



Food and Drug Administration
Rockville, MD 20857

December 13, 2021

Mr. Aaron Siri
Siri & Glimstad LLP
200 Park Avenue
Seventeenth Floor
New York, NY 10166

Sent via email: aaron@sirillp.com

Re: FDA FOIA Request 2021-5683; *Public Health and Medical Professionals for Transparency*
v. FDA, 21-cv-01058-P

Dear Mr. Siri,

This is a partial response to the Freedom of Information Act (FOIA) request number **2021-5683** that is the subject of the Complaint filed in *Public Health and Medical Professionals for Transparency v. FDA*, 21-cv-01058, now pending in the U.S. District Court for the Northern District of Texas.

Enclosed are 2,890 pages of records, some of which contain redaction to prevent the disclosure of material exempt from the FOIA.

In addition to those 2,890 pages, please find enclosed three txt files from page 10 and one txt file from page 11 of the provided Index as you requested in prioritized item number 5.¹ We have also enclosed one xpt (SAS) file from page 13 and four xpt (SAS) files from page 14 of the Index.² Because we have assessed that there is no exempt material in these txt and xpt files, there have been no deletions to the txt or xpt files. Per your request, we have provided data files in their native format.

We have withheld portions of pages under FOIA Exemption (b)(4), 5 U.S.C. § 552(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

¹ Plaintiff provided its priority list of records via two emails from you to Courtney Enlow at the Department of Justice on November 4, 2021.

² In your request for records listed on page 10 of the Index, you indicated that you were interested in obtaining “sample” SAS files. Although the files listed on page 10 and 11 all may appear to be SAS files, we have determined that none of the files listed on page 10 and 11 are SAS files. As indicated above, we processed three files from page 10 and one file from page 11 for this production because you requested a record from page 10. To accommodate your request for sample SAS files, we also processed one xpt (SAS) file that was listed on page 13 and four xpt (SAS) files that were listed on page 14 of the Index, even though you did not prioritize files from pages 13 and 14 of the Index.

We have withheld portions of pages under FOIA Exemption (b)(6), 5 U.S.C. § 552(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Please direct any questions regarding this response to Courtney Enlow of the Department of Justice, at (202) 616-8467 or Courtney.D.Enlow@usdoj.gov.

Sincerely,

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research

Enclosure(s)