IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JUUL LABS, INC.,
1000 F. St. NW
Washington, DC 20004,

Plaintiff,

v.

FOOD & DRUG ADMINISTRATION,
10903 New Hampshire Ave.
Silver Spring, MD 20993,

Defendant.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Case No. _____

INTRODUCTION

1. This case arises out of Plaintiff Juul Labs Inc. ("JLI")'s attempts to obtain documents related to the Food & Drug Administration ("FDA")'s decision to order all of JLI's products off of the U.S. market. Less than a day after FDA's decision, JLI served two Freedom of Information Act ("FOIA") requests for the scientific disciplinary reviews underlying FDA's decision. The agency invoked one of the most widely abused exemptions—the deliberative process privilege—to withhold the majority of those materials. But the withheld materials are central to understanding the basis for FDA's marketing denial order ("MDO"), whether FDA balanced the public health benefits and risks of JLI's products as the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA") requires, and whether FDA's reasoning is scientifically sound. They also remain relevant to JLI's pending appeal of FDA's decision, in which JLI is challenging FDA's findings and conclusions based on the agency's review and the complete science and evidence in JLI's applications. Withholding the disciplinary reviews that would answer these questions impedes JLI's ability to seek appropriate relief from

FDA's decision and is also completely at odds with the purpose of FOIA and the transparency Congress expects from administrative agencies. The public deserves a complete picture of the scientific facts behind one of the agency's most controversial and closely scrutinized decisions in recent years, especially where even FDA recognizes its order is suspect.

2. JLI submitted premarket tobacco product applications ("PMTAs") to FDA for its currently marketed electronic nicotine delivery system ("ENDS") products and a new device with age-verification technology in July 2020. The PMTAs included over 125,000 pages of data, information, and analysis from over 110 scientific studies to support the marketing of JUUL products. JLI also assessed its products relative to combustible cigarettes, an FDA-authorized heated tobacco product, and other marketed ENDS products. The goal of JLI's PMTAs was to show FDA that, after a holistic analysis across multiple scientific disciplines, its products would reduce harm from tobacco use and that marketing them would be appropriate for the protection of public health.

3. On June 23, 2022, FDA issued an MDO for JLI's PMTAs, as well as a press release making clear that the agency was ordering JLI's products off the United States market. The MDO and accompanying press release triggered rapid and widely publicized events. JLI's customer, supplier, and retailer relationships were upended and JLI moved to quickly seek emergency relief in the D.C. Circuit, all under the scrutiny of relentless press coverage. Having examined the arguments in JLI's emergency motion for a stay, FDA then stayed its own order and admitted that its decision may not have been correct after all. In the letter announcing the administrative stay, FDA acknowledged that, after "reviewing the briefing materials," "there are scientific issues unique to this application that warrant additional review." Ex. 1 (FDA July 5, 2022 Letter to JLI).

4. JLI has made repeated attempts to better understand FDA's marketing decision and its underlying scientific evaluation of JLI's PMTAs. On July 29, 2022, JLI submitted a request for supervisory review under 21 C.F.R. § 10.75, appealing FDA's decision and asking that the MDO be rescinded on account of its substantive and procedural flaws. Almost a month earlier, JLI submitted two FOIA requests to the agency, asking that it disclose scientific disciplinary reviews related to JLI's PMTAs. In addition to these formal requests, JLI had several informal discussions with FDA to explain its position and the importance of the withheld material. But even though FDA regularly releases these materials when making marketing decisions for other tobacco products, the agency invoked the deliberative process privilege and refused to provide that same information to JLI.

5. None of the requested material is protected by the deliberative process privilege. FDA explicitly incorporated or relied upon two of the withheld scientific disciplinary reviews—its engineering review and its behavioral and clinical pharmacology review—in its MDO and the supporting Technical Project Lead Review ("TPL Review"). Materials incorporated or relied on in final agency action are, by definition, no longer pre-decisional materials protected by the deliberative process privilege. All of the withheld materials, moreover, reflect the fact-based scientific conclusions reached by FDA scientists, not discretionary policy-making judgments. The deliberative process privilege has never protected purely factual information or what are supposed to be objective, scientific conclusions even if those decisions require exercising scientific judgment. The privilege is supposed to promote candid policy debates within agencies. It was never meant to shield an agency's scientific work from public scrutiny.

6. Disclosing the requested materials also would not interfere with the agency's deliberative process. FDA routinely makes available its scientific disciplinary reviews and

reviewer notes when it grants marketing authorization for a tobacco product, including ENDS. The TPL review memorandum published for every granted application likewise summarizes the underlying scientific assessment across all disciplines. Even when it denies an application, FDA's final response to JLI's FOIA requests shows that the agency will make available reviewer notes and other materials FDA "considered," "reviewed," or "relied in part on" in reaching its decision. Ex. 2 (July 21, 2022 Final Response) at 2. In these circumstances, there can be no reasonably foreseeable harm to the interests protected by the deliberative process privilege. Any scientific reviewer already knows his or her scientific review of a PMTA will likely become public after FDA issues its decision, and whatever chilling effect this supposedly may have thus already exists as a result of FDA's own prior, voluntary actions. Making JLI's requested materials publicly available thus will not discourage candid opinions or the frank exchange of information.

7. Given FDA's actions to publicize its decision, it should not be permitted to hide its supporting work in the shadows. FDA's decision to deny JLI's PMTAs generated immense public interest. Government officials with knowledge of FDA's order leaked the decision to *The Wall Street Journal* before it was even issued to JLI. The following day, when the order issued, FDA published a provocative press release, blaming JLI for a purported youth vaping epidemic (even though this purported epidemic was not the stated reason for denying the applications). This press release, along with the order itself, JLI's successful attempts to temporarily stay the order, and FDA's decision to ultimately re-review its own decision all received extensive press coverage.

8. FDA also made its decision in a politically charged environment. Members of Congress lobbied FDA for years to deny JLI's PMTAs while they were under review. FDA's decision to deny JLI's PMTAs was praised on the Senate floor, while its decision to stay the MDO

was criticized by Senators both on the floor and in the press. FOIA requires FDA make public the scientific facts behind such a high-profile, politically charged agency decision.

9. JLI likewise cannot have a fair opportunity to challenge FDA's decision without the withheld materials. The marketing decision was supposed to be based on a science- and evidence-based review of JLI's over 125,000-page PMTAs as a whole and on a careful balancing of the potential public health benefits and risks of the JUUL products based on that holistic review. The company ultimately needed to submit its request for supervisory review despite not having access to all the information FDA relied on when making its decision. As part of that request, JLI expressly "reserve[d] the right to amend or supplement this § 10.75 request based on additional information it may obtain under the Freedom of Information Act (FOIA)." FDA is thus gaining a tactical advantage through its meritless invocations of the deliberative process privilege to withhold responsive documents. The FOIA Improvement Act of 2016 was supposed to put an end to this type of abusive privilege assertion.

10. FOIA reflects Congress's judgment that federal agencies should be at least as transparent as the companies they regulate. But FDA is not living up to that congressional mandate—FDA has instead become less transparent over time about its regulatory decisions concerning ENDS products. The agency would not even respond to JLI's administrative appeal of its decision to withhold the requested material by the statutorily imposed deadline, leaving JLI no choice but to seek judicial relief. For these reasons, JLI requests injunctive and declaratory relief to compel FDA to produce all the scientific disciplinary reviews and reviewer notes related to JLI's PMTA submission.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 5 U.S.C. § 552(a)(4)(B), which states that the "district court of the United States" in "the District of Columbia, has jurisdiction to enjoin [an]

agency from withholding agency records" in violation of FOIA. This Court also has jurisdiction under 28 U.S.C. § 1331 (providing federal question jurisdiction).

12. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B), which permits parties to bring FOIA actions in the District of Columbia.

PARTIES

13. Plaintiff Juul Labs, Inc. is a Delaware corporation with its principal place of business in Washington, D.C. JLI manufacturers the JUUL family of ENDS products. Its mission is to transition the world's billion adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of its products.

14. Defendant, the U.S. Food & Drug Administration, is a federal agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1). FDA is responsible for regulating tobacco products (including JUUL products), and has possession, custody, and control of the records to which JLI seeks access.

FACTUAL ALLEGATIONS

I. Background on FDA Regulation of JUUL Products

A. The JUUL System

15. Congress has recognized that combustible cigarettes "cause[] over 400,000 deaths in the United States each year" and that "approximately 8,600,000 Americans have chronic illnesses related to smoking." Pub. L. No. 111-31, § 2(13), 123 Stat. 1776, 1777 (2009). JLI designed its JUUL products to address that problem by providing a less harmful, noncombustible alternative for adult smokers. Rather than burning tobacco, the JUUL System uses proprietary heating technology to heat a nicotine-containing liquid within a controlled temperature range to produce an aerosol that the user inhales. JUUL products thus significantly reduce exposure to harmful or potentially harmful constituents associated with smoking cigarettes.

16. Although JUUL was not the first ENDS product, it was one of the first devices that adult smokers found sufficiently satisfying to switch from combustible cigarettes. For these smokers, the product needs to be easy-to-use and satisfy the nicotine cravings they previously satisfied through cigarettes. The JUUL products overcame this challenge through a combination of features that ensure consistent nicotine delivery that more closely resembles the experience of cigarette smoking. Since JUUL products were introduced in 2015, millions of adult smokers have used JUUL products as a substitute for cigarettes. More than half switched from cigarettes completely.

B. The Tobacco Control Act and JLI's PMTAs

17. JLI's FOIA requests arise out of its attempts to comply with FDA regulations. In 2009, Congress passed the Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) to regulate tobacco products and encourage the development and introduction of alternatives to traditional cigarettes that reduce tobacco-related death and disease. As originally enacted, the TCA applied only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" products, not electronic cigarettes or ENDS products. *Id.* § 387a(b). But Congress delegated to FDA discretion to "deem[]" other products subject to the statute. *Id.* FDA deemed ENDS products subject to the TCA in 2016. *See* 81 Fed. Reg. 28,973.

18. Following this "Deeming Rule," all ENDS products were made subject to "premarket review" under the TCA, even though many ENDS products (including JUUL products) were already on the market. FDA deferred enforcement authority against those products while premarket review was pending. To comply with the TCA's "premarket review" requirements, manufacturers of ENDS products must submit PMTAs seeking FDA authorization. 21 U.S.C. §§ 387j(a)(1)–(2). These PMTAs are required to show that, following a holistic analysis, the products are "appropriate for the protection of the public health." *Id.* § 387j(c)(4).

C. FDA's Marketing Denial Order

19. In July 2020, JLI submitted its PMTAs with over 125,000 pages of information, data, and analysis, seeking authorization to market two devices and four types of JUULpods (Virginia Tobacco and Menthol flavors in 5.0% and 3.0% nicotine concentrations). On June 22, 2022, almost two years after JLI's initial submission, JLI received word that FDA was planning to deny its applications and order all JUUL products off the U.S. market. That notice came from the press, not FDA. *See* "FDA to Order Juul E-Cigarettes Off U.S. Market," *The Wall Street Journal* (June 22, 2022). Officials with knowledge of FDA's order leaked the matter to the press, which left JLI and its suppliers and retailer customers in disarray.

20. FDA issued its formal MDO the next day via a letter addressed to JLI. A few days later, outside the FOIA process, FDA provided JLI with a "Technical Project Lead (TPL) Review of PMTAs (Toxicology)" (i.e., TPL Review) containing FDA's analysis of JLI's products PMTAs and basis for the MDO. The TPL Review acknowledged that "exposure to carcinogens and other toxicants present in cigarette smoke were greatly reduced with exclusive use of the new products compared to [cigarette] smoking." But the MDO and TPL Review nevertheless focused on purported "toxicological" shortcomings in JLI's PMTAs, and asserted that the PMTAs "lack[ed] sufficient evidence to demonstrate that permitting the marketing of the products subject to these applications is appropriate for the protection of the public health."

21. Although FDA focused its decision on limited toxicological aspects of JLI's PMTAs, FDA's analysis also referenced other aspects of those applications. For example, the MDO links the toxicology analysis to the engineering review, explaining that the delivery of toxic constituents is mediated and controlled by the "device functional parameters"—meaning toxicology cannot be fully evaluated in isolation from how the devices operate. The MDO explains:

> The device functional parameters mediate and control the delivery of these toxic constituents to the user and are a critical factor in assessing user exposure to genotoxic constituents. This means that the inability to perform a full and accurate toxicological evaluation of the new product e-liquids (PM0000864, PM0000872, PM0000874 and PM0000876) precludes the completion of a full and accurate toxicological evaluation of the JUUL devices (PM0000878 and PM0000879) as these devices play a critical role in the production and delivery of genotoxic constituents to the product user.

22. Similarly, the TPL Review discusses and incorporates FDA's behavioral and clinical pharmacology review. On page 13 of the TPL Review, FDA explicitly references and relies on findings about JLI's clinical studies:

> In the clinical studies, significant reductions in blood and urinary BOEs indicate that exposure to carcinogens and other toxicants present in cigarette smoke were greatly reduced with exclusive use of the new products compared to CC smoking. While it is theoretically possible for the decreased HPHC yields and reduced BOE levels to offset the risk posed by the genotoxic leachables, the applicant provided no data indicating if, and how much of, these leachables are transferred into mainstream aerosol.

23. At the same time, FDA issued a press release stating that it "has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods."[1] FDA nevertheless demanded that JLI stop selling its products and that wholesalers and retailers remove JUUL products "or risk enforcement action." Commentators observed that JLI had been "singled out": there had been "so much opposition to Juul" from "legislators in state legislatures and Congress," that "FDA simply could not have authorized the sale of JUUL" without provoking a "fierce" backlash and jeopardizing its funding.[2]

---

[1] *See* FDA, "FDA Denies Authorization to Market JUUL Products," (June 23, 2022).

[2] *See*, *e.g.*, "Experts say the FDA ban on Juul e-cigarettes could be the 'opening gun' for a crackdown on the entire industry," *Business Insider* (June 23, 2022), available at https://www.businessinsider.com/juul-ban-could-impact-entire-e-cigarette-industry-experts-fda-2022-6.

II. JLI's Petition For Review And FDA's Decision To Stay Its Own Order

24. Within hours of FDA's decision, JLI sought an administrative stay of FDA's order to give it time to file an emergency motion for a stay pending appeal. The D.C. Circuit granted the stay on June 24, 2022. JLI then filed its motion for a stay pending appeal three days later, on June 27, 2022. *Juul Labs, Inc. v. FDA*, D.C. Cir. No. 22-1123, Dkt. No. 1952202 (June 27, 2022). The motion argued FDA denied JLI's applications for arbitrary and capricious reasons. In more than two dozen places, FDA claimed JLI did not provide aerosol data measuring the toxicological impact of four chemicals. But JLI's motion pointed out that JLI did provide that data—6,000 pages of it. Had FDA done a more thorough review, JLI argued, FDA would have seen data showing that the relevant chemicals were not observable in the aerosol that JUUL users inhale.

25. FDA initially indicated that it opposed a stay. On July 5, 2022, however, FDA reversed course. After JLI informed the agency that it would be submitting a request for supervisory review under 21 C.F.R. § 10.75, FDA administratively stayed the MDO because "in the course of reviewing the briefing materials in *JUUL v. FDA*, No. 22-1123 (D.C. Cir.), [FDA] determined that there are scientific issues unique to this [JUUL] application that warrant additional review."[3] The next day, FDA and JLI submitted a joint motion to the D.C. Circuit, asking that that court hold JLI's petition for review in abeyance pending further administrative proceedings. The parties agreed that FDA would stay its order and would not take enforcement action against JUUL products "pending FDA's consideration of JLI's § 10.75 submission and completion of FDA's supervisory review process" and for an additional 30 days after FDA's decision if the review process results in an adverse decision. *See Juul Labs, Inc. v. FDA*, D.C. Cir. No. 22-1123, Dkt. No. 1953737 (Joint Motion). The D.C. Circuit granted the parties' joint motion.

[3] *See* Ex. 1 (FDA July 5, 2022 Letter to JLI).

III. JLI'S FOIA Request and FDA's Decision to Withhold Documents

26. As soon as FDA issued its MDO, JLI began working on its § 10.75 appeal. To support that submission, JLI submitted two letters to FDA requesting certain materials pursuant to FOIA the same day FDA issued its order.

a. First, JLI asked that FDA "please provide us with . . . the technical project lead review ("TPL") and any related documents for the mid-cycle review of" JLI's PMTAs, including all documents pertaining to the first and second cycle scientific reviews and all disciplinary reviewer notes. *See* Ex. 3 (June 23, 2022 TPL Request).

b. Second, JLI also asked that FDA provide "the disciplinary review documents for" JLI's applications. *See* Ex. 4 (June 23, 2022 Disciplinary Review request).

27. Each of JLI's requests made clear that "[t]he Company is willing to pay any fees associated with this request," and asked that "[i]f the Agency denies any part of this request, please cite each specific reason that justifies the refusal to release the requested information." *See* Exs. 3, 4.

28. FDA responded to JLI's requests in two letters, dated July 8, 2022 and July 21, 2022. On July 8, FDA provided a partial response that included the "Technical Project Lead Review (Toxicology)," as well as the "First and Second Cycle Toxicology Reviews," but not documents related to topics other than toxicology. *See* Ex. 2 at 1.

29. On July 21, 2022, FDA provided its final response to the FOIA requests. FDA explained that it had identified "a total of 292 pages" of documents responsive to JLI's requests, but would only "release 115 pages in full." Ex. 2 at 1–2. FDA stated that, in addition to the toxicology documents it had provided earlier, it would also "releas[e] the First and Second Cycle

Environmental Science and Chemistry Reviews because the Environmental Science Reviews, like the Toxicology Reviews, were reviewed and considered for the TPL Review (Toxicology), and the Toxicology Reviews relied in part on analysis in the Chemistry Reviews." *Id.* at 2. FDA contended that the "TPL Review (Toxicology) did not reach other aspects of the applications beyond the potential toxicological health risks of the new products." *Id.*

30. Ostensibly for that reason, FDA is withholding the remaining 177 pages of responsive documents based on the deliberative process privilege. *Id.* FDA has refused to provide disciplinary reviews or reviewer notes for the remaining disciplines, such as its engineering, environmental, chemistry, microbiology, behavioral and clinical pharmacology, epidemiology, and social science analysis of JLI's PMTAs.

31. FDA offered little justification for its privilege claim. It contends the scientific disciplinary reviews it withheld "contain the thinking of [the] scientists deliberating as part of the review of the PMTAs." *Id.* According to FDA, "[t]he release of this internal, predecisional, deliberative information would discourage the expression of candid opinions, [and] would inhibit the free and frank exchange of information among agency personnel." *Id.* This generic statement simply parrots the policies underlying the privilege. It does not articulate why disclosure of these specific disciplinary reviews will undermine agency deliberations on future PMTAs.

32. FDA thus has not demonstrated that the deliberative process privilege protects these materials from disclosure or that the disclosure of these materials would cause specific, reasonably foreseeable harms to interests that the deliberative process privilege protects.

33. JLI's outside counsel informally raised these concerns with FDA. On July 28, 2022, FDA responded that the Center for Tobacco Products "considered [JLI's] request, and we are continuing to withhold the additional records pursuant to FOIA Exemption (b)(5)." Ex. 5.

34. The next day, on July 29, 2022, JLI filed an administrative appeal of FDA's decision to withhold the materials. As part of that appeal, JLI challenged FDA's decision on three separate grounds. *First*, the information in the withheld documents is incorporated into the MDO and TPL Review. FDA explicitly incorporated the engineering review and the behavioral and clinical pharmacology review into the TPL Review. The agency cannot rely on the scientific analysis in those disciplinary reviews, making that analysis part of its final agency action, and then refuse to provide the materials showing the scientific basis for its decision. FDA also could not conclude JLI's products were not appropriate for the protection of the public health without performing the holistic review and balancing analysis that the Tobacco Control Act requires. Under the TCA, FDA must consider the "risks and benefits to the population as a whole, … taking into account (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will starting using such products." 21 U.S.C. §§ 387j(c)(4)–(5). This necessarily requires considering not just toxicology data, but also, among other things, product information and characteristics, manufacturing controls, chemistry data, clinical data, behavioral data, and sales and marketing plans discussed in the other disciplinary reviews that FDA has withheld. FDA's marketing decision, if it is legally proper, must have considered and relied on the findings of those other disciplinary reviews.

35. *Second*, the materials that FDA is withholding are factual and non-decision-making materials. The deliberative process privilege does not protect purely factual materials. Nor does it protect the neutral scientific review FDA is supposed to conduct when performing its disciplinary reviews. Those scientific reviews reflect the fact-based conclusions of FDA's scientific primary reviewers, not discretionary policy-making judgments.

36. *Third*, FDA may not withhold information under the deliberative process privilege unless it "reasonably foresees that disclosure would harm an interest protected by an exemption" or if "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8)(A)(i). FDA has not adequately explained what, if any, reasonably foreseeable harm to its interests would result if it were to provide JLI with the withheld materials.

37. There would be no harm. FDA regularly makes disciplinary reviews available for authorized PMTAs. In response to FOIA requests, for example, FDA produced all disciplinary reviews for the IQOS PMTAs, Submission Tracking Numbers PM0000424-PM0000426, PM0000479. Even for denied applications, FDA's final response to JLI here shows that the agency will make available reviewer notes and other materials FDA "considered," "reviewed," or "relied on" in its TPL Review. Ex. 2 at 2. The administrative record in Fontem's recent D.C. Circuit appeal challenging a marketing denial order includes disciplinary reviews and other internal agency communications across a range of disciplines. *See Fontem US, LLC v. FDA*, No. 22-1076, Doc. No. 19560007 at 2, 9–11 (D.C. Cir. July 21, 2022). Against this backdrop, any FDA employee preparing the materials JLI requested already knows that this information will likely become publicly available after FDA issues its decision. Making the materials available to JLI thus will not discourage candid opinions or the frank exchange of information.

38. FDA acknowledged receipt of JLI's administrative appeal on August 1, 2022. In its acknowledgment letter, FDA stated that under "5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under 'unusual circumstances' in that our office will need to consult with another office that has substantial interest in the determination of the appeal." FDA's statutory deadline for resolving JLI's administrative appeal was accordingly September 13, 2022.

39. FDA did not meet this statutory deadline. September 13, 2022, has come and gone, and JLI has not received any further word regarding its administrative appeal from the agency.

40. FDA's refusal to produce the requested documents and its lack of transparency undermine the public interests FOIA is supposed to protect. The basic purpose of FOIA is to ensure an informed citizenry and to hold the government accountable for its actions. FDA's decision to deny JLI's PMTAs has already received considerable public attention and scrutiny. But the public cannot hold FDA accountable if it keeps key documents central to its MDO hidden. JLI has already submitted its § 10.75 appeal, despite not having access to all the information FDA relied on when making its decision, while "reserv[ing] the right to amend or supplement this § 10.75 request based on additional information it may obtain under the Freedom of Information Act (FOIA)."

41. FDA's refusal to comply with the FOIA requests at issue in this Complaint is part of a troubling pattern of decreasing transparency at the agency. FDA used to more transparently respond to FOIA requests related to other MDOs and MGOs, but has released less and less information in response to those requests over time. FOIA instructs agencies to operate openly and transparently, but as this pattern illustrates, FDA is not living up to that congressional mandate.

CLAIM FOR RELIEF: VIOLATION OF FOIA, 5 U.S.C. § 552

42. JLI restates and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

43. FDA's failure to make available the complete records sought by JLI violates FOIA, which provides that agencies, "upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A).

44. JLI has exhausted its administrative remedies under 5 U.S.C. § 552(a)(6)(C)(i). The company filed an administrative appeal on July 29, 2022. FDA acknowledged receipt of the appeal on August 1, 2022, and the statutory deadline for the agency to resolve the administrative appeal was September 13, 2022. *See* 5 U.S.C. § 552(a)(6)(A)(ii); *id.*§ 5 U.S.C. § 552(a)(6)(B)(i). FDA did not meet that statutory deadline, and as of the date of this complaint, still has not resolved JLI's administrative appeal.

45. JLI is being harmed by FDA's continued unlawful withholding of responsive records. JLI will continue to be harmed until FDA complies with FOIA's requirements.

46. JLI is entitled to injunctive relief compelling the release and disclosure of the requested documents.

PRAYER FOR RELIEF

JLI requests that the Court:

1. Assume jurisdiction in this matter and maintain jurisdiction until FDA complies with FOIA and every order of this Court.

2. Enjoin FDA from continuing to withhold responsive agency records.

3. Order FDA to disclose all responsive records, including those it claims the deliberative process privilege exempts from disclosure.

4. Declare that FDA's failure to disclose responsive agency records violates 5 U.S.C. § 552(a).

5. Award JLI its attorneys' fees and other litigation costs reasonably incurred pursuant to 5 U.S.C. § 552(a)(4)(E).

6. Grant such other relief as the Court deems just and proper.

Dated: September 20, 2022

Respectfully submitted,

By: */s/ Jason M. Wilcox*

David M. Bernick (DC Bar No. 1724860)
Renee D. Smith (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

Peter A. Farrell (DC Bar No. 53608)
Jason M. Wilcox (DC Bar No. 1011415)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave, NW
Washington, D.C. 20004
(202) 389-5000

Attorneys for Plaintiff Juul Labs, Inc.

Exhibit 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

July 5, 2022

BY E-MAIL

Juul Labs Inc.
Attention: Angela Ho-Chen, Director, Regulatory Affairs
1000 F Street NW, Suite 800
Washington, D.C. 20004

Re: June 23, 2022 marketing denial order related to certain products under Premarket Tobacco Product Application ("PMTA") PM0000864, PM0000872, PM0000874, PM0000876, PM0000878, PM0000879; *Juul Labs, Inc. v. FDA*, 22-1123 (D.C. Cir.)

Dear Angela Ho-Chen:

FDA's Center for Tobacco Products ("CTP") issued a marketing denial order to Juul Labs Inc. ("Juul") on June 23, 2022, for the above-captioned products. Juul filed a petition for review in the D.C. Circuit the same day. On June 24, 2022, the court granted Juul's motion for a temporary administrative stay, noting that it was not ruling on the merits of Juul's motion. Juul filed an emergency motion to stay on June 27, 2022, and the government's response brief is due July 7, 2022. Juul has indicated that it may seek administrative review of the marketing denial order.

Pursuant to 21 C.F.R. § 10.75, CTP has concluded that it will review the marketing denial order it issued to Juul related to certain products outlined in Appendix A of the marketing denial order. CTP is undertaking this review because in the course of reviewing the briefing materials in *JUUL v. FDA*, No. 22-1123 (D.C. Cir.), CTP determined that there are scientific issues unique to this application that warrant additional review. Pursuant to 21 C.F.R. § 10.35(a), I am staying Juul's marketing denial order pending this review. I have determined that a stay is in the public interest to help reduce potential confusion about the status of the marketing denial order during this review. Neither this stay of the marketing denial order nor CTP's review of the marketing denial order constitute authorization to market, sell, or ship the products outlined in Appendix A of the marketing denial order.

Accordingly, the marketing denial order issued to Juul, dated June 23, 2022, related to certain products outlined in Appendix A of the marketing denial order, is hereby stayed pending FDA's prompt review.

Brian A. King, PhD, MPH
Center Director
Center for Tobacco Products
U.S. Food and Drug Administration

cc: John C. O'Quinn, P.C., Kirkland & Ellis LLP (by email)
Jason M. Wilcox, P.C., Kirkland & Ellis LLP (by email)
Devin S. Anderson, Kirkland & Ellis LLP (by email)

Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 21, 2022

Sent via Email
Elizabeth Copeland
JUUL Labs Inc.
1000 F Street N.W., Suite 800
Washington, DC 20004
elizabeth.copeland@juul.com

Re: FOIA Requests 2022-4621 and 2022-4625
Final Response

Dear Ms. Copeland,

This is a final response to your June 23, 2022, Freedom of Information Act (FOIA) requests to the U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP). You requested the following documents:

- 2022-4621: A copy of the technical project lead review (TPL) and any related documents for the mid-cycle review of the JUUL Labs, Inc. Premarket Tobacco Product Applications: JUULpods (Menthol 3.0%) – PM0000864.PD1; JUULpods (Menthol 5.0%) – PM0000872.PD1; JUULpods (Virginia Tobacco 3.0%) – PM0000874.PD1; JUULpods (Virginia Tobacco 5.0%) – PM0000876; JUUL Device – PM0000878.PD1; JUUL Locked Device – PM0000879.
- 2022-4625: A copy of the disciplinary review documents for the above PMTAs.

Your requests were received in CTP on June 26, 2022.

In an email discussion on July 1, 2022 you clarified the meaning of the 2022-4621 request regarding "mid-cycle" documents as "all documents pertaining to both the first and second cycle scientific reviews, including all disciplinary reviewer notes."

Your requests have been processed under the FOIA, 5 U.S.C. § 552.

On July 8, 2022, we sent you a partial response that included the Technical Project Lead Review (Toxicology) and the First and Second Cycle Toxicology Reviews. The TPL Review (Toxicology) provided the basis for the Agency's Marketing Denial Order (MDO) decision on the products listed above, and the Toxicology Reviews were reviewed and considered for the TPL Review (Toxicology).

An additional search for responsive records was conducted in CTP's Office of Science's Submission Tracking database. This search produced a total of 292 pages. After reviewing the

responsive pages, CTP FOIA has determined to release 115 pages in full. One-hundred-seventy-seven have been withheld pursuant to FOIA exemption (b)(5) as described below.

FOIA Exemption (b)(5) protects from disclosure those inter- and intra-agency records that are normally privileged in the civil discovery context. The three most frequently invoked privileges are the deliberative process privilege, the attorney work-product privilege, and the attorney-client privilege. After carefully reviewing the responsive records, CTP FOIA has determined that some of the responsive documents qualify for protection under the following privilege:

- **Deliberative Process Privilege** protects the integrity of the deliberative or decision-making processes within the agency by exempting from mandatory disclosure opinions, conclusions, and recommendations included within inter-agency or intra-agency memoranda or letters. The release of this internal, predecisional, deliberative information would discourage the expression of candid opinions, would inhibit the free and frank exchange of information among agency personnel, and could cause public confusion as to the grounds of the Agency's decision.

In this situation, the scientific disciplinary reviews contain the thinking of CTP's scientists deliberating as part of the review of the PMTAs. We are, however, releasing the First and Second Cycle Environmental Science and Chemistry Reviews because the Environmental Science Reviews, like the Toxicology Reviews, were reviewed and considered for the TPL Review (Toxicology), and the Toxicology Reviews relied in part on analysis in the Chemistry Reviews. The TPL Review (Toxicology) did not reach other aspects of the applications beyond the potential toxicological health risks of the new products.

This concludes the response for CTP. You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter **"FDA Freedom of Information Act Appeal."**

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Rosemary White at 301-796-7297 or via email at Rosemary.White@fda.hhs.gov and/or CTPFOIA@fda.hhs.gov. You may also contact the FDA FOIA Public Liaison for assistance at: Division of Freedom of Information, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; Telephone 202-741-5770; Toll free 1-877-684-6448; Facsimile 202-741-5769; and E-mail ogis@nara.gov.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. As a courtesy, CTP will not charge the fees incurred in the processing of this request.

We appreciate the opportunity to assist you!

Sincerely,

Jennifer J. German -S

Digitally signed by Jennifer J. German -S
Date: 2022.07.21 20:20:04 -04'00'

For
Ms. Marqui Barnes
Chief FOIA Officer
Office of Health Communication and Education
Center for Tobacco Products
U.S. Food and Drug Administration

Enclosures

Exhibit 3

JUUL LABS

June 23, 2022

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

Re: **FDA Submission Tracking Numbers (STN): PM0000864.PD1, PM0000872.PD1, PM0000874.PD1, PM0000876.PD1, PM0000878.PD1, PM0000879.PD9 – Technical Project Lead Review (TPL) and Any Related Documents for the Mid-Cycle Review**

Dear Sir or Madam:

On behalf of JUUL Labs, Inc., pursuant to the provisions of the Freedom of Information Act, please provide us with a copy (electronic preferred) of the following documents.

I respectfully request the technical project lead review (TPL) and any related documents for the mid-cycle review of the following JUUL Labs, Inc. Premarket Tobacco Product Applications:

Product	Submission Tracking Number (STN)
JUULpods (Menthol 3.0%)	PM0000864.PD1
JUULpods (Menthol 5.0%)	PM0000872.PD1
JUULpods (Virginia Tobacco 3.0%)	PM0000874.PD1
JUULpods (Virginia Tobacco 5.0%)	PM0000876.PD1
JUUL Device	PM0000878.PD1
JUUL Locked Device	PM0000879.PD9

The Company is willing to pay any fees associated with this request. If the Agency denies any part of this request, please cite each specific reason that justifies the refusal to release the requested information.

Sincerely,

Elizabeth J. Copeland
Sr. Director, Regulatory Submissions and Compliance
Authorized Representative for JUUL Labs, Inc

Email: elizabeth.copeland@juul.com
Cell: 804-572-8356

Exhibit 4

JUUL LABS

June 23, 2022

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

Re: **FDA Submission Tracking Numbers (STN): PM0000864.PD1, PM0000872.PD1, PM0000874.PD1, PM0000876.PD1, PM0000878.PD1, PM0000879.PD9 – Request for Disciplinary Review Documents**

Dear Sir or Madam:

On behalf of JUUL Labs, Inc., pursuant to the provisions of the Freedom of Information Act, please provide us with a copy (electronic preferred) of the following documents. I respectfully request the disciplinary review documents for the following JUUL Labs, Inc. Premarket Tobacco Product Applications:

Product	Submission Tracking Number (STN)
JUULpods (Menthol 3.0%)	PM0000864.PD1
JUULpods (Menthol 5.0%)	PM0000872.PD1
JUULpods (Virginia Tobacco 3.0%)	PM0000874.PD1
JUULpods (Virginia Tobacco 5.0%)	PM0000876.PD1
JUUL Device	PM0000878.PD1
JUUL Locked Device	PM0000879.PD9

The Company is willing to pay any fees associated with this request. If the Agency denies any part of this request, please cite each specific reason that justifies the refusal to release the requested information.

Sincerely,

Elizabeth J. Copeland
Sr. Director, Regulatory Submissions and Compliance
Authorized Representative for JUUL Labs, Inc

Email: elizabeth.copeland@juul.com
Cell: 804-572-8356

Exhibit 5

From: White, Rosemary <Rosemary.White@fda.hhs.gov>
Date: Thursday, Jul 28, 2022, 6:34 PM
To: elizabeth.copeland@juul.com <elizabeth.copeland@juul.com>
Cc: Klasmeier, Coleen <cklasmeier@sidley.com>, CTP FOIA <CTPFOIA@fda.hhs.gov>, Barnes, Marqui <Marqui.Barnes@fda.hhs.gov>, German, Jennifer <Jennifer.German@fda.hhs.gov>, Wright, John <John.Wright@fda.hhs.gov>
Subject: FOIA Requests 2022-4621 and 2022-4625 Final Response

Dear Ms. Copeland,

We understand that outside counsel for JUUL spoke with the Office of the Chief Counsel on July 22, 2022, and that JUUL asked additional questions regarding the final response to your June 23, 2022, Freedom of Information Act (FOIA) requests to the U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP). Your FOIA requests asked for the following documents:

- 2022-4621: A copy of "the technical project lead review (TPL) and any related documents for the mid-cycle review" of the JUUL Labs, Inc. Premarket Tobacco Product Applications: JUULpods (Menthol 3.0%) – PM0000864.PD1; JUULpods (Menthol 5.0%) – PM0000872.PD1; JUULpods (Virginia Tobacco 3.0%) – PM0000874.PD1; JUULpods (Virginia Tobacco 5.0%) – PM0000876; JUUL Device – PM0000878.PD1; JUUL Locked Device – PM0000879.
- 2022-4625: A copy of "the disciplinary review documents" for the above PMTAs.

In your conversation with the Office of the Chief Counsel, you stated that you believe additional documents informed the Marketing Denial Order and should have been disclosed. Specifically, we understand that you requested additional discipline reviews that could have informed the toxicological concerns outlined in the TPL Review (Toxicology) (hereinafter "TPL Review"), such as those from the Engineering and/or Behavioral and Clinical Pharmacology disciplines. Additionally, you requested an index of the documents withheld, similar to a *Vaughn* index.

We have considered your request, and we are continuing to withhold the additional records pursuant to FOIA Exemption (b)(5). We have already provided you with the responsive records that CTP reviewed and considered as part of the TPL Review. The TPL Review cited the Toxicology and Environmental Science discipline reviews. *See* TPL Review at 8. We have provided you with those discipline reviews. The TPL Review stated that it "[did] not reach other aspects of the applications." *See id.* As explained in the July 21, 2022 final response, we nevertheless provided you with the Chemistry discipline reviews because the Toxicology discipline reviews relied in part on the Chemistry discipline reviews. *See, e.g.,* Cycle 2 Toxicology Review at 6 ("The Toxicology evaluation of the new applicant-provided data was performed in consultation with the Chemistry reviewers . . ."). By contrast, the points you noted in the TPL Review that mention engineering principles (TPL Review at 20 (n. 12)) and clinical pharmacology study data regarding biomarkers of exposure (BOEs) (*id.* at 12-13), did not entail reliance on, or consideration of, the Engineering or Behavioral and Clinical Pharmacology discipline reviews. Those records are subject to FOIA Exemption (b)(5) and we decline to provide them. Finally, we decline to provide an index of the documents withheld. FOIA requesters whose requests are pending in the administrative stage of processing are not entitled to such an index. Our final response to your request reasonably states the basis for withholding the additional records, and thus no further description is warranted.

Our July 21, 2022 response explained that you have the right to appeal that response. As also noted in that response, if you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact me at 301-796-7297 or via email at Rosemary.White@fda.hhs.gov and/or CTPFOIA@fda.hhs.gov. You may also contact the FDA FOIA Public Liaison for assistance at: Division of Freedom of Information, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; Telephone 202-741-5770; Toll free 1-877-684-6448; Facsimile 202-741-5769; and E-mail ogis@nara.gov.

Sincerely,

Rosemary White
Government Information Specialist

Center for Tobacco Products
Office of Health Communication and Education
U.S. Food and Drug Administration
Tel: 301-796-7297
Rosemary.White@fda.hhs.gov