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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To:	File
From:	Anne Radway, MS Associate Director Division of Regulatory Project Management Office of Science Anne M. Radway -S Digitally signed by Anne M. Radway -S Date: 2021.05.27 08:04:09 -04'00'
Through:	Benjamin J. Apelberg, PhD Deputy Director Office of Science Digitally signed by Benjamin Apelberg -S Date: 2021.05.27 08:39:08 -04'00'
Subject:	Addendum to Environmental Assessment Criteria to Support Refuse to Accept or Refuse to File actions on Premarket Applications

Background

On July 16, 2020, FDA signed the Environmental Assessment Criteria to Support Refuse to Accept or Refuse to File Actions on Premarket Applications memo, which outlined FDA's basis to support Refuse to Accept (RTA) or Refuse to File (RTF) actions on premarket applications within the Substantial Equivalence (SE) Report, Exemption from Substantial Equivalence (EX REQ) Request and Premarket Tobacco Application (PMTA) pathways. This memo seeks to apply the basis to support RTF or RTA identified for PMTAs to modified risk tobacco applications (MRTPAs).

Discussion

Although mentioned in the July 16, 2020 memo, MRTPAs were not specifically included in the conclusion section, however, these applications are also subject to NEPA regulations and RTA Rule.

Conclusion

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