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August 9, 2022

Director, Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857

Submitted via email:
FDAFOIA@fda.hhs.gov

Re: FDA Freedom of Information Act Appeal
FOIA Request Number 2022-4622

Dear FOIA Officer:

I am appealing FDA's August 3, 2022 denial of my entire Freedom of Information Act (FOIA) request (FOIA Request Number 2022-4622) for the Marketing Denial Orders for JUUL Labs Inc. dated June 23, 2022.

On June 23, 2022, I submitted a FOIA request for the Marketing Denial Orders[1] issued to Juul Labs Inc. for all of their products currently marketed in the United States, including the JUUL device and four types of JUUL pods: Virginia tobacco flavored pods at nicotine concentrations of 5.0% and 3.0% and menthol flavored pods at nicotine concentrations of 5.0% and 3.0%. I intended that request to include the Technical Project Lead (TPL) Decision Summaries associated with the JUUL Marketing Denial Orders, but did not explicitly state that. Subsequently, on August 8, 2022, I submitted a separate FOIA request for the Technical Project Lead Decisions Summaries associated with the JUUL Marketing Denial Orders.

On June 24, 2022, the US Court of Appeals for the DC Circuit entered a temporary administrative stay of the Marketing Denial Orders for Juul Labs Inc.

On July 5, 2022, FDA administratively stayed the marketing denial order, stating that "the agency has determined that there are scientific issues unique to the JUUL application that warrant additional review" and noted that the administrative stay "temporarily suspends the marketing denial order during the additional review but does not rescind it."[1]

On August 3, 2022, I received an email from Sarah Kotler, Director, Division of Freedom of Information, denying my entire request for the JUUL Marketing Denial Orders. The email stated that the reason for denying my entire request was because the requested documents contained

[1] FDA News Release: FDA Denies Authorization to Market JUUL Products, June 23, 2022. Available: https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products?utm_medium=email&utm_source=govdelivery

trade secret and confidential commercial information not previous publicly disclosed that is exempt from public disclosure. The email invited me to discuss the denial with Ms. Kotler to attempt to resolve the dispute before filing an appeal.

On August 8, 2022, I spoke with Ms. Kotler about the denial. Ms. Kotler advised me in our telephone conversation that the requested documents were "rife with confidential information" that was "inextricably intertwined" and therefore even a partial disclosure could not be made. As we were not able to resolve the dispute, Ms. Kotler advised me of my right to appeal.

In her August 3, 2022 email denying my request, Ms. Kotler provided citations to the regulations supporting the denial. Specifically, the denial was based on the 5 USC 552(b)(4) exemption for "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." This provision is implemented by 45 CFR 5.31(d), which authorizes the Department of Health and Human Services (HHS) to "withhold trade secrets and commercial or financial information obtained from a person and privilege or confidential." FDA's implementing regulations at 21 CFR 20.61 define "trade secrets and commercial or financial information which is privileged or confidential" and therefore exempt from disclosure to include:

> (b) "Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs;" and
>
> (c) "Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure."

I am appealing FDA's decision to deny my entire FOIA request for the following reasons:

1. FDA's policy on disclosure of its records provides that FDA "will make the fullest possible disclosure of records to the public… consistent with ***the need for the agency to promote frank internal policy deliberations*** and to pursue its regulatory activities without disruption" while also protecting trade secrets and confidential commercial or financial information. (21 CFR 20.20(a)).

2. FDA has repeatedly stated that it is committed to transparency. In June 2009 FDA launched a Transparency Initiative, and in January 2011 FDA recommitted its focus "on increasing the transparency of FDA operations and decision-making."[2] As recently as August 3, 2022, CTP Director Brian King published his "Perspective: Update on FDA Review and Enforcement of Non-Tobacco Nicotine Products" in which he stated, "Our goal is clear communication and transparency…"[3]

3. The Supreme Court has found that the basic objective of FOIA is disclosure, and the "(b)(4)" exemptions for trade secrets are *permissive,* not mandatory. The

[2] https://www.fda.gov/about-fda/transparency/transparency-initiative
[3] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-update-fda-review-and-enforcement-non-tobacco-nicotine-products

Supreme Court stated, "Congress did not design the FOIA exemptions to be mandatory bars to disclosure."[4] Therefore, while FOIA permits FDA and other agencies to withhold information containing trade secrets, it does not require them to do so.

4. I am not seeking information that constitutes industry trade secret or confidential commercial or financial information; rather, I am seeking information contained in the Marketing Denial Orders ***which describe FDA's reasons for reaching its decision and reveal FDA's decision-making processes which are neither privileged nor confidential information.***

5. FDA's Tobacco Products Marketing Orders website[5] provides information on companies that have been issued marketing denial orders "only if products from that company are currently marketed." JUUL products are currently marketed in the US and abroad. Moreover, Neither FDA nor JUUL has made a secret of the fact that FDA initially issued Marketing Denial Orders for JUUL. On June 23, 2022, FDA published a News Release to announce that FDA "issued marketing denial orders (MDOs) to JUUL Labs Inc. for all of their products currently marketed in the United States."[6] (On July 5, 2022, FDA administratively stayed the marketing denial order.)

6. If particular sections of FDA's Marketing Denial Orders do contain proprietary, commercial, or financial information that is truly confidential and truly contain trade secrets, FDA can redact those sections. Pursuant to FOIA provision 5 USC 552(b), "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection." The Supreme Court has held that under this provision, "agencies and courts [must] differentiate among the contents of a document rather than…treat it as an indivisible 'record' for FOIA purposes."[7]

7. However, FDA provided no justification for denying the entire request. 45 CFR 5.2(a) provides that FOIA requests for HHS records will be administered "with a presumption of openness." Further, 45 CFR 5.2(a) states that HHS "will consider whether partial disclosure is possible whenever we determine that a full disclosure of a requested record is not possible. This includes taking reasonable steps to segregate and release nonexempt information." 21 CFR 20.22 provides, "If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record." FDA offered no justifcation for why they considered the clearly non-exempt information in the Marketing Denial Order (for example, statements of FDA's decision-making

[4] Chrysler Corp. v. Brown, 441 US 281, 293 (1979)
[5] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders
[6] https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products?utm_medium=email&utm_source=govdelivery
[7] Fed. Bureau of Investigation v. Abramson, 456 US 615, 626 (1982)

processes or rationale) is "inextricably intertwined" with purportedly exempt information.

8. FDA provides a link to a "Sample Decision Summary Document" on its website[8] which demonstrates how FDA is able to disentangle non-exempt information from information that claims (b)(4) trade secret protection. This sample document is a PDF of the 20-page Technical Project Lead (TPL) Review of PMTAs for certain unnamed "ENDS (VAPES)" for which the PMTA submission tracking numbers and a few other small sections on only three pages (pages 14, 15, 16) have been redacted. This TPL recommended that FDA issue marketing denial orders for the new tobacco products which were the subject of the review and provides FDA's reasoning and scientific review explaining why the applications lacked evidence to demonstrate that permitting the marketing of the subject products would be appropriate for the protection of the public health. FDA did not offer any reason why it did not provide similar information in response to my FOIA request. Indeed, there is no rational explanation for denying my request.

9. In situations where there is a request for public disclosure, the burden is on the person (in this case, Juul Labs) to demonstrate that the information should *not* be disclosed, not on FDA to prove that the information may be disclosed. (21 CFR 20.47)

10. A "trade secret" is defined as any information that benefits a business commercially and is kept secret.[9] Matters of public or general knowledge in an industry are therefore *not* trade secrets, nor is information that can be gleaned by examining a product that is sold on the open market. Tobacco companies routinely analyze their competitors' products, reverse engineer them, and often produce knockoffs of popular products, so much of their product information is publicly known or available and by definition not trade secrets.[10] Notably, not only has JUUL been continuously marketed in the US since 2015, but also many counterfeit JUUL products are on the market, and JUUL has filed multiple lawsuits[11] against "fake," "copied", and "counterfeit" rivals. Therefore, it is nearly certain that to the extent that FDA's Marketing Denial Orders contain information about JUUL, it has already been discovered by competitors and/or is publicly available. Therefore, it is no longer confidential commercial information, it is not

[8] https://www.fda.gov/media/152504/download

[9] National Conference of Commissioners on Uniform State Laws. Uniform Trade Secrets Act, Section 1(4) (as Amended 1985). http://www.uniformlaws.org/Act. 59 aspx?title=Trade%20Secrets%20Act; American Law Institute. St. Paul, MN Restatement of the Law, First: Torts (Sect. 757, Comment B) American Law Institute Publishers. http://www.lrdc.pitt.edu/ ashley/RESTATEM.HTM

[10] Velicer C, Lempert LK, Glantz S. Cigarette company trade secrets are not secret: an analysis of reverse engineering reports in internal tobacco industry documents released as a result of litigation. Tobacco control. 2015 Sep 1;24(5):469-80.

[11] See, e.g., https://lawstreetmedia.com/news/tech/juul-sues-tobacco-company-for-selling-counterfeit-products/; https://www.bloomberg.com/news/articles/2020-08-14/juul-files-new-round-of-suits-against-fake-copied-vape-rivals#xj4y7vzkg; https://www.law.com/ctlawtribune/2021/12/15/juul-labs-sues-in-connecticut-over-alleged-counterfeit-vaping-products/?slreturn=20220703162101#:~:text=JUUL%20Labs%2C%20the%20popular%20vaping,and%20fals

commercially valuable, and it is not entitled to (b)(4) trade secret exemption from disclosure.

FDA should honor its commitment to transparency by providing me and other members of the public valuable information on how it arrives at its marketing authorization and denial decisions and how it determines whether products are or are not appropriate for the public health. If FDA determines that some parts of the requested documents do, in fact, contain information that is legitimately entitled to (b)(4) trade secret protection, FDA should redact just those portions and otherwise produce the records as required by the Freedom of Information Act. There is no justification for FDA's denial of my entire request.

Thank you for your addressing this appeal.

Sincerely,

Lauren Kass Lempert, JD, MPH
UCSF Center for Tobacco Control Research and Education

cc: Robert Califf, MD, Commissioner, Food and Drug Administration
Brian King, Director, FDA Center for Tobacco Products
Sarah Kotler, Director, Division of Freedom of Information
Xavier Becerra, Secretary, Department of Health and Human Service