

FINDING OF NO SIGNIFICANT IMPACT
Marketing Order for
Davidoff Colorado Claro Special T
Marketed by Davidoff of Geneva USA, Inc.

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required.

Davidoff of Geneva USA, Inc. wishes to introduce one unfiltered, leaf-wrapped cigar into interstate commerce for commercial distribution in the United States and submitted to FDA one substantial equivalence report to obtain a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared an environmental assessment (EA), dated March 31, 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 finding of no significant impact. The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The EA evaluates potential environmental effects due to manufacturing, use, and disposal of the new product. No increased or new types of environmental impacts due to manufacturing the new product would be anticipated. The Agency does not foresee that use of the new product would result in new or different environmental impacts. The Agency believes that the disposal of the new product is the same as the disposal conditions of other cigars that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed action as a result of manufacturing, use, and disposal of the new product.

Digitally signed by Luis G. Valerio -S
Date: 2022.03.31 09:59:01 -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