

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

NJOY ACE DEVICE, NJOY ACE POD CLASSIC TOBACCO 2.4%, NJOY ACE POD CLASSIC TOBACCO 5%, and NJOY ACE POD RICH TOBACCO 5%

Marketed by NJOY, LLC

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact 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.

NJOY LLC wishes to continue marketing four electronic nicotine delivery system (ENDS) products in interstate commerce in the United States and submitted to FDA four premarket tobacco product applications to obtain marketing orders under the provisions of section 910 of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated April 22, 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. FDA does not foresee that use of the new products would result in new or different environmental impacts. FDA believes that the disposal of the new products is the same as the disposal conditions of other ENDS components and closed e-liquids that are currently marketed in the United States. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

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Approved by

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