

## **FINDING OF NO SIGNIFICANT IMPACT**

### **Marketing Order for**

### **Marlboro Amber HeatSticks**

### **Marketed by Philip Morris Products S.A.**

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that the 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 introduce one heated tobacco product (HTP) into interstate commerce for commercial distribution in the United States and submitted to FDA one supplemental premarket tobacco product applications to obtain marketing orders 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 19, 2022, for the HTP 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 EA concluded that the marketing order would have 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 are anticipated. FDA does not foresee that use of the new product would result in new or different environmental impacts. FDA believes that the disposal of the new product is the same as the disposal conditions of other HTPs that are currently marketed in the United States. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed action from manufacturing, use, and disposal of the new product.

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