

FINDING OF NO SIGNIFICANT IMPACT

Marketing Order for

Altadis 60 x 5 ¹/₂ Figurado, Altadis 42 x 5 ¹/₁₆ Parejo, Altadis 48 x 6 ¹/₂ Figurado, Altadis 42 x 6 ⁷/₈ Parejo, 46 x 4 ¹/₄ Figurado, Altadis 42 x 5 ⁹/₁₆ Parejo, Altadis 52 x 5 Figurado, Altadis 48 x 7 ¹/₂ 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, an environmental impact statement is not required.

Tabacalera de Garcia S.A.S. wishes to introduce eight new, 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 16, 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 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 are the same as the disposal conditions 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 action as a result of the manufacturing, use, and disposal of the new products.

Digitally signed by Luis G. Valerio -S

Date: 2022.05.17 08:05:16 -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