

Temporary Compliance Waiver Notice

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FINDING OF NO SIGNIFICANT IMPACT

Marketing Order for

IQOS 3 Holder and Charger

Manufactured by Philip Morris Products S.A.

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 significant effects on the quality of the human environment. Therefore, an environmental impact statement is not required.

Philip Morris Products S.A. wishes to introduce a new heat-not-burn tobacco product into interstate commerce for commercial distribution in the United States and submitted to FDA a supplemental premarket tobacco product application to obtain a marketing order under the provisions of section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated October 6, 2020, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 1500) 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 these findings 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 are anticipated. The Agency does not foresee use of the new tobacco product would result in new or different environmental impacts. The Agency believes that the disposal of the new tobacco product is the same as the disposal conditions of other heat-not-burn tobacco products 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 tobacco product.

Approved by

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