

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

“Black & Mild® Shorts”, “Black & Mild® FT”, and Two “Black & Mild® Cream”

Manufactured by John Middleton Co.

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts 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.

John Middleton Co. wishes to introduce four new sheet-wrapped, plastic tipped cigars (three unfiltered and one filtered) into interstate commerce for commercial distribution in the United States and submitted to FDA four requests for exemption from substantial equivalence to obtain marketing orders under the provisions of 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated February 5, 2019, 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) to support the finding of no significant impact. The evidence supporting this finding is contained in the attached PEA, which is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee that use of the new products would result in new or different environmental impacts. The Agency believes that the disposal of the new products is the same as the disposal conditions of other unfiltered and filtered cigars that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed actions as a result of the manufacturing, use and disposal of the new products.

Hans M. 2019.02.05
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Approved by

For Kimberly Benson, Ph.D.
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