

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Altadis 47 x 6 Parejo, Montecristo Corona Grande, VegaFina Corona, Altadis 44 x 4 1/4 Parejo, Altadis 47 x 5 Parejo, Altadis 40 x 4 Parejo, Altadis 39 x 6 3/4 Parejo, Altadis 48 x 6 Parejo, Altadis 32 x 6 Parejo, Altadis 45 x 5 Parejo, Altadis 40 x 5 Parejo, Altadis 42 x 4 1/4 Parejo, Altadis 60 x 6 1/2 Parejo, and Altadis 55 x 5 Parejo

Manufactured by Tabacalera de Garcia S.A.S.

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.

Tabacalera de Garcia S.A.S. wishes to introduce 14 new, unfiltered leaf wrapped, cigar products into interstate commerce for commercial distribution in the United States and submitted to FDA 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 FDA prepared the programmatic environmental assessment (PEA), dated May 19, 2022, 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 FDA does not foresee that use of the new products will result in new or different environmental impacts. The FDA believes that the disposal of the new products is the same as the disposal condition of other cigars that are currently marketed in the United States. Therefore, the FDA 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.

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Approved by

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