No. 22-1123

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

JUUL LABS, INC.,
Petitioner,

v.

U.S. FOOD AND DRUG ADMINISTRATION,
Respondents.

On Petition for Review of an Order of the U.S. Food and Drug Administration

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JOINT MOTION TO HOLD CASE IN ABEYANCE PENDING COMPLETION OF AGENCY PROCEEDINGS AND TO WITHDRAW EMERGENCY MOTION FOR STAY

July 6, 2022

Petitioner Juul Labs, Inc. ("JLI") and Respondent the United States Food and Drug Administration jointly move to hold this case in abeyance pending completion of agency proceedings. JLI also withdraws without prejudice its pending emergency motion for a stay pending review.

1. JLI petitioned on June 23, 2022 for review of the marketing denial order issued by FDA earlier that day.

2. The next day, this Court issued an administrative stay and set a briefing schedule for JLI's request for a stay pending review. JLI filed its emergency motion for a stay pending review on June 27, 2022. FDA's response is currently due by July 7 at noon, and JLI's reply is due at noon on July 12.

3. JLI informed FDA that it would be submitting a request for supervisory review of the marketing denial order under 21 C.F.R. § 10.75. On July 5, 2022, FDA entered an administrative stay of the marketing denial order, Ex. A, and published on its website that the marketing denial order is stayed. *See* https://go.usa.gov/xSqXZ. That administrative stay remains in effect pending FDA's consideration of JLI's § 10.75 submission and completion of FDA's supervisory review process. FDA does not intend to take enforcement action against the products subject to JLI's marketing denial order while the administrative stay is in place.

4. FDA has agreed to leave in place the administrative stay for an additional thirty days if a decision on JLI's § 10.75 submission is made either to

maintain or re-issue the marketing denial order to afford JLI an opportunity to seek further judicial relief if necessary.

CONCLUSION

For these reasons, the parties jointly request that this case be held in abeyance pending completion of FDA's supervisory review of the marketing denial order and JLI's premarket tobacco product application. JLI also withdraws without prejudice its pending emergency motion for a stay pending review.

Respectfully submitted,

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July 6, 2022

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

Petitioner is Juul Labs, Inc. (JLI), and respondent is the U.S. Food and Drug Administration (FDA). Amici curiae National Association of Convenience Stores, 38 national and state electronic nicotine delivery system product advocacy associations, David B. Abrams, Scott D. Ballin, Clive D. Bates, Martin J. Jarvis, David T. Sweanor, and the Vapor Technology Association have appeared in this Court.

B. Ruling Under Review

JLI has petitioned for review of FDA's June 23, 2022 order denying its premarket tobacco product applications (PMTAs). On July 5, 2022, FDA to entered an administrative stay of that order pending its review of the order pursuant to 21 C.F.R. § 10.75.

C. Related Cases

The June 23, 2022 order denying Juul Labs' applications has been previously before this Court on JLI's Emergency Motion for Administrative Stay and JLI's Emergency Motion for Stay Pending Review, but it has not otherwise been before this Court, or any other court. Counsel is also not aware of any other related cases currently pending in any other court involving substantially the same parties and the same or similar issues.

July 6, 2022

/s/ Jason M. Wilcox
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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) because it contains 310 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1).

2. This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

July 6, 2022

/s/ Jason M. Wilcox
Jason M. Wilcox

Exhibit A

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)

CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. All parties in this case are represented by registered CM/ECF users and will be served by the CM/ECF system.

/s/ Jason M. Wilcox
Jason M. Wilcox