response to your Citizen Petition."

As can be clearly seen, FDA-CVM did not provide answers to my questions regarding the specifics of what actions FDA-CVM is taking, which were questions I asked after receiving FDA-CVM's vague citizen petition response.

Under FOIA law, I ask FDA-CVM to clarify the below questions that FDA-CVM did not cover in their citizen petition response for FDA-2022-P-0119, and which FDA-CVM refused to provide answers for via my email inquiry dated above. I also note I had a separate email exchange with FDA-FOIA director Sarah Kotler, and this FOIA director also refused to provide clarification on these questions.

- Is FDA-CVM hiring two additional employees as part of the efforts CVM stated are already underway?
- Is FDA-CVM aiming to hire more than two additional employees as part of the efforts CVM is stating are "already underway?"
- How many employees has FDA-CVM attempted to hire over the past 2 years? Zero? One, two, three?
- How many additional staff is FDA-CVM attempting to hire going forward? Zero? One, two, three? More?
- Is FDA-CVM increasing the staff positions available for their FOIA department? For example, is a staff of (10 as an example) being expanded to a staff of 15 employees? The numbers are only examples in this case, and FDA-CVM can provide exact detail as to if the staffing positions are increasing for the FOIA department.
- I am aware FDA-CVM just asked for $48 million in additional funding from congress in their 2023 budget. I don't see additional FOIA listed as part of the $48 million in FDA-CVM's funding request. Why aren't you attempting to improve this regarding FOIA funding requests FDA makes themselves?

- Has Sarah Kotler ever requested FDA-CVM hire additional staff? If so, when did she make those official requests?
- Has Sandra Cepeda ever requested FDA-CVM hire additional staff? If so, when did she make those official requests?

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 C.F.R. §§ 25.30 and 25.34.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by FDA following review of the petition. The undersigned will promptly provide this information if requested.

E. Certification

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

Harry Duty

Harry Duty (Jun 30, 2022 05:25 CDT)

Harry Duty
Citizen & Stakeholder
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