

EXHIBIT 3



June 27, 2022

VIA OVERNIGHT U.S. MAIL, FACSIMILE, AND E-MAIL

Ms. Sarah Kotler, Director
Food and Drug Administration
Division of Freedom of Information
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Mr. Guruprasad Udapi, Branch Chief
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Office of Regulatory Policy, CDER
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Re: **FOIA Appeal (Control No. 2022-2942)**
Ranitidine Products Cases, JCCP No. 5150 (Alameda County Superior Court –
State of California)

Dear Ms. Kotler:

This is an appeal under the Freedom of Information Act (“FOIA”). My FOIA request (submitted April 22, 2022) was assigned the following control number: 2022-2942. On May 31, 2022, I received a written response to my FOIA request in an email signed by Mr. Guruprasad Udapi (who is copied here). Mr. Udapi constructively denied my request and failed to comply with 5 U.S.C. § 552(a). Specifically, Mr. Udapi stated that “the minimum estimated processing timeframe is 24 months.” This is insufficient under FOIA. Moreover, Mr. Udapi also explained telephonically (on May 27, 2022) that this processing time did not mean my request would be complied with. He advised that even if my request was determined to be appropriate (in whole or in part), it would likely take another 12 months after the initial 24 months to procure and produce the documents, perhaps even longer.

Courts have found constructive denial when an agency has failed to provide a substantive response within the 20-day statutory time limit spelling out: (1) the agency's determination of whether or not to comply with the request; (2) the reasons for its decision; and (3) notice of the right of the requester to appeal to the head of the agency if the initial agency decision is adverse. See *Oglesby v. U.S. Dept. of Army*, 920 F.2d 57, 65 (D.C. Cir. 1990); *Natl. Sec. Counselors v. C.I.A.*, 931 F. Supp. 2d 77, 95 (D.D.C. 2013); 5 U.S.C. §§ 552(a)(6)(A)(i), (a)(6)(C). Here, Mr. Udapi's response, both telephonic and written, fails all three prongs.

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Mr. Udapi's email confirms that the FDA has not made any determination of whether or not to comply with my request (i.e., limited its response to "processing") and also failed to give the reasons for the granting or denying any and all parts of my six-item request and fails to notify me of my right to appeal. This is improper. I strongly urge the FDA to reconsider.

As I explained in my initial FOIA request and my conversation with Mr. Udapi (which my colleague, Mr. Adam Foster, Esq. participated in), I am the co-lead counsel for thousands of cancer victims in California state court who have alleged that a popular antacid, Zantac (ranitidine), caused their cancer. The communications that are the subject of my FOIA request, focus on an FDA-sponsored study of Zantac that the Defendants in the above-listed litigation are using to support their claims that Zantac does not cause cancer. Indeed, those Defendants are trying to use the authority and color of office of the FDA and its taxpayer funded Zantac study—which has many issues—to defeat these cases despite the FDA's recall of Zantac. The need for the requested documents is compelling and urgent. Trial for the first bellwether case begins on February 13, 2022.

Mr. Udapi's response is a constructive denial by the letter of the law and in spirit. I strongly encourage the FDA to reconsider its present course of action and produce the requested documents on an expedited basis.

If you need to discuss this request, I can be reached at (310) 207-3233. I look forward to your prompt and final reply in 20 working days as required by FOIA. Thank you for your time and your consideration of this appeal.

Sincerely,

/s/ R. Brent Wisner

R. Brent Wisner

Senior Shareholder

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Enclosures: E-mail correspondence with Mr. Guruprasad Udapi; Acknowledgement Letter