United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

DEBRA ANN LIVINGSTON
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: September 27, 2021
Docket #: 21-2426
Short Title: Magellan Technology, Inc., v. United States Food and Drug Ad

Agency #: PM0001594
Agency: Food & Drug Administration

DOCKETING NOTICE

A petition for review filed by Magellan Technology, Inc., in the above referenced case was docketed today as 21-2426. This number must appear on all documents related to this case that are filed in this Court. For pro se parties the docket sheet with the caption page, and an Acknowledgment and Notice of Appearance Form are enclosed. In counseled cases the docket sheet is available on PACER. Counsel must access the Acknowledgment and Notice of Appearance Form from this Court's website http://www.ca2.uscourts.gov.

The form must be completed and returned within 14 days of the date of this notice. The form requires the following information:

YOUR CORRECT CONTACT INFORMATION: Review the party information on the docket sheet and note any incorrect information in writing on the Acknowledgment and Notice of Appearance Form.

The Court will contact one counsel per party or group of collectively represented parties when serving notice or issuing our order. Counsel must designate on the Acknowledgment and Notice of Appearance a lead attorney to accept all notices from this Court who, in turn will, be responsible for notifying any associated counsel.

CHANGE IN CONTACT INFORMATION: An attorney or pro se party who does not immediately notify the Court when contact information changes will not receive notices, documents and orders filed in the case.

An attorney and any pro se party who is permitted to file documents electronically in CM/ECF must notify the Court of a change to the user's mailing address, business address, telephone number, or e-mail. To update contact information, a Filing User must access PACER's Manage

My Appellate Filer Account, https://www.pacer.gov/psco/cgi-bin/cmecf/ea-login.pl. The Court's records will be updated within 1 business day of a user entering the change in PACER.

A pro se party who is not permitted to file documents electronically must notify the Court of a change in mailing address or telephone number by filing a letter with the Clerk of Court.

CAPTION: In an appeal, the Court uses the district court caption pursuant to FRAP 12(a), 32(a). For a petition for review or original proceeding the Court uses a caption pursuant to FRAP 15(a) or 21(a), respectively. Please review the caption carefully and promptly advise this Court of any improper or inaccurate designations in writing on the Acknowledgment and Notice of Appearance form. If a party has been terminated from the case the caption may reflect that change only if the district court judge ordered that the caption be amended.

APPELLATE DESIGNATIONS: Please review whether petitioner is listed correctly on the party listing page of the docket sheet and in the caption. If there is an error, please note on the Acknowledgment and Notice of Appearance Form. Timely submission of the Acknowledgment and Notice of Appearance Form will constitute compliance with the requirement to file a Representation Statement required by FRAP 12(b).

For additional information consult the Court's instructions posted on the website.

Inquiries regarding this case may be directed to 212-857-8626.

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

MAGELLAN TECHNOLOGY, INC., Petitioner, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Respondent.	)	Case No.

PETITION FOR REVIEW

Appellant Magellan Technology, Inc. ("Magellan"), pursuant to Section 912 of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 387*l*, and Rule 15(a) of the Federal Rules of Appellate Procedure, respectfully submits this petition for review of the Marketing Denial Order ("MDO") dated September 8, 2021, issued by Respondent United States Food and Drug Administration ("FDA") for Magellan's non-tobacco- and non-menthol-flavored electronic nicotine delivery system ("ENDS") products. A copy of the MDO is attached hereto as Exhibit A.

Magellan appeals FDA's MDO on the ground that FDA's denial of Magellan's application for a marketing order is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and thus must be set aside and vacated pursuant to 5 U.S.C. § 706(2)(A). Among the reasons FDA's denial of

Magellan's application for a marketing order is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law are the following:

1. FDA's adoption of a comparative efficacy standard for non-tobacco- and non-menthol-flavored ENDS products versus tobacco-flavored ENDS products lacks any statutory basis, as the standard for approval of marketing orders for tobacco products under Section 910 of the FDCA, 21 U.S.C. § 387j, unlike the standard for drugs, does not require an applicant to prove that non-tobacco and non-menthol-flavored products are more efficacious at adult smoking cessation than tobacco-flavored products and, indeed, manufacturers of such products are prohibited from making such comparative efficacy claims without an approved modified risk tobacco product order under Section 911 of the FDCA, 21 U.S.C. § 387k;

2. FDA's adoption of a comparative efficacy standard for the granting of a marketing order for non-tobacco- and non-menthol-flavored ENDS products versus tobacco-flavored ENDS products is, in reality, a disguised tobacco product standard that has been adopted and is being applied by FDA through adjudication rather than adopted through notice-and-comment rulemaking, as required by Section 907 of the FDCA, 21 U.S.C. § 387g;

3. FDA's adoption of a comparative efficacy standard for non-tobacco- and non-menthol-flavored ENDS products versus tobacco-flavored ENDS products

violates Section 910 of the FDCA, 21 U.S.C. § 387j, insomuch as the standard overlooks entirely the benefits to adult nonusers of Magellan's subject flavored ENDS products who are current users of combustible cigarettes and would not try or switch to a tobacco- or menthol-flavored version of Magellan's less-harmful subject ENDS products, but would try or switch to the subject flavored less-harmful ENDS products;

4. FDA failed to provide adequate notice or warning of its adoption of a comparative efficacy standard for the granting of a marketing order for non-tobacco- and non-menthol-flavored ENDS products versus tobacco-flavored ENDS products, including in its relevant guidance documents and proposed rule governing the contents of premarket tobacco applications ("PMTAs"), despite FDA's stating publicly since at least March 2018 that it was concerned about the role of non-tobacco flavors in ENDS products with respect to youth initiation and having years in which to do so prior to the September 9, 2020 deadline for submission of such PMTAs, and, if anything, FDA suggested in such guidance documents that the long-term clinical studies it is now requiring were likely unnecessary;

5. FDA's issuance of an MDO in the absence of a finalized rule setting forth the required contents of a PMTA is unlawful;

6. FDA's requirement for product-specific adult smoking cessation data for Magellan's non-tobacco- and non-menthol-flavored ENDS products on the one

hand, while relying on non-product-specific studies on the role of flavors in youth initiation of ENDS fails to adequately consider that Magellan's non-tobacco- and non-menthol-flavored ENDS products are unlikely to be accessible to youth or to cause any significant youth update of nicotine or tobacco products because they would be sold only in age-gated specialty vape and tobacco shops and through age-gated online sales, and not through mass-market retailers such as convenience stores, and would not be advertised through mass media marketing campaigns; and

7. FDA's adoption of a comparative efficacy standard for non-tobacco- and non-menthol-flavored ENDS products versus tobacco-flavored ENDS products fails to consider that, as a practical matter, it is virtually impossible for Magellan to collect such consumer switching data given that FDA, since March 2020, has prohibited the marketing and sale of cartridge-based non-tobacco- and non-menthol-flavored ENDS products, like Magellan's subject products, to consumers.

Magellan respectfully requests that the Court vacate or modify, in whole or in part, the Marketing Denial Order and grant such other and further relief to which Magellan may be entitled.

Respectfully submitted,

THOMPSON HINE LLP

Dated: September 24, 2021

By: /s/ Richard De Palma

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EXHIBIT A

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

September 08, 2021

DENIAL

Magellan Technology Inc.
Attention: Dr. Angelico
820 Southlake Boulevard
North Chesterfield, VA 23236

FDA Submission Tracking Number (STN): PM0001594, see Appendix A

Dear Dr. Angelico:

We are denying a marketing granted order for the products identified in Appendix A.

Based on our review of your PMTAs[1], we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is appropriate for the protection of the public health (APPH). Therefore, you cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1). You may provide information to fulfill some of these requirements by including an authorization for FDA to cross-reference a Tobacco Product Master File.[2] You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTAs, we identified the following key basis for our determination:

1. All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS.

   Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. Although your PMTAs contained a cross-

[1] Premarket Tobacco Product Application (PMTA) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

sectional survey from a probability-based sample examining demographics and usage of current and former smokers including product-specific (i.e., Juno) items, a focus group of perceptions and intentions, a diary study of users of the products focused on usage and attitudes, and a human factors study, this evidence is not sufficient to support the benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette reduction resulting from use of these products over time nor evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors evaluate product switching or cigarette reduction based on flavor type to enable comparisons between tobacco and other flavors. Accordingly, this is insufficient to evaluate the magnitude of the potential benefit to adult users that is needed to complete our assessment.

Without this information, FDA concludes that your applications are insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be appropriate for the protection of the public health.

We cannot find that the marketing of your new tobacco products is APPH. The review concluded that key evidence demonstrating APPH is absent. Therefore, scientific review did not proceed to assess other aspects of these applications. FDA finds that it is not practicable to identify at this time an exhaustive list of all possible deficiencies.

Your PMTAs lack sufficient information to support a finding of APPH; therefore, we are issuing a marketing denial order. Upon issuance of this order, your products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

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

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; if the due date falls on a weekend or holiday, the delivery

[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Kenna Randall, Regulatory Health Project Manager, at (301) 796-4164 or Kenna.Randall@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.08 14:48:16 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosure **(if provided electronically, the Appendix is not included in physical mail):**
Appendix A – New Tobacco Products Subject of This Letter

Appendix A
New Tobacco Products Subject of This Letter

STN	PD Number	Product Name	Category	Subcategory	Package Type	Package Quantity	Characterizing Flavor	Additional Property
PM0001594	PD12	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 48mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD20	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 48mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD16	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 48mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD14	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 18mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD10	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 18mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD13	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 0mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD9	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 0mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD19	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 36mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD15	Juno Pods Blue Razz	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Blue Raspberry	Nicotine: 36mg/mL, PG/VG: 70/30, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD18	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 18mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD17	Juno Pods Pretzel Graham	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Pretzel Graham	Nicotine: 0mg/mL, PG/VG: 68/32, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device
PM0001594	PD11	Juno Pods Mango	ENDS(VAPES)	ENDS Component	Pod	1 Pod	Mango	Nicotine: 36mg/mL, PG/VG: 62/38, E-Liquid Volume: 1.6mL, Length: 19.95mm, Diameter: 18.7mm, Coil Resistance: 1.4ohm, Compatible with Juno Device