Exhibit 2

Subject: RE: [EXTERNAL] Appeal of FOIA Control # 2021-8224 (IR#0656)

Date: Tuesday, October 11, 2022 at 5:26:29 AM Pacific Daylight Time

From: FDA FOIA

To: S&G Information Request Staff, FDA FOIA

CC: Colin Farnsworth

Appeal file: 22-000121AA

October 11, 2022

Sending via Email: foia@sirillp.com

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, submitted to the Food and Drug Administration (FDA). We received your appeal on October 11, 2022. Your appeal challenges the *Food and Drug Administration (FDA's)* response to your original request #2021-8224. Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Your appeal is summarized below: Full Denial

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal. For more information about how your appeal will be processed please refer to the HHS FOIA regulations <u>https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations</u>).

The FOIA and the HHS FOIA regulations are available at the following web addresses: <u>https://www.justice.gov/oip/freedom-information-act-5-usc-552</u> and <u>https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations.</u>

If you have any questions, please call (301)796-8975, or email us at fdafoia@fda.hhs.gov.

Sincerely yours,

Sarah Kotler FDA FOIA Sarah B. Kotler, J.D. Director, Division of Freedom of Information US FDA 301-796-8976

From: S&G Information Request Staff <foia@sirillp.com>
Sent: Friday, October 7, 2022 6:36 PM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Cc: Colin Farnsworth <cfarnsworth@sirillp.com>
Subject: [EXTERNAL] Appeal of FOIA Control # 2021-8224 (IR#0656)

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Dear Sir or Madam,

Attached please find our client's appeal.

Thank you,

Annalise Beube, Law Clerk

Siri | Glimstad

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