

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

“Camel Gold, Camel Royal, Pall Mall Menthol 100’s Box, Pall Mall Menthol Box, Camel Silver, Camel Classic Menthol Silver, Camel Gold 100’s, Camel Jade, Camel Jade 100’s, Camel Jade Silver, and Camel Jade Silver 100’s”

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 these actions and has concluded that these actions 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 two combusted, filtered cigarette products into interstate commerce for commercial distribution in the U.S. and submitted to FDA an application for exemption from substantial equivalence (SE) reports to obtain market authorizations pursuant to Section 905(j)(3) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated August 18, 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 PEA, which is available to the public upon request.

The PEA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new products. The PEA also provides analyses on energy and resource use as well as impacts on endangered or threatened species or critical habitat as a result of marketing the new products.

The new products are 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 products. The only difference between the new products and the corresponding original products for EX0000155, EX0000156, EX0000159, and EX0000161-EX0000165 is the deletion of the monogram ink on the barrel of the cigarette; and changing the name and cork-on-white tipping paper with white tipping paper for EX0000157; and changing the name and cork-on-white tipping paper with white tipping paper for EX0000158; and changing the name and white tipping paper with cork-on-white tipping paper for EX0000160. 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 products.

During use, the new products, like other cigarette products, are 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 products

as they are from the original products and other combusted, filtered cigarettes. The released substances during use of the new products 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 the new cigarettes in Tobaccolville, NC, the first- and fifth-year projections of market share for the new products were provided. The new products will replace their corresponding predicate products. 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 products, 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 cigarettes 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 products.

The Agency believes that the disposal of the new products resembles the disposal conditions of other cigarettes that are currently marketed. The waste generated from use of the products may be disposed into the environment as litter, transferred to publicly owned treatment works (POTW), and disposed of in landfills in the same manner as the waste generated from other combusted tobacco products used in the U.S. The amount of projected tobacco waste and packaging materials waste, including paper, due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated due to use of cigarette products. Also, it is a negligible fraction of municipal solid 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 POTW and landfills is not anticipated as a result of the proposed actions.

No significant environmental impacts are expected from marketing the new products 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 products is anticipated.

Approved by _____
Digitally signed by Kimberly A. Benson -S
Date: 2017.08.30 13:31:47 -04'00'
Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration