

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

on! PLUS nicotine pouches 6 mg Mint, on! PLUS nicotine pouches 9 mg Mint, on! PLUS nicotine pouches 6 mg Tobacco, on! PLUS nicotine pouches 9 mg Tobacco, on! PLUS nicotine pouches 6 mg Wintergreen, on! PLUS nicotine pouches 9 mg Wintergreen

By Helix Innovations LLC

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental effects of these actions and has concluded that these actions will not have significant impact on the quality of the human environment. Therefore, environmental impact statements are not required.

Helix Innovations LLC wishes to introduce six oral nicotine pouch products into interstate commerce for commercial distribution in the United States and submitted to FDA six 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 December 16, 2025, in accordance with the National Environmental Policy Act (NEPA) and FDA's NEPA implementation regulations (21 CFR 25.40). The evidence supporting the finding of no significant impact 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 effects due to manufacturing the new products are anticipated. The Agency does not foresee that use of the new products would result in new or different environmental effects. The Agency believes that the disposal of the new products is the same as the disposal conditions of other oral nicotine pouch products that are currently marketed in the United States. Therefore, the Agency does not foresee significant impact on the environment due to the proposed actions as a result of manufacturing, use, and disposal of the new products.

Approved by

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