IN THE SUPREME COURT OF THE UNITED STATES

No. _____

AVAIL VAPOR, LLC; BLACKSHIP TECHNOLOGIES DEVELOPMENT, LLC; BLACKBRIAR REGULATORY SERVICES, LLC,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

APPLICATION FOR EXTENSION OF TIME TO FILE PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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RULE 29. 6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, the undersigned counsel of record certifies that Petitioners Avail Vapor, LLC; Blackship Technologies Development, LLC; and Blackbriar Regulatory Services, LLC have no parent corporation and that no publicly held corporation owns 10 percent or more of the stock of any of Petitioners. There is no other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of this case.

/s/ Eric N. Heyer

APPLICATION FOR EXTENSION OF TIME

TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT:

Pursuant to Supreme Court Rule 13.5, Avail Vapor, LLC; Blackship Technologies, Development, LLC; and Blackbriar Regulatory Services, LLC (collectively, "Avail"), hereby move for an extension of 60 days, to and including May 11, 2023, for the filing of a petition for a writ of certiorari. Unless an extension is granted, the deadline for filing the petition for certiorari will be March 12, 2023.

In support of this request, Applicants state as follows:

1. The United States Court of Appeals for the Fourth Circuit rendered its decision on December 12, 2022 (Exhibit 1). This Court has jurisdiction under 28 U.S.C. § 1254(1).

2. This case results from a marketing denial order issued by the United States Food and Drug Administration ("FDA") in September 2021 in response to an application for marketing authorization for Avail's flavored Electronic Nicotine Delivery System ("ENDS") products. Avail timely filed its petition for review in the U.S. Court of Appeals for the Fourth Circuit pursuant to 21 U.S.C. §387*l*(a)(1)(B).

3. This case will present the Court with the question of whether FDA's issuance of the marketing denial order was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A). More broadly, the case presents questions of when and what notice an agency must provide to a regulated party of applicable evidentiary standards governing applications to be submitted to the agency. The case raises the issue of what constitutes "fair notice" to

a regulated party when the agency changes its standards or requirements, and thereby applies new or undisclosed requirements while discounting evidence it previously indicated was necessary, and to what extent an agency can change its evidentiary standards and approach after the fact. The case also poses questions regarding a regulated party's burden under the harmless error doctrine in instances where the agency changed the procedure used to evaluate the regulated party's application.

4. Further, the Court will be asked to address a circuit split on these issues in the context of FDA issuing marketing denial orders to manufacturers of flavored ENDS products based on the manufacturers' lack of evidence from particular types of studies that FDA had either previously indicated were not required or had never suggested may be required at all, and without the agency considering evidence which it had previously emphasized as critical to its review and determination of any application for marketing authorization.

5. The Eleventh Circuit found in *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022), that FDA acted arbitrarily in applying its new and undisclosed evidentiary standard to marketing applications for flavored ENDS products while failing to consider a relevant factor, the applicants' marketing and sales-access restriction plans, which FDA had emphasized were critical to its determination.

6. However, in addition to the Fourth Circuit in the decision at issue, the Third, Seventh, and District of Columbia Circuits all reached the opposite conclusion, finding FDA provided fair notice of the evidentiary standard it ultimately applied and

that FDA's failure to consider the applicants' marketing and sales-access restriction plans was harmless error. *See Liquid Labs v. FDA*, 52 F.4th 533 (3rd Cir. 2022); *Gripum LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022).

7. The Fifth Circuit recently vacated a 2-1 ruling in favor of FDA, and granted a petition for rehearing *en banc*, in a case where undersigned counsel represents the petitioners. *Wages and White Lion Invs., LLC v. FDA*, No. 21-60766, __ F.4th __, 2023 U.S. App. LEXIS 1397 (5th Cir. Jan. 19, 2023). The Fifth Circuit had previously granted a motion to stay FDA's marketing denial order. *Wages and White Lion Ins., LLC v. FDA*, 16 F.4th 1130 (5th Cir. 2021). Rulings are also presently pending in appeals in the Second and Ninth Circuits, in which undersigned counsel also represents petitioners. *Magellan Technology, Inc. v. FDA*, No. 21-2426 (2nd Cir.); *Lotus Vaping Technologies, LLC v. FDA*, No. 21-71328 (9th Cir.).

8. Good cause exists for granting Avail a 60-day extension to file a petition for writ of certiorari. The extension will hopefully allow the Second and Ninth Circuits to rule on the cases presently before them, potentially clarifying the depth and extent of the current circuit split. Supplemental briefing before the Fifth Circuit in *Wages* is set to be completed in March 2023, with oral argument before the *en banc* court to occur during the week of May 15, 2023, if the case is not decided on the supplemental briefing. A 60-day extension will provide Avail's counsel sufficient time to prepare and file its petition, as counsel for Avail had significant professional obligations during much of the period in which the petition would have otherwise

been prepared, including the *en banc* briefing in *Wages*, which was just filed on February 22, 2023, oral argument in the Second Circuit case, and an emergency motion to stay a preliminary injunction order in an unrelated trademark dispute pending before the United States Court of Appeals for the Federal Circuit.

9. Neither FDA nor the United States will be prejudiced by the requested extension.

10. Accordingly, good cause exists for this application, and Avail respectfully requests a 60-day extension of time within which to file a petition for a writ of certiorari, to and including May 11, 2023.

Respectfully submitted,

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