## **Juul Labs**

JUUL Labs, Inc. 1000 F Street NW Suite 800 Washington, DC 20004

Dear Valued JUUL Partners,

Today, the U.S. Court of Appeals for the D.C. Circuit granted Juul Labs an emergency administrative stay of enforcement (attached), which temporarily blocks the FDA's marketing denial order so that Juul Labs can seek a formal stay of the FDA's action. In granting the emergency stay, the Court considered the irreparable harm caused by FDA's action absent a stay, the lack of harm to the government, and that public interest favors granting the stay. We now continue to pursue all of our legal and regulatory options while continuing to operate in the market.

As a result of the Court's action, we will continue to responsibly market our products as we have up to this point pending the Court's ruling on our forthcoming motion to stay.

While a stay is in effect, all of our products remain available for sale and there is no legal prohibition against continuing to market JUUL products. Additionally, we have every intention to honor our current contractual obligations and pay valid invoices.

As we previously said, we strongly disagree with the FDA's decision and continue to believe we have provided sufficient information and data based on high-quality research to address all issues raised by the agency.

We continue to believe our application provided robust data showing JUUL products meet the statutory standard of being "appropriate for the protection of the public health." This order allows us to continue engaging with our regulators in pursuit of a science and evidence based determination for our products.

I want to thank you for your patience and understanding as we navigate the current situation around marketing of our products.

Sincerely,

Gregg Augustine Senior Vice President, US Commercial

## United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 22-1123

September Term, 2021

FDA 06/23/22 Order

Filed On: June 24, 2022

Juul Labs, Inc.,

Petitioner

V.

United States Food and Drug Administration,

Respondent

**BEFORE:** Henderson, Wilkins, and Katsas, Circuit Judges

#### ORDER

Upon consideration of the emergency motion for temporary administrative stay, and the motion for leave to file the emergency motion for administrative stay under seal, it is

**ORDERED** that the motion for leave to file the emergency motion for administrative stay under seal be granted. It is

**FURTHER ORDERED** that respondent's June 23, 2022, marketing denial order be administratively stayed pending further order of the court. The purpose of this administrative stay is to give the court sufficient opportunity to consider petitioner's forthcoming emergency motion for stay pending court review and should not be construed in any way as a ruling on the merits of that motion. See D.C. Circuit Handbook of Practice and Internal Procedures 33 (2021). It is

**FURTHER ORDERED** that the following briefing schedule will apply to petitioner's emergency motion for stay pending court review:

Petitioner's Emergency Motion June 27, 2022, by 12:00 noon

Respondent's Response July 7, 2022, by 12:00 noon

Reply July 12, 2022, by 12:00 noon

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The parties are directed to hand-deliver the paper copies of their submissions to the court by the time and date due.

### **Per Curiam**

FOR THE COURT: Mark J. Langer, Clerk

BY: /s/

Scott H. Atchue Deputy Clerk