

FDA ATTY

CONTRACT IN-HOUSE COUNSEL & CONSULTANTS, LLC

May 9, 2022

Re: Confirmation of International Supply Wholesale, LLC's PMTA Submission

To Whom It May Concern:

My name is Marc C. Sanchez, a food and drug attorney in private practice ("Counsel"). At the request of my client International Supply Wholesale, LLC (the "Company"), I am qualified to make the following written opinion. I am an attorney in good standing with 12-years experience in FDA regulatory law, including tobacco product regulation.

Counsel hereby acknowledges and represents that Company successfully filed a pre-market tobacco applications (PMTA) on May 9, 2022 for the Mr. Vapor Disposable ENDS with synthetic nicotine. The Mr. Vapor PMTAs covering the Curve, Flex, and Maxx devices will now undergo an Acceptance Review.

Any synthetic nicotine product currently on the U.S. market as of April 14, 2022, can remain on the market for an additional 30 days until May 14, 2022 (the "Synthetic Nicotine PMTA Submission Deadline"). Manufacturers of synthetic nicotine products wishing to take advantage of FDA's compliance policy and enforcement discretion after that date must submit a PMTA to FDA by that date. If a PMTA is submitted in a timely manner, the product(s) may remain on the market for an additional 90 days after the effective date, i.e., until July 13, 2022.

Based on the timely submission the Mr. Vapor Curve, Flex, and Maxx Disposable ENDS with synthetic nicotine may remain on the market.

Kind Regards,



Marc C. Sanchez, Esq.

(msanchez@fdaatty.com)

Regulatory Counsel

International Supply Wholesale, LLC

