

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

EC Pipe Gold (1 ounce), EC Pipe Gold (2 ounce), EC Pipe Gold (3 ounce), EC Pipe Gold (8 ounce), EC Pipe Gold (12 ounce), EC Pipe Gold (16 ounce)

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

Alliance One Specialty Products, LLC wishes to introduce six new pipe tobacco filler products into interstate commerce for commercial distribution in the United States and submitted to FDA six substantial equivalence reports to obtain marketing orders under the provisions of Sections 905(j) and 910 of the Federal Food, Drug, and Cosmetic Act.

FDA reviewed the applicant's environmental assessments (EA), dated June 16, 2021, for the six tobacco products 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). The EAs concluded that the marketing orders would have no significant impact. The applicant's EAs are 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 pipe tobacco filler products 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.

Digitally signed by Luis G. Valerio -S Date: 2021.10.12 10:41:23 -04'00'

Approved by

Luis G. Valerio, Jr., Ph.D., ATS Associate Director Division of Nonclinical Science Office of Science Center for Tobacco Products U.S. Food and Drug Administration