

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.04.16 13:07:15 -04'00'

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CDR, US Public Health Service
Deputy Director
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Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2020.04.16 13:47:27 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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FDA, a report under section 905(j)(1)(A)(ii) (an Abbreviated Report) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Report.

For EX0000997, EX0000998, and EX0001000 – EX0001003, FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An Exempt order should be issued for the new tobacco products in EX0000997, EX0000998, and EX0001000 – EX0001003, as identified on the cover page of this review.

For EX0000999, FDA has examined the environmental effects of finding this new tobacco product exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an Exempt order.

An Environmental Information Request letter should be issued requesting the following information:

1. EX0000999 indicates that the original tobacco product will not continue to be marketed upon receiving a marketing order for the new tobacco product. However, your EX Request includes conflicting statements regarding current marketing status for the original tobacco product. On page 16 of the EX Request, you state that the original tobacco product “is currently on the market but will be replaced in the marketplace by the new product.” On page 20 of the EX Request, you state that the “new product will replace the already discontinued [original] product.” Clarify if the original tobacco product is currently marketed. If so, provide current market volume for the original tobacco product. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. Table 1 can be used to present this information.

Original Tobacco Product	Current Market Volume (Number of Cigarettes)
Maverick Gold Box	

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco product in EX0000999, as identified on the cover page of this review.