U.S. FOOD & DRUG ADMINISTRATION

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Vuse Solo Power Unit, Vuse Replacement Cartridge Original 4.8% G1, and Vuse Replacement Cartridge Original 4.8% G2

Marketed by R.J. Reynolds Vapor Company

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of these actions and has concluded that these actions will not have significant effects on the quality of the human environment. Therefore, environmental impact statements are not required.

R.J. Reynolds Vapor Company wishes to introduce one electronic nicotine delivery (END) component and two closed e-liquids into interstate commerce for commercial distribution in the United States and submitted to FDA premarket tobacco product applications to obtain marketing orders under the provisions of section 910 of the Federal Food, Drug, and Cosmetic Act.

FDA reviewed the applicant's environmental assessments (EA), dated October 20, 2020, for the three ENDS tobacco products in accordance with the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40). The EAs concluded that the marketing orders would have no significant impact. The applicant's EAs are available to the public upon request.

The applicant's EAs evaluated potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing the new products are anticipated. FDA does not foresee that use of the new products would result in new or different environmental impacts. FDA believes that the disposal of the new products is the same as the disposal conditions of other ENDS components and closed e-liquids that are currently marketed in the United States. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

Approved by

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