FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for
USA Gold Blue 100s Box, USA Gold Blue 100s Soft Pack, USA Gold Blue Kings Soft Pack, USA Gold Red Kings Box, USA Gold Red Kings Soft Pack, USA Gold Menthol Dark Green 100s Box, USA Gold Menthol Green 100s Box, USA Gold Menthol Green 100s Soft Pack, USA Gold Menthol Green Kings Soft Pack, USA Gold Non-Filter Kings Soft Pack, USA Gold Gold 100s Box, USA Gold Gold 100s Soft Pack, USA Gold Gold Kings Box, USA Gold Menthol Dark Green 100s Soft Pack, USA Gold Menthol Dark Green Kings Box, USA Gold Menthol Dark Green Kings Soft Pack, USA Gold Gold Kings Soft Pack, USA Gold Red 100s Box, and USA Gold Red 100s Soft Pack

Marketed by Commonwealth Brands, Inc.

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.

Commonwealth Brands, Inc. wishes to introduce eighteen new combusted, filtered cigarettes and one new combusted, non-filtered cigarette into interstate commerce for commercial distribution in the United States and submitted to FDA nineteen requests for exemption from substantial equivalence to obtain marketing orders under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated June 26, 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 combusted cigarettes 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.

Approved by

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

Digitally signed by Kimberly A. Benson -S
Date: 2019.06.26 09:23:58 -04'00'