

FINDING OF NO SIGNIFICANT IMPACT FOR

Marketing Orders for

“Natural American Spirit 100% US Grown Tobacco Mellow Taste, Natural American Spirit Made with Organic Tobacco Mellow Taste, Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste, Natural American Spirit Mellow Taste, Natural American Spirit Full-Bodied Taste, Natural American Spirit Perique Blend Rich Robust Taste, Natural American Spirit Smooth Mellow Taste, Natural American Spirit Perique Blend Rich Taste”

Manufactured by Santa Fe Natural Tobacco Company

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.

Santa Fe Natural Tobacco Company wishes to introduce eight new filtered, combusted cigarettes into interstate commerce for commercial distribution in the United States and submitted to FDA eight 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 November 6, 2018, 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 use of the new products to 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 filtered, 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.

Digitally signed by Kimberly A. Benson -S Date:
2018.11.06 10:24:31 -05'00'

Approved by

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