

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

EC Pipe Blue (1 ounce), EC Pipe Blue (3 ounce), EC Pipe Blue (6 ounce), EC Pipe Blue (8 ounce), EC Pipe Blue (12 ounce), EC Pipe Red (1 ounce), EC Pipe Red (3 ounce), EC Pipe Red (6 ounce), EC Pipe Red (8 ounce), EC Pipe Red (12 ounce), EC Pipe Menthol (1 Ounce), EC Pipe Menthol (3 Ounce), EC Pipe Menthol (6 Ounce), EC Pipe Menthol (8 Ounce), EC Pipe Menthol (12 Ounce)

Manufactured by Alliance One Specialty Products, LLC

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 a significant effect on the quality of the human environment. Therefore, environmental impact statements are not required.

Alliance One Specialty Products, LLC wishes to introduce 15 pipe tobacco fillers into interstate commerce for commercial distribution in the United States and submitted to FDA 15 substantial equivalence 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 April 17, 2020, 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 pipe tobacco fillers that are currently marketed in the United States. Therefore, the Agency does not foresee significant impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

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Date: 2020.04.17 12:57:17 -04'00'

Approved by

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