FDA Issues Update on Review of Non-Tobacco Nicotine and Synthetic Nicotine Products

Recently, the U.S. Food and Drug Administration issued an announcement regarding the status of Pre-Market Tobacco Applications (PMTAs) for products that contain non-tobacco derived nicotine or synthetic nicotine.

On April 14, 2022, a new federal law went into effect clarifying that the FDA has the authority to regulate tobacco products containing nicotine from any source, including non-tobacco derived nicotine (NTN) or synthetic nicotine. As a result of the law change, manufacturers were required to submit PMTAs to the FDA by May 14, 2022, for all of the tobacco products they make that contain non-tobacco derived nicotine or synthetic nicotine.

PMTAs for more than one million non-tobacco derived nicotine or synthetic nicotine products were submitted to the FDA from more than 200 manufacturers. According to the agency, all PMTA applications submitted by May 14, 2022, have been processed, and 95 percent have been assessed to determine if they meet the minimum requirements to be accepted for further review. As of October 7, 2022, the FDA has issued Refuse to Accept (RTA) letters for more than 889,000 out of the one million products containing non-tobacco derived nicotine or synthetic nicotine which were the subject of PMTAs. A RTA letter means that the application did not meet the criteria for the FDA to accept the application for further review and the product cannot be sold in the marketplace. At the same time, the FDA has accepted over 1,600 PMTAs for further review, with the vast majority being for electronic-cigarette or e-liquid products that contain non-tobacco derived nicotine or synthetic nicotine.

According to its announcement, the FDA has not authorized for sale any products containing non-tobacco derived nicotine or synthetic nicotine. Therefore, the agency stated that “all NTN [non-tobacco nicotine] products on the market are marketed unlawfully and risk FDA enforcement action. It is illegal for a retailer or distributor to sell or distribute e-cigarettes that the FDA has not authorized, and those who engage in such conduct are at risk of FDA enforcement, such as a seizure, injunction, or civil money penalty.” This includes those products covered by the 1,600 PMTAs accepted for further agency review.