Elizabeth Brehm

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, May 26, 2022 5:07 PM
To: Elizabeth Brehm
Subject: RE: [EXTERNAL] FW: Discrepancies in deaths in Pfizer clinical trial

Dear Ms. Brehm,

We acknowledge your correspondence on behalf of Informed Consent Action Network related to the posted reviews for Comirnaty (COVID-19 vaccine, mRNA), specifically, the Summary Basis of Regulatory Action, Clinical Review memo and Statistical Review memo.

We are unable to respond substantively at this time due to resource constraints and the ongoing pandemic response. It is thus necessary for the Agency to prioritize its responses to individual inquiries. We note that the Agency is providing to your law firm, in response to a FOIA request, an unprecedented volume of records that comprise the license application for this product. Additionally, there are more than 50 pending FOIA requests submitted by your firm for data and information about COVID-19 vaccines.

Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

From: Elizabeth Brehm <ebrehm@sirillp.com>
Sent: Thursday, May 12, 2022 1:22 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Wollersheim, Susan <Susan.Wollersheim@fda.hhs.gov>; Ann.Schwartz@fda.hhs.gov; Yang, Ye <Ye.Yang@fda.hhs.gov>
Cc: Aaron Siri <aaron@sirillp.com>; Catherine Cline <ccline@sirillp.com>
Subject: [EXTERNAL] FW: Discrepancies in deaths in Pfizer clinical trial

Dear Dr. Marks and Dr. Woodcock,

I write to follow-up one last time on the attached letter and below emails. Our client would like to receive a response to the important questions raised. If we do not receive a response by May 19, 2022, we have been

directed to file a formal petition with the FDA seeking answers. We'd much prefer to avoid that formality if possible.

Thank you for your time and attention to this matter.

Regards,
Elizabeth

From: Elizabeth Brehm
Sent: Tuesday, April 12, 2022 9:37 AM
To: Woodcock, Janet <Janet.woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Ramachandra.Naik@fda.hhs.gov; Susan.Wollersheim@fda.hhs.gov; Ann.Schwartz@fda.hhs.gov; Ye.Yang@fda.hhs.gov
Cc: Aaron Siri <aaron@sirillp.com>; Catherine Cline <ccline@sirillp.com>
Subject: FW: Discrepancies in deaths in Pfizer clinical trial

Dear Drs. Woodcock, Marks, Naik, Wollersheim, Schwartz, and Yang:

Attached please find a follow-up letter which demands your attention.

Regards,
Elizabeth

From: Elizabeth Brehm
Sent: Tuesday, November 16, 2021 9:30 PM
To: Ramachandra.Naik@fda.hhs.gov; Susan.Wollersheim@fda.hhs.gov; Ann.Schwartz@fda.hhs.gov; Ye.Yang@fda.hhs.gov
Cc: 'Aaron Siri' <aaron@sirillp.com>
Subject: Discrepancies in deaths in Pfizer clinical trial

Dear Drs. Naik, Wollersheim, Schwartz, and Yang:

Attached please find a letter which demands your immediate attention. Kindly confirm receipt.

Regards,
Elizabeth

Elizabeth A. Brehm, Esq.
Siri | Glimstad

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