Press Coverage | September/October 2026

The US Food and Drug Administration's Regulatory Reset

RELATED PROFESSIONALS

Bryan M. Haynes | Agustin E. Rodriguez | Zie Alere

Bryan Haynes, Agustin Rodriguez, and Zie Alere, attorneys in Troutman Pepper Locke's Tobacco + Nicotine industry group, were quoted in the September/October 2026, *Tobacco Asia* article, "The US Food and Drug Administration's Regulatory Reset."

> Agustin E. Rodriguez, a partner with the law firm of Troutman Pepper Locke, told *Tobacco Asia* that the guidance greatly increases the incentives to submit (or improve) a PMTA. "Only products with applications that have cleared the acceptance and filing review qualify for enforcement forbearance," he said. "This gives manufacturers a concrete reason to invest in application quality."
>
> Rodriguez stressed that while enforcement discretion is a step forward, questions remain. The big one: what will US states do? "We know that certain states and localities act in ways that are more prohibitionist and do not align with FDA's present view on promoting harm reduction via selective enforcement," he said. "Will states choose to use the underlying non-authorized nature of these deprioritized products as a way to try to keep them off the market, even as cigarettes continue to be lawfully sold in their jurisdictions?"
>
> …
>
> Attorneys Bryan Haynes, Agustin Rodriguez, and Zie Alere of the law firm Troutman Pepper Locke noted in an analysis of the proposal that foreign manufacturers would be required not only to register their establishments before offering products for import into the United States, but also to designate a US-based agent and agree to permit FDA inspections of their overseas facilities as a condition of registration.
>
> Haynes and his colleagues stated that the proposed product listing requirements exceed FDA's current guidance for domestic manufacturers. In addition to identifying each product, manufacturers would be required to report the nicotine source and concentration, characterize flavors, and, for electronic nicotine delivery systems (ENDS), provide technical specifications such as e-liquid volume, propylene glycol/vegetable glycerin ratios, wattage, and battery capacity.
>
> "By linking each listed product to its submission tracking number (STN), FDA can cross-reference product listings against its database of pre-market submissions to identify products on the market without authorization," the attorneys stated.
>
> The Troutman attorneys emphasized that establishment registration should not be confused with FDA marketing authorization. "Registration and product listing do not constitute marketing authorization; products subject to the premarket review requirements remain unauthorized unless and until a marketing authorization is in effect," the Troutman team wrote.

RELATED INDUSTRIES + PRACTICES

- Tobacco + Nicotine