Vuse Solo First to Receive US FDA Vapor Marketing Authorization

“We are pleased that, today, Vuse Solo received the first of its kind U.S. Food and Drug Administration (“FDA”) marketing authorization for vapor products, authorizing the sale of our U.S. subsidiary’s Vuse Solo product in Original flavor. FDA’s orders confirm that the marketing of Vuse Solo products are appropriate for the protection of the public health, underscoring years of scientific study and research dedicated to ensuring that adult nicotine consumers (ANCs) age 21+ have access to innovative and potentially less harmful alternatives to traditional tobacco products.

While Alto awaits further review from FDA unless and until FDA directs otherwise, Reynolds can lawfully sell products for which has submitted PMTAs, subject to FDA’s ongoing enforcement discretion. FDA has stated it is focusing resources on reviewing products with the largest market share, though it has limited the number of applications any one manufacturer may have under review at one time. Vuse Alto PMTA was submitted nearly a year after Vuse Solo, and five months after Vuse Vibe and Ciro, and those applications share foundational science. We remain confident in the quality of our applications.

The PMTA process allows the FDA to evaluate whether the marketing of certain tobacco products is appropriate for the protection of the public health. While these applications may include relative health impact information, it should be noted that the marketing orders sought are not statements of modified risk.

In addition to our PMTA authorizations, FDA also issued Marketing Denial Orders for five flavors that are not currently on the market. Regarding FDA’s limited concerns on those applications not currently on the market, we are carefully studying the agency analysis and decision.

Today’s order represents an important moment for Reynolds; FDA evaluates vapor product PMTAs against a rigorous, science-driven standard that requires the sales of these products are appropriate for the protection of the public health and represents a high regulatory bar for these transformational products.

Reynolds is committed to reducing the health impact of its business through a multi-category approach, and today’s marketing orders for Premarket Tobacco Product Applications are a critical regulatory accomplishment.”

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