U.S. FOOD & DRUG ADMINISTRATION

August 29, 2024

Kohl Harrington
(b) (6)

Dear Mr. Harrington,

This letter responds to your citizen petition, FDA-2024-P-1380, dated March 4, 2024. Your petition requests the "FDA to adhere to FOIA law and promptly publish on the FDA FOIA Reading Room website all records and response letters related to FOIA request 2020-5368, as these records have been requested multiple times."

As grounds for the petitions, you state that "[t]he FOIA mandates that federal agencies make available for public inspection, in electronic format, copies of all records that have previously been released under FOIA and have been requested three or more times. 5 U.S.C. § 552(a)(2)(D)."

You state that you are requesting "all records and response letters related to FOIA request 2020-5368." You state that "FDA has provided this response letter three or more times."

Your request for FDA to make the above-referenced records available for public inspection in an electronic format is denied. 5 U.S.C. § 552(a)(2)(D) states, in part:

> Each agency … shall make available for public inspection in an electronic format … copies of all records … that have been released to any person under [FOIA]; and … that have been requested 3 or more times[.]

Your petitions did not provide the control numbers for the FOIA requests that you claim triggered this provision of the FOIA or any other information supporting your assertion that the records have been requested or provided '3 or more times' and FDA is now required to comply with 5 U.S.C. § 552(a)(2)(D). Therefore, your citizen petition does not include factual grounds supporting your contention that FDA is required to post the calendar records. 21 CFR 10.30(b)(3).[1]

[1] FDA regulations specify that a petition must request the Commissioner of Food and Drugs to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 CFR 10.30(b)(3). Furthermore, a petition must contain "[a] full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position." We note that in the past, FDA has granted at least some citizen petitions requesting that the Agency post records consistent with 5 U.S.C. 552(a)(2)(D) regardless of whether the petition alleged sufficient factual grounds for that request. We believe that the current approach is more appropriate in light of the text of 21 CFR 10.30(b)(3), and it will enable FDA to better serve the interests of all petitioners.

Nonetheless, when CVM determines that the posting requirement in 5 U.S.C. § 552(a)(2)(D) has been triggered, it posts the records in accordance with that requirement. If we determine that there are records that have been requested 3 or more times and they have been released under FOIA, we intend to post the record to the CVM FOIA Electronic Reading Room. FDA is required to comply with the electronic and information technology requirements in the Rehabilitation Act of 1973 (Pub. L. 93-112), section 508 [29 U.S.C. § 794d(a)] when posting records to our electronic reading room or elsewhere on our website. Section 508 requires us to ensure that individuals with disabilities have access to and use of these records. Once the records have been converted to a section 508-compliant format, we will post the records to the CVM FOIA Electronic Reading Room at: https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.

For the reason(s) stated above, we are denying your petition.

Sincerely,

William T. Flynn -S Digitally signed by William T. Flynn -S
Date: 2024.08.29 08:23:11 -04'00'

William T. Flynn, DVM, MS
Deputy Center Director
Center for Veterinary Medicine