U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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Fact Sheet

Advocacy Encourages FDA To Seek Extension of Court-Ordered One-Year Moratorium on FDA Enforcement Actions Against Timely Submitted PMTAs and To Reverse the Order of Its Review of PMTAs by Market Share

On June 7, 2021, the Office of Advocacy sent a letter to the Food and Drug Administration (FDA) encouraging the agency to seek an extension of the one-year moratorium of FDA enforcement actions against manufacturers of timely filed premarket tobacco product applications (PMTA), which was included in United States District Court for the District of Maryland's remedy order dated July 11, 2019.

- The one-year moratorium on FDA enforcement actions against manufacturers that timely filed PMTAs expires on September 9, 2021.
- As of May 2021, there are timely submitted PMTAs for over 6 million electronic nicotine delivery systems (ENDS) products.
- The FDA Center for Tobacco Products is prioritizing review of timely submitted PMTAs by market share, reviewing the products of large ENDS manufacturers first.
- Advocacy encourages the FDA to seek an extension of the court-ordered moratorium of FDA enforcement actions.
- Advocacy also encourages the FDA to reverse its order of review of PMTAs so that more small ENDS manufacturers can keep their products on the market as waiting longer for approval may result in these small businesses closing permanently.

A complete copy of Advocacy's letter to the FDA is available at: https://advocacy.sba.gov/. For more information please contact Assistant Chief Counsel Charles Jeane at 202.205.7168.