UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
Tyler Division

MAGELLAN TECHNOLOGY, INC.; 2225 Kenmore Avenue, Suite 110 Buffalo, New York 14207, and VAPOR TRAIN 2 LLC; 3500 McCann Road Longview, Texas 75605, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., Commissioner for Food and Drugs; 10903 New Hampshire Avenue Silver Spring, Maryland 20903, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, Secretary of Health and Human Services; 200 Independence Avenue, S.W. Washington, D.C. 20201, Defendants.	)	Case No.

VERIFIED COMPLAINT
(TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION REQUESTED)

Plaintiffs Magellan Technology, Inc. ("Magellan") and Vapor Train 2 LLC ("Vapor Train"), for their Verified Complaint against the United States Food and Drug Administration, Robert M. Califf, M.D., Commissioner for Food and Drugs (collectively, "FDA"), the United States Department of Health and Human Services, and Xavier Becerra, Secretary of the Department of Health and Human Services (collectively, "HHS"), hereby state as follows:

NATURE OF THE ACTION

1. Through this action, Plaintiffs seek a declaratory judgment that FDA has violated the Administrative Procedure Act by issuing a Refuse to Accept ("RTA") order for twelve bundled Premarket Tobacco Product Applications ("PMTAs") that Magellan submitted for various electronic nicotine delivery system products it markets.

2. Plaintiffs contend that FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the RTA order because the agency (i) invoked regulations governing PMTA acceptance that do not apply to Magellan's PMTA and (ii) failed to consider timely amendments containing required content that Magellan properly submitted but which FDA failed to link to the corresponding applications because of its own failure to issue Submission Tracking Numbers ("STNs") to Magellan for the underlying applications.

3. Plaintiffs seek (i) a temporary restraining order and preliminary injunction staying the RTA order pending the outcome of this action; and (ii) a final judgment setting aside the RTA order and remanding to FDA for further review of Magellan's PMTAs.

THE PARTIES

4. Plaintiff Magellan Technology, Inc., is a corporation headquartered in Buffalo, New York. Magellan distributes ENDS products nationwide, including in this district. Magellan is the master distributor of all Hyde- and JUNO-branded ENDS products. Through its scientific advisors, on May 12 and 13, 2022, Magellan submitted twelve bundled applications for marketing authorization for a range of Hyde- and JUNO-branded ENDS products to FDA.

5. Plaintiff Vapor Train 2 LLC is a Texas limited liability company headquartered and with two retail stores in Longview, Texas. Until FDA issued the RTA order, Vapor Train

purchased Hyde-branded ENDS products from Magellan and sold them to consumers at retail through its two stores.

6. Defendant United States Food and Drug Administration is a division of Defendant Department of Health and Human Services ("HHS"). The headquarters and principal place of business of FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903. The headquarters and principal place of business of HHS is 200 Independence Avenue, S.W., Washington, D.C. 20201. Defendant Robert M. Califf, M.D., is the Commissioner of the Food and Drug Administration and is sued in his official capacity. Defendant Xavier Becerra is the Secretary of Health and Human Services and is sued in his official capacity.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court has the authority to grant the declaratory relief requested by Plaintiffs pursuant to 28 U.S.C. §§ 2201 and 2202. The Court also has the authority to hold unlawful and set aside FDA's actions pursuant to 5 U.S.C. §§ 702 and 706 and to grant temporary and preliminary injunctive relief pursuant to 5 U.S.C. § 705.

8. This Court has personal jurisdiction over Defendants FDA, HHS, Commissioner Califf, and Secretary Becerra in their official capacities, as each is an agency or official of the United States Government.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) as the district wherein Plaintiff Vapor Train 2 LLC resides.

FACTS

A. ENDS Products are "Tobacco Products" under the Tobacco Control Act

10. Electronic nicotine delivery system ("ENDS") products are regulated by FDA as "tobacco products" under the Tobacco Control Act ("TCA"), 21 U.S.C. §§ 387, *et seq.*, because they "contain[] nicotine from any source" and are "intended for human consumption." 21 U.S.C. § 321(rr)(1). As such, they are subject to the requirements of Subchapter IX of the Federal Food, Drug and Cosmetic Act ("FDCA").

11. Section 910 of the FDCA, 21 U.S.C. § 387j, requires that any tobacco product that was not commercially marketed as of February 15, 2007, receive a marketing order from FDA prior to being commercially marketed in the United States.

12. Prior to April 15, 2022, ENDS products containing nicotine that was synthetically manufactured or otherwise not derived from tobacco plants did not qualify as "tobacco products" and were not subject to Section 910's premarket authorization requirements because the statutory definition of a "tobacco product" extended only to products "made or derived from tobacco that [are] intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr) (2009). However, the Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) expanded the statutory definition to include products containing nicotine "from any source" effective April 15, 2022.

13. As a result, manufacturers and distributors of ENDS products were required to submit premarket tobacco applications for these synthetic nicotine products. If they submitted PMTAs by May 14, 2022, they would not be in violation of the Section 910's marketing authorization requirement during the 60-day period up through July 13, 2022. *See id.* at § 111(d).

B. FDA has Historically Extended Enforcement Discretion to ENDS Products with Timely Submitted and Pending PMTAs

14. May 14, 2022, was not the first time that manufacturers and distributors of ENDS products were required to submit PMTAs for their products in order to keep them on store shelves.

15. When the Tobacco Control Act was first enacted in 2009, its requirements originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The TCA's requirements would only apply to other products meeting the statutory definition of a "tobacco product" if FDA "by regulation deems" such products to be "tobacco products." *Id*.

16. Through its so-called "Deeming Rule," 81 Fed. Reg. 28974 (May 10, 2016) (codified at 21 C.F.R. § 1143.1), FDA deemed ENDS products containing nicotine derived from tobacco plants to be tobacco products.

17. However, because thousands, if not millions, of ENDS products were already commercially marketed in the United States, in the Deeming Rule's preamble, FDA introduced a discretionary enforcement policy that allowed for delayed compliance periods for ENDS products. *See* 81 Fed. Reg. at 29009-15.

18. Under this discretionary enforcement policy, PMTA submissions were originally required to be filed in 24 months, or by August 8, 2018. 81 Fed. Reg. at 28977-78, 29011. Tobacco products, including ENDS products, already on the U.S. market would not be subject to FDA enforcement action in the meantime or while a timely submitted PMTA was pending FDA review. *Id*.

19. FDA's deadline for the filing of PMTAs under its discretionary enforcement policy, however, changed multiple times over the succeeding years, and these changes resulted in

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