

Environmental Review of an SE Report Submitted by Philip Morris USA, Inc. for a Combusted Filtered Cigarette

SE0013711: Marlboro Box	
Applicant	Philip Morris USA, Inc.
Status	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Conclusion	
This review includes comments to convey to the applicant in Section 3.3	

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Concur Non-concur (see separate memo)

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1. BACKGROUND

1.1. REGULATORY ACTIVITY RELATED TO THIS ENVIRONMENTAL REVIEW

Altria Client Services, LLC on behalf of Philip Morris USA, Inc. submitted one substantial equivalence (SE) report seeking a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), on 09/23/2016. The applicant submitted an environmental assessment (EA) as part of the SE Report.

1.2. THE NEW AND PREDICATE PRODUCTS INFORMATION

The new and predicate products are combusted filtered cigarettes. The predicate product is a grandfathered product and the applicant stated the new product will replace the predicate product if the new product receives a marketing order.

The applicant submitted the following information for the new and predicate products:

STN	Pack Size (cigarettes/pack)		New Product	Predicate Product	Grandfathered Product	Amendments
	New	Predicate				
SE0013711	20	20	Marlboro Box	Marlboro Box (2007)	GF1200090	SE0014422, SE0014432, SE0014230

1.3. BASIS FOR SUBSTANTIAL EQUIVALENCE CLAIM

The applicant claimed that the new and predicate products have the same characteristics (sec. 910(a)(3)(A)(i)).

1.4. SCOPE OF THIS REVIEW

This environmental review identifies information lacking in the SE Report and the applicant-submitted (EA). This information is needed to evaluate the environmental effects of the proposed marketing orders, as required by the National Environmental Policy Act (NEPA).

2. EVALUATION OF SUBMISSION

2.1. CHANGES BETWEEN NEW AND PREDICATE PRODUCTS

In the SE Report, the applicant stated that the differences between the new and predicate product are in the cigarette paper weight, tobacco blend, and minor ingredient changes. There are no other differences in the characteristics of the new and predicate products.

2.2. PRODUCT DESIGN

The applicant provided information about the new and predicate products' design features. The applicant claimed that the design features for the new product differ from those of the predicate product only in the ventilation.

2.3. PRODUCT COMPOSITION

The applicant stated there is a difference in tobacco weight between the new product and the predicate product. The applicant provided information for individual packaging materials for the new product only; no packaging information for the predicate product was provided. In addition, the applicant did not provide packaging composition and corresponding packaging component weights for the new product shipping materials, if applicable.

New Product Packaging Information					
STN	Empty Pack (grams)	Inner Foil (grams)	Pack Inner Frame (grams)	Outer Polypropylene Film (grams)	Tear Tape (grams)
SE0013711	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

2.4. MANUFACTURING INFORMATION

The manufacturing address for the new product is Philip Morris USA Manufacturing Center, FEI – 3008255477, 3601 Commerce Road, Richmond, Virginia 23234.

The applicant did not state if the new product differs in the levels of substances entering the environment due to manufacturing or whether it results in new emissions, as compared to manufacturing the predicate product.

Additionally, the applicant did not state whether manufacturing the new product would generate different solid or liquid waste. The applicant did not address the environmental effects of potential facility expansion a, as well as whether new or additional environmental controls would be used.

2.5. USE INFORMATION

The applicant did not state if the combustion products from the new product are released in the same manner or differently as the combustion products from the predicate product and other conventional cigarettes currently marketed. The applicant did not state if new compounds are anticipated to be emitted due to the use of the new product. Furthermore, the applicant did not state if the new product has the potential to yield an increase in emissions compared with the predicate product or similar products marketed in the United States.

2.6. DISPOSAL INFORMATION

The applicant did not fully address the environmental impact from disposal of the product, including the cigarette butt, product packaging and shipping packaging wastes.

2.7. MARKET PROJECTIONS

The applicant stated the new product will replace the predicate product if the new product receives a marketing order. It is not clear if the predicate product is currently marketed; the current market volume was not included if the predicate product is currently marketed. The applicant provided the first- and fifth-year market projections for the new product.

New Product Market Share Information		
STN	First-Year Predicate	Fifth-Year Predicate
SE0013711	(b) (4)	

2.8. COMPLIANCE WITH RELEVANT ENVIRONMENTAL REGULATIONS

The applicant stated that they submit a yearly Title V air permit for emissions control to the Virginia Department of Environmental Quality and the United States Environmental Protection Agency. The applicant did not address whether or not the manufacturing facility is in compliance with solid, liquid, and hazardous waste environmental regulations.

2.9. ENVIRONMENTAL SUSTAINABILITY

The applicant did not discuss whether ingredients and packaging materials for the new product are produced from renewable and sustainable resources, or whether manufacturing the new product aligns with controls and standards addressed under the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

3. OVERALL CONCLUSION

3.1. CONCLUSION

Eleven issues were identified pertaining to the environmental review of the SE Report and the applicant-submitted EA in section 3.2. Eleven comments to convey to the applicant are identified in section 3.3.

3.2. ISSUES IDENTIFIED

The SE Report and submitted EA do not provide enough information for an EA as required by 21 CFR 25.40. The following issues were noted:

1. The applicant did not state if the predicate product is currently marketed.
2. The applicant did not provide the current-market projection for the predicate product if it is currently on the market.
3. The applicant did not fully address the environmental effects of manufacturing the new product.
4. The applicant did not address if the manufacturing facility was in compliance with all relevant federal, state, and local environmental regulations.

5. The applicant did not provide information as to whether the raw materials used to manufacture the new product are from renewable and sustainable resources that would not impact critical habitats or endangered species.
6. The applicant did not fully discuss the environmental consequences of use of the new product, specifically addressing differences in combustion products, new compounds emitted, and the potential to yield increased emissions.
7. The applicant did not fully address the environmental impacts associated with disposal of the new product.
8. There was no discussion or supporting evidence that the applicant is in compliance with ESA and CITES.
9. The applicant did not provide the individual packaging information for the predicate product, if currently on the market.
10. The applicant did not provide shipping packaging (if applicable) information about the number of cigarette packs per retail box, the number of retail boxes per shipping case, the weights of the packaging (retail box and shipping case), and the material types (composition) for the new product.
11. The applicant did not provide cigarette filter weight for the new product, and for the predicate product, if currently marketed.

3.3. COMMENTS TO CONVEY TO APPLICANT

1. Your SE Report is unclear as to the current status of the predicate product. The status of the predicate product is used to fully assess the environmental impacts of the proposed action of issuing marketing orders for the new product. Clarify if the predicate product is currently marketed in the United States.
2. Your SE Report lacks information on the environmental effects from manufacturing the new and predicate products. This information is used to assess the environmental impact of marketing the new product. Address the following issues concerning the potential effects of manufacturing:
 - a. Provide the address for the manufacturer of the predicate product if it is currently marketed.
 - b. Will there be increased manufacturing due to the new product? If so, will that require additional resources for handling manufacturing waste disposal, such as increases in onsite solid or hazardous waste accumulation capacity, new or expanded landfills, increases in other types of waste disposal, or increase in waste volumes? If so, describe the environmental effects of these increased resources.
 - c. Will manufacturing the new product result in an expansion of the manufacturing facility? If so, identify and evaluate any potential environmental impacts due to the expansion. If not, provide a statement that there will not be an expansion of the manufacturing facility.
 - d. Will there be new compounds emitted or an increase in compounds emitted from manufacturing the new product compared to the current compounds emitted from the facility? If so, list the compounds and describe the

- environmental effects of those new compounds being emitted. If not, provide a statement that there will be no new or increase in compounds emitted from manufacturing the new product.
- e. Will manufacturing the new product lead to changes in air emissions or wastewater discharges from increased manufacturing? Will a revised or new air emissions or wastewater discharge permit be required?
 - f. Will manufacturing the new product require any additional environmental controls? If yes, what are these controls and describe the environmental effects of these controls? If not, provide a statement that the manufacturing of the new product will not require any additional environmental controls.
3. Your SE Report lacks a relevant discussion of the environmental effects of disposal of the new product. This information is used to assess the environmental impact of marketing the new product. To address the potential effects of disposal, provide answers to the following questions:
- a. Will disposal of the new product require additional resources (e.g., new landfills, recycling centers) for waste disposal? If so, describe the environmental effects of these increased resources. If not, provide a statement that there will not be increased resources needed.
 - b. When the new product is disposed of, will any compounds that are emitted from the new product be (i) different from compounds emitted by the predicate product or (ii) increased over what would be emitted from the predicate product or similar products marketed in the United States?
4. Your SE Report lacks information on the manufacturing facility and compliance with all relevant federal, state, and local environmental regulations including the Clean Water Act and the Resource Conservation and Recovery Act. If applicable, provide a statement, and support for the statement, that you comply with these and any other relevant solid, liquid, and hazardous waste regulations. Otherwise, discuss potential violations of any federal, state and local environmental regulations and your mitigation to comply with the regulations.
5. Your SE Report lacks evidence that you are compliant with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). All federal actions are required to comply with ESA or CITES, therefore FDA evaluates the potential for violations of ESA and CITES due to its proposed product authorization actions. To assess if any adverse effects are anticipated from the proposed action, address the following:
- a. Is any critical habitat affected from materials or ingredients used to manufacture the new product, or from the production of the new product?
 - b. Discuss any adverse effects, if applicable, on any endangered species or the critical habitat of the species identified under ESA and CITES due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product. If there are no anticipated adverse effects, provide support for this statement.

6. Your SE Report lacks information on how manufacturing the new product affects environmental sustainability. Provide supporting information relative to sources of the raw materials and energy used to manufacture the new product; indicate whether these sources are renewable and the manufacturing practices are sustainable.
7. Your SE Report lacks detailed information on environmental consequences of use of the new product. Specifically, information addressing differences in emissions of any new combustion products and the potential to yield an increase in emissions compared to the predicate product or similar products marketed in the United States. Provide a statement whether the combustion products from the new product are released in the same manner or a different manner as combustion products from the predicate product and other conventional cigarettes currently marketed. Also, provide a statement whether new compounds are anticipated to be emitted due to the use of the new product. This information allows for an accurate assessment of environmental consequences of use of the new product.
8. Your SE Report lacks the current-year market projection for the predicate product, if the predicate product is currently marketed. This information allows for an accurate assessment of the solid waste generated from use of the product. Provide the current-market projection for the predicate product in Table 1. Place an NA if the predicate product is not currently marketed.

Table 1: Market Share Information for the Predicate Product	
STN	Current-Year
SE0013711	

9. Your SE Report lacks detailed information about how the predicate product is packaged. This information allows for an accurate assessment of the solid waste generated from end use of the product. In Table 2, provide the average weights (in grams) of the empty packaging material for the predicate product. If there are additional components to the packaging, add those components and weights to the table. Place an NA in the cells if the predicate product is not currently marketed.

Table 2: Packaging Information for the Predicate Product					
STN	Empty Pack (grams)	Inner Foil (grams)	Pack Inner Frame (grams)	Outer Polypropylene Film (grams)	Tear Tape (grams)
SE0013711 Predicate					

10. Your SE Report lacks detailed information about how the new and predicate products are packaged for shipping. Packaging materials include the retail boxes and shipping cases (if applicable). This information allows for an accurate assessment of the solid waste generated from use of the products. In Table 3, provide information on how the new and predicate products are packaged. This includes the number of cigarette packs contained per retail box and the number of retail boxes per shipping case for the new and predicate products. Provide the average weights (in grams) and material types (composition) of the empty packaging material for the new and predicate products. Place an NA in the cells if the predicate product is not currently marketed; place an NA in any cells if that packaging item does not exist for the new or predicate products.

Table 3: Packaging Information for New and Predicate Products - SE0013711						
Product	Number of Packs per Retail Box	Weight of Retail Box (grams)	Material Type of Retail Box	Number of Retail Boxes per Shipping Case	Weight of Shipping Case (grams)	Material Type of Shipping Case
New						
Predicate						

11. Your SE Report lacks cigarette filter weights for both the new and predicate products. This information allows for an accurate assessment of the solid waste generated from use of the products. In Table 4, provide cigarette filter weights for both the new and predicate products. Place an NA in the cell if the predicate product is not currently marketed.

Table 4: Cigarette Butt Information for New and Predicate Products – SE0013711	
Product	Cigarette Butt Weight (grams)
New	
Predicate	