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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: File

From: Matthew R. Holman, Ph.D.
Director, Office of Science, CTP
Digitally signed by Matthew R. Holman -S
Date: 2020.07.16 07:48:29 -04'00'

Through: Cristi L. Stark, M.S.
Director, Division of Regulatory Project Management
Office of Science, CTP
Cristi L. Stark -S
2020.07.16 11:52:10 -04'00'

Subject: Environmental Assessment Criteria to Support Refuse to Accept or Refuse to File Actions on Premarket Applications

Background

Effective October 26, 2015, FDA issued the National Environmental Policy Act (NEPA); Environmental Assessments for Tobacco Products; Categorical Exclusions final rule. This rule revised implementation of NEPA regulations to (1) allow certain tobacco product marketing applications to be excluded from the requirements to prepare an Environmental Assessment (EA)[1], and (2) to require FDA to assess the environmental impacts of any proposed Federal action.

Furthermore, FDA has been granted authority to base Refuse to Accept (RTA) or Refuse to File (RTF) decisions on EA-related deficiencies under NEPA regulations, the RTA Rule, and the Exemption Request Rule[2]. In general, these rules support refusal actions based on the failure to provide an adequate EA.

For incoming premarket applications, FDA will evaluate all of the following items in an EA:

- Brief discussion of the need for the proposal (i.e., the intended marketing order)
- Brief discussion of alternatives to the proposal
- Environmental impacts of the proposed action and alternatives
- Listing of the agencies and persons consulted
- Relevant environmental issues relating to the use of the product
- Relevant environmental issues relating to the disposal from use of the product[3]

Discussion

FDA's NEPA regulations support RTA actions on premarket applications based on lack of an EA when categorical exclusions do not apply. Additionally, FDA's NEPA regulations support RTA actions for Exemption Requests and SE Reports and RTF actions on premarket applications based on an inadequate EA. Therefore, there is support for an RTA or RTF due to missing information that is "environmental" in nature, or is not readily available to FDA, or obtaining it would result in a delay. The following information is necessary for an adequate EA:

[1] No categorical exclusions apply to new premarket applications. Categorical exclusions exist only for negative actions (i.e., denial, rescission, or temporary suspension), or for authorizations of provisional SE Reports.
[2] NEPA regulations (21 CFR 25.15(a)); RTA Rule (21 CFR 1105.10(a)(10)); and Exemption Request Rule (21 CFR 1107.1(b)(9))
[3] For the PMTA and MRTPA pathways, the items would form the basis for an RTF decision. Because SE and EX do not include a filing stage, the items would form the basis for an RTA decision in those pathways. *See* RTA Rule, 81 FR 52375.

- Environmental impacts of the proposed action
- Environmental impacts related to the use of the product
- Environmental impacts related to disposal from use of the product

FDA's NEPA regulations do not support RTA or RTF actions for the absence of the following environmental impact criteria due to the environmental impact of authorizing a product that meets the statutory standard is always the same, or because on face value they may appear as environmental issues they are not:

- Alternatives to the proposed action
- Environmental impacts of alternatives
- Brief discussion of the need for the proposal
- Listing of agencies and persons consulted

Pursuing RTA or RTF on these four issues may require interpreting our regulations to require recitation of this information, which could be challenged as arbitrary.

Conclusion

For premarket applications within the EX/SE pathway, FDA will issue an RTA letter on the basis that either an EA was inadequate or lack of an EA where a categorical exclusion does not apply.

For premarket applications within the PMTA pathway, FDA will issue an RTA letter for lack of an EA and an RTF letter on the basis of an inadequate EA.