

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Order for

Vantage Silver

Manufactured by R.J. Reynolds Tobacco Company

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required.

R.J. Reynolds Tobacco Company wishes to introduce a new combusted cigarette product into interstate commerce for sale in the U.S. and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations pursuant to Section 910(a)(3)(A)(ii) and Section 910(b) of the FD&C Act.

The Agency prepared the environmental assessment, dated August 17, 2017, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act and in accordance with 21 CFR 25.41 to support the finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The EA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new product. The Agency does not anticipate the market volume for combusted cigarette products to be noticeably changed based on the provided information because the new products will completely replace the predicate product. Consequently, no additional use of resources and energy due to marketing the new products is anticipated. In addition, the Agency does not anticipate impacts on endangered or threatened species or critical habitat as a result of marketing the new product.

The new product is manufactured, used and disposed of in the U.S. The applicant stated that manufacturing facility would not need to be expanded in order to produce the new product. The only difference between the new product and the original product is the replacement of non-fire standard compliant (FSC) cigarette paper with FSC cigarette paper. Therefore, the Agency anticipates no new substances or new type of emissions to be released into the environment as a result of manufacturing the new product.

During use, the new product, like other cigarette products, is usually burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products are released in a similar manner from the new product as they are from the original products and other combusted, filtered cigarettes. The released substances during use of the new product are negligible compared to the original product, from the environmental viewpoint.

To evaluate the environmental introduction for the proposed action due to the manufacturing of Vantage Silver cigarettes in Tobaccoville, NC, the first- and fifth-year projections of market share for the new product were provided. The new product will replace the predicate product to

comply with State mandated fire standard compliant (FSC) paper. Otherwise the new and predicate products are identical. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the environmental introduction for the proposed action due to the use of the new product, the Agency utilized historical data of the use of combusted cigarette products from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of combusted cigarette products consumed and found the projection for use of these products is declining. Also, the Agency does not foresee new substances or additional greenhouse gas emissions to be released into the environment as a result of use of the new product.

The Agency believes that the disposal of the new product resembles the disposal conditions of cigarette products that are currently marketed. The waste generated as a result of use of the product will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other cigarette products used in the U.S. The amount of projected total waste due to use and disposal of the new product is a minute fraction of the forecasted tobacco product waste generated in the U.S., based on information presented in the U.S. Environmental Protection Agency's report "*Advancing Sustainable Materials Management: Facts and Figures 2014*". Therefore, construction of new POTWs and landfills are not anticipated as a result of the proposed action. Furthermore, no additional control of greenhouse gas emissions is anticipated in the existing landfills.

No significant environmental impacts are expected from marketing the new product because no new control practices of air emission, water discharge, or solid waste disposal are foreseen; no release of new substances, no expansion of the manufacturing facility, no additional use of resources and energy, and no impact on endangered or threatened species or critical habitat due to marketing the new product is anticipated.

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Approved by _____
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