

Elizabeth Brehm

From: Elizabeth Brehm
Sent: Monday, December 12, 2022 8:10 PM
To: Elizabeth Brehm
Subject: FW: [EXTERNAL] Complaints soon to be filed for 2022-4856/22-000126AA (0802N) & 2022-4857/22-000107AA (0802O)

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Date: Thursday, December 1, 2022 at 8:00 AM
To: Colin Farnsworth <cfarnsworth@sirillp.com>, Nelson, Jonathan (OS) <Jonathan.Nelson@hhs.gov>
Subject: RE: [EXTERNAL] Complaints soon to be filed for 2022-4856/22-000126AA (0802N) & 2022-4857/22-000107AA (0802O)

When you contacted me last week about your client's threat to sue over a different request, I responded within a few days (over a holiday weekend in fact) but our additional information did nothing to avoid a litigation. If you can't make your client understand that bombarding us with appeals (and litigation) delays processing the later-received appeals, I am not sure what I can possibly say to persuade him. We stand by our responses, and we will process the appeals based on the date of receipt (unless he sues us, in which case the appeals are moot). If he has earlier-submitted appeals in which he is no longer interested, we would be happy to close those and move on the more recent appeals more quickly. Approximately 30% of our pending appeals are from your client.

Have a good day.

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

From: Colin Farnsworth <cfarnsworth@sirillp.com>
Sent: Thursday, December 1, 2022 10:45 AM
To: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>; Nelson, Jonathan (OS) <Jonathan.Nelson@hhs.gov>
Subject: [EXTERNAL] Complaints soon to be filed for 2022-4856/22-000126AA (0802N) & 2022-4857/22-000107AA (0802O)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kotler and Mr. Nelson,

Next week, our client intends to file complaints for 2022-4856/22-000126AA (0802N) & 2022-4857/22-000107AA (0802O) for the agency's time limit violations in processing these appeals. I'm reaching out to see if FDA is willing to do anything to persuade my client to hold off on these filings. Please let me know if anything can be done, they have a special interest in resolving these matters.

Regards,

Colin Farnsworth, Attorney

Siri | Glimstad

745 Fifth Ave, Suite 500

New York, NY 10151

Main: 212-532-1091

Facsimile: 646-417-5967

www.sirillp.com

This email may contain material that is confidential, privileged and/or attorney work product for the sole use of the intended recipient. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.