FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for Black & Mild[®] Jazz and Black & Mild[®] Jazz Wood Tip

Manufactured by John Middleton Co.

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, environmental impact statements are not required.

John Middleton Co. wishes to introduce two new unfiltered, sheet wrapped cigars with tips into interstate commerce for commercial distribution in the United States and submitted to FDA two substantial equivalent reports to obtain marketing orders under the provisions of sections 905(j) and 910 of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated September 30, 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 the new products 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 cigars that are currently marketed in the United States. Therefore, the Agency does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

Digitally signed by Kimberly A. Benson -S Date: 2019.09.30 09:12:23 -04'00'

Approved by

Kimberly Benson, Ph.D. Director Division of Nonclinical Science Office of Science Center for Tobacco Products U.S. Food and Drug Administration