

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

PRINCIPES CORONA ORIGINAL (Box of 55), PRINCIPES CORONA ORIGINAL (Box of 30), PRINCIPES CORONA BLOND (Box of 55), PRINCIPES CORONA BLOND (Box of 30), PRINCIPES CORONA BROWN (Box of 55), PRINCIPES CORONA BROWN (Box of 30), PRINCIPE CORONA CARIBBEAN (Box of 55), and PRINCIPE CORONA CARIBBEAN (Box of 30)

Marketed by La Aurora S.A.

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.

La Aurora S.A. wishes to introduce eight leaf-wrapped cigar products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence reports to obtain marketing orders under the provisions of Sections 905(j) and 910 of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the Programmatic Environmental Assessment (PEA), dated February 2, 2022, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 1500–1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40) to support the findings of no significant impact. The evidence supporting these findings 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 including air quality, water resources, soil, land use, zoning, biological resources, socioeconomics, environmental justice, solid waste hazardous materials, floodplains, wetlands, and costal zones. 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 leaf-wrapped cigar 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 manufacturing, use, and disposal of the new products.

Approved by **Hans M. Rosenfeldt -S** Hans M. Rosenfeldt -S
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