EXHIBIT 1

BAUM HEDLUND
CLIENT FOCUSED. TRIAL READY. BILLIONS WON.

April 21, 2022

VIA ELECTRONIC SUBMISSION

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: **FOIA Request**

Dear Assistant Commissioner for Public Affairs (or delegatee):

Pursuant to the Federal Freedom of Information Act, I hereby request that the Food and Drug Administration ("FDA") produce a copy of the documents listed below. I am authorized to make this request as the Plaintiffs' Liaison Counsel and legal representative for over 2,000 cancer victims in California state court. The *Ranitidine Products Cases* (JCCP No. 5150) concern allegations by thousands of cancer victims that Zantac (ranitidine) caused their cancer. There is a compelling need for the following documents:

Document Requests

1. Between January 1, 2020 and January 1, 2022, email correspondence and attachments of Jeffery Florian, David G. Strauss, Murali K. Matta, Victoria Gershuny, Vikram Patel, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, and Joyce Korvick, relating to the "concept and design" of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

2. Between January 1, 2020 and January 1, 2022, email correspondence and attachments of Jeffery Florian, David G. Strauss, Murali K. Matta, Victoria Gershuny, Vikram Patel, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, and Joyce Korvick, relating to the diet of participants in the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

3. Between January 1, 2020 and January 1, 2022, email correspondence and attachments, between Jeffery Florian and/or David G. Strauss with editors of Journal of the American Medical Association regarding the publication of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

4. Between June 1, 2019 and January 1, 2022, email correspondence and attachments, between Jeffry Florian, Murali K. Matta, Ryan DePalma, Victoria Gershuny, Vikram Patel, Cheng-Hui Hsiao, Robbert Zusterzeel, Rodney Rouse, Kristin Prentice, Colleen Gosa Nalepinski, Insook Kim, Sojeong Yi, Liang Zhao, Miyoung Yoon, Susan Selaya, David Keire, Joyce Korvick, David G. Strauss, and any third-party (non-FDA) regarding the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

5. All drafts of the manuscript of the FDA-funded (tax-payer funded) & sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021.

Ranitidine was withdrawn from the market by the FDA on April 1, 2020, after independent laboratories discovered, and FDA testing confirmed, the presence of unsafe levels of N-Nitrosodimethylamine ("NDMA") in finished ranitidine products. As part of the FDA's investigation, and with taxpayer funds, the FDA designed, sponsored, and oversaw the completion of a randomized clinical trial designed to test whether NDMA formed in humans following ingestion. That study was ultimately published as "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)", ("Florian Study") in the Journal of the American Medical Association in 2021. As stated on the publication, "The study was funded by the US Food and Drug Administration (FDA)" and "The FDA oversaw the design and overall conduct of the study, including overseeing the management, analysis, and interpretation of the data. The FDA also prepared, reviewed, and approved the manuscript for submission for publication."

Various decisions were made regarding the design of the Florian Study that need further investigation by the public, especially when the Florian Study is being used by the manufacturers of ranitidine to argue, to various courts, that it reflects the FDA's judgment that there is no risk of NDMA formation from the ingestion of ranitidine, or any risk of cancer. For example, the Florian Study looks at urinary excretion of NDMA as the primary endpoint, but the only human study on urinary excretion of NDMA indicates that less than 0.05% of NDMA is excreted in the urine. By making urinary excretion the primary endpoint, the study was designed to not see anything. Additionally, it is well

established that ascorbic acid (vitamin C) efficiently inhibits the formation of NDMA from ranitidine and sodium nitrite. And yet, in the FDA's Florian Study, participants were fed high levels of ascorbic acid as part of a prescribed diet on the vary days they were set to take a dose of ranitidine. Again, this design choice is puzzling; and why the FDA would spend taxpayer money on a study that was designed to show nothing raises serious public concerns regarding regulatory capture and/or collusion with industry.

Given that the Florian Study was conducted by the FDA with a third party, Spaulding Clinical Research, LLC (who has refused to produce any documents pursuant to its contract with the FDA), and this study was sponsored and funded with taxpayer dollars, it is critical for the Plaintiffs in JCCP No. 5150 and the public at large to know how this study was done, the circumstances of its review, and for Plaintiffs' experts—and the Court—to have a proper understanding of the Florian Study.

These documents should be produced immediately. If this request is denied in whole or part, please justify the basis for such denial by referencing the specific exemptions of the Act. Please also release all segregable portions of otherwise exempt material. I reserve the right to appeal any decision to withhold any information—including, but not limited to, litigation with the FDA.

I am willing to pay fees for this request up to a maximum of $5,000.00. If you estimate that fees will exceed this limit, please advise.

Please copy my paralegal, Valeriya Adlivankina, on any email communications at vadlivankina@baumhedlundlaw.com. I look forward to your response within 20 (twenty) working days, as required by statute 20 C.F.R. § 20.41.

Thank you so much for your prompt attention to this matter. If you have any questions or wish to discuss this request, please do not hesitate to contact me me via telephone at (310) 207-3233 or rbwisner@baumhedlund.com.

Sincerely,

/s/ R. Brent Wisner
R. Brent Wisner
Senior Shareholder
BAUM HEDLUND ARISTEI & GOLDMAN, PC
rbwisner@baumhedlundlaw.com

FDA Receipt of FOI Request Control # 2022-2942

FDA_FOI@fda.gov <FDA_FOI@fda.gov>

Fri 4/22/2022 5:15 AM

To: Wisner, R. Brent <rbwisner@baumhedlundlaw.com>

Cc: FDAFOIA@fda.hhs.gov <FDAFOIA@fda.hhs.gov>

1 attachments (57 KB)

Acknowledgement Letter.PDF;

Control number: 2022-2942

Please find the attached acknowledgement regarding your FOIA request.

Note: Do NOT reply directly to this E-mail

U.S. FOOD & DRUG ADMINISTRATION

April 22, 2022

BAUM HEDLUND ARISTEI & GOLDMAN, PC
ROBERT BRENT WISNER
10940 Wilshire Blvd., 17th Floor
Los Angeles CA 90024 US

In Reply refer to
FOIA Control #:
2022-2942

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

1) Email correspondence from 1/1/2020 to 1/1/2022 among authors and FDA personnel relating to the concept and design of the FDA-sponsored study, "Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA)," published in the Journal of the American Medical Association in 2021. etc

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Rochelle A. Coleman, Information Technician, at (301) 796-8982 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director