

12/21/2022



Re: Docket No. FDA-2022-P-1407

Dear Mr. Duty

This letter is a final response to your petition (FDA-2022-P-1407), filed on June 30, 2022, requesting "FDA-CVM to clarify question[s] in relation to FDA-CVM's compliance under FOIA [the Freedom of Information Act]."

For the reason described below, we are denying your petition in accordance with 21 CFR 10.30(e)(3). However, we are pleased to let you know that since our May 20, 2022, response to your earlier petition (FDA-2022-P-0119) requesting that we hire two additional FOIA staff for the Center for Veterinary Medicine (CVM), we have done so.

Your petition contains several questions regarding CVM's FOIA program, including staffing and funding of that program.¹ However, your petition does not ask the Commissioner to take a specific administrative action, which is an element of citizen petitions. Our regulations at 21 CFR 10.30(b)(3) require that a petition request the Commissioner to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action. Your petition does not request such action.

• Is FDA-CVM hiring two additional employees as part of the efforts CVM stated are already underway?

¹ These questions are:

[•] 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 [the director of FDA's Division of Freedom of Information] ever requested FDA-CVM hire additional staff? If so, when did she make those official requests?

[•] Has [the director of CVM's FOIA staff] ever requested FDA-CVM hire additional staff? If so, when did she make those official requests?

Your petition also notes that CVM has not answered all of your questions submitted to AskCVM². AskCVM is a resource provided by CVM that allows members of the public to submit questions to CVM. AskCVM also may respond on behalf of individual CVM staff members who receive questions directly from the public. CVM requests that stakeholders use the AskCVM mailbox so that inquiries can be properly logged, tracked, and forwarded to the appropriate parties for response. Having one email address that receives questions and disseminates information allows for the best use of CVM resources. It allows CVM to triage inquiries and seek appropriate input from subject matter experts. Moreover, to the extent that AskCVM can provide responses to questions that have already been answered, it frees up CVM staff and management to work on other pressing matters. Although CVM tries to respond to inquiries in full and in an expeditious manner, we are not always able to do so.³

Again, although we are denying your petition because it does not request the Commissioner take any type of administrative action contemplated by 21 CFR 10.30, we are happy to report that we were able to hire two additional CVM FOIA reviewers this year.

Thank you for your continued interest in the work CVM does.

Sincerely,

Steven

Digitally signed by Steven Solomon -S Solomon -S Date: 2022.12.21

Steven M. Solomon, DVM, MPH Director, Center for Veterinary Medicine

² On May 19, 2022, you also emailed some of your questions to CVM FOIA. A response was provided to you from the CVM FOIA mailbox on May 23, 2022.

³ For example, CVM does not always respond to questions submitted to the AskCVM mailbox that appear rhetorical in nature, that are duplicate questions already asked and answered, or that involve describing internal practices, discussions, or deliberations.