



MEMORANDUM

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Subject: Finding that the environmental assessment and its discussion to support a finding of no significant impact (FONSI) for the product authorized under PM0000013 are relevant to the proposed market authorization for the same product, General Classic Blend Portion White Large 12 CT (SE0010528)

Background

Upon consultation with the Office of Chief Counsel, CTP believes that the environmental assessment (EA) and its decision, a finding of no significant impact (FONSI), for PM0000013 are relevant to the proposed market authorization submitted to the FDA by Swedish Match North America (SMNA) for the same product (SE0010528). The Agency's decision on SMNA's SE report does not have the potential to change SMNA's ability to market this product, and the EA and FONSI in the PMTA record already address the potential environmental impacts of marketing this product.

Although under 21 CFR 25.20(o) the issuance of an SE order normally requires at least the preparation of an EA, SMNA's SE Report is an exceptional case due to the fact that this product already has a marketing authorization in place through the PMTA pathway. Section 102(2)(C) of NEPA requires an environmental statement for every proposal for legislation or other major federal action significantly affecting the quality of the human environment. As defined by CEQ's regulations, "major federal actions" are those with effects that may be major and which are potentially subject to federal control and responsibility" [40 CFR 1508.18]. "Effects," in turn, are defined by CEQ's regulations to include both direct and indirect effects caused by the agency action [40 CFR 1508.08].

Because SMNA's product is already authorized to be marketed under a PMTA marketing order, any subsequent decision by FDA on this SE report—whether an SE

finding, an NSE finding, or no action—for the same product will not change the manufacturer’s (SMNA) existing ability to market this product. Therefore, the Agency’s action is not capable of “causing” any direct or indirect effects such that the SE decision would constitute a “major federal action” per CEQ’s interpretation of section 102(2)(C) of NEPA, and an EA need not be prepared for this action. The potential environmental effects for this product were analyzed during the first marketing authorization under the PMTA pathway. Accordingly, interested persons should be advised to review the EA and FONSI for this product’s PMTA decision.

Conclusion

The EA and its discussion to support a FONSI for the product authorized under PM0000013 are relevant to the proposed market authorization for the same product, General Classic Blend Portion White Large 12 CT (SE0010528). Therefore, we have determined that it is appropriate not to prepare an EA and FONSI for SE0010528, and to direct interested persons to the EA and FONSI for the market authorization for the premarket tobacco application for PM0000013.