



August 16, 2022

Harry Duty

(b) (6)

Re: Docket No. FDA-2022-P-0208

Dear Mr. Duty:

We are granting your Citizen Petition (FDA-2022-P-0208) filed with the Food and Drug Administration (FDA) on February 19, 2022.

The petition requests FDA to “comply with FOIA law and post publicly on the FDA FOIA reading room all documents requested through various FOIA requests pertaining to *Testing Records From 2015 Bravo Recall Due To FDA-CVM Regulating By Their Opinion.*”

As grounds for the petition, you claim the “information has been requested through FOIA ‘3 or more times’ and FDA is now required to comply with 5 U.S.C. § 552(a)(2)(D) and publish these records on the FDA FOIA reading room.” 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 release d to any person under [FOIA]; and ... that have been requested 3 or more times[.]”

Your petition did not provide the control numbers for, or otherwise identify with any specificity, the FOIA requests that you claim triggered this provision of the FOIA. Nevertheless, we have been able to locate at least three FOIA requests for “*Testing Records From 2015 Bravo Recall Due To FDA-CVM Regulating By Their Opinion.*” Although we disagree with the requests’ characterization of FDA’s regulatory approach, we confirm that records responsive to this request have been released under the FOIA.

Consistent with Agency practice, we intend to post the records to the ORA FOIA Electronic Reading Room. When posting records to our electronic reading room or elsewhere on our website, however, 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)]. Section 508 requires each agency to ensure that individuals with disabilities have access to and use of these records.

We will post this video after we have made it compliant with section 508’s requirements. It will be posted to the ORA FOIA Electronic Reading Room at: <https://www.fda.gov/about-fda/office-regulatory-affairs/ora-foia-electronic-reading-room>, in the “Resources for You” section, under the heading “Other Requested Records.”

Sincerely,

Judith McMeekin, Pharm.D.
Associate Commissioner for Regulatory Affairs