IN THE SUPREME COURT OF THE UNITED STATES

No. _____

MAGELLAN TECHNOLOGY, INC.,

*Petitioner*,

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 SECOND CIRCUIT**

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## RULE 29. 6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, the undersigned counsel of record certifies that Petitioner Magellan Technology, Inc. has no parent corporation and that no publicly held corporation owns 10 percent or more of the stock of Petitioner. 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 SONIA SOTOMAYOR, ASSOCIATE JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT:**

Pursuant to Supreme Court Rule 13.5, Petitioner Magellan Technology, Inc. ("Magellan"), hereby moves for an extension of 60 days, to and including January 23, 2024, 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 November 24, 2023.

In support of this request, Petitioner states as follows:

1. The United States Court of Appeals for the Second Circuit rendered its panel decision on June 16, 2023. (Exhibit 1.) Magellan timely requested panel rehearing and, alternatively, rehearing *en banc* on July 31, 2023, and the Second Circuit denied the petition on August 25, 2023. (Exhibit 2.)

2. This Court has jurisdiction under 28 U.S.C. § 1254(1).

3. 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 Magellan's flavored Electronic Nicotine Delivery System ("ENDS") products. Magellan timely filed its petition for review in the U.S. Court of Appeals for the Second Circuit pursuant to 21 U.S.C. §387*l*(a)(1)(B).

4. 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.

5. 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.

6. 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.

7. However, in addition to the Second Circuit in the decision at issue, the Third, Fourth, Seventh, Ninth, and District of Columbia Circuits have all reached the

opposite conclusion, finding FDA provided fair notice of the evidentiary standard it ultimately applied and, in some cases, 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); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Gripum LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657 (2023); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022).

8. Earlier this year, the Fifth Circuit 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, 58 F.4th 233, 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). The *en banc* Fifth Circuit heard oral arguments on May 16, 2023, and the decision in that case is pending. The Fifth Circuit has also recently published an opinion granting a stay in a similar pending case addressing FDA marketing denial orders for menthol-flavored ENDS products. *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023).

9. Good cause exists for granting Magellan a 60-day extension to file a petition for writ of certiorari. The extension will hopefully allow the Fifth Circuit to rule on the *en banc* case presently before it, potentially clarifying the depth and extent of the current circuit split. A 60-day extension will also provide Magellan's counsel sufficient time to prepare and file its petition, as counsel for Magellan has had significant professional obligations during much of the period in which the petition

would have otherwise been prepared, including preparing a motion to dismiss and opposition to a motion for preliminary injunction in a district court action brought against multiple clients by the City of New York, preparing an opposition to a motion to dismiss for a case in the Southern District of Georgia, preparing and filing multiple submissions opposing institution of an investigation by the International Trade Commission pursuant to 19 U.S.C. § 1337, and preparing a motion for summary judgment in a trademark infringement matter in the U.S. District Court for the Southern District of New York.

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

11. Accordingly, good cause exists for this application, and Magellan respectfully requests a 60-day extension of time within which to file a petition for a writ of certiorari, to and including January 23, 2024.

Respectfully submitted,

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