

Technical Project Lead (TPL) Review: SE0015566

SE0015566: Grizzly Premium Wintergreen Long Cut	
Package Type	Plastic Can and Lid
Package Quantity	7.2 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Wintergreen ²
Attributes of SE Report	
Applicant	American Snuff Company, LLC
Report Type	Product Quantity Change Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue a Substantially Equivalent (SE) order.	

¹ Cuts per inch

² As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2020.02.05 14:29:40 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of Science

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: 2020.02.05 14:34:48 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND 4

 1.1. PREDICATE TOBACCO PRODUCT 4

 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 4

 1.3. SCOPE OF REVIEW 4

2. REGULATORY REVIEW 4

3. COMPLIANCE REVIEW 4

4. SCIENTIFIC REVIEW 5

5. ENVIRONMENTAL DECISION..... 5

6. CONCLUSION AND RECOMMENDATION 5

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015566: Grizzly Premium Wintergreen Long Cut	
Product Name	Grizzly Long Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	1.2 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Wintergreen ²

The predicate tobacco product is loose moist snuff smokeless tobacco manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 12, 2019, FDA received a Product Quantity Change SE Report from RAI Services Company on behalf of American Snuff Company, LLC. FDA issued an Acceptance letter to the applicant on November 19, 2019. On November 26, 2019, the Office of Compliance and Enforcement (OCE) contacted the applicant to request a numerical value for tobacco cut size for the predicate tobacco product since the applicant only provided a descriptor (i.e., long cut). In response, FDA received amendment SE0015580 on December 2, 2019.

Product Name	SE Report	Amendments
Grizzly Premium Wintergreen Long Cut	SE0015566	SE0015580

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Sarah Amyot on November 19, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

OCE completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated December 16, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated February 5, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and predicate tobacco products are identical except for a change in product quantity. OS prepared a memorandum³ summarizing its current thinking on product quantity changes. With respect to product quantity increases, the currently available scientific evidence examines the effects of product quantity in other consumer products on consumer behavior and perception but is not specific to tobacco products generally or the specific category of tobacco product under review. This evidence suggests that changes in product quantity of consumer products may influence consumer behavior but was not specific enough for OS to determine if such changes always lead to changes in behavior, and, if not, under what condition it would; what threshold (if any) would trigger a change in consumer behavior; what tobacco products would be affected by a quantity change and which would not; and how findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, from a social science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on December 20, 2019.

The environmental review found that the applicant provided contradictory market volume information for the new tobacco product and did not provide the first- and fifth-year projected market volumes of the predicate tobacco product, which is used to quantitatively assess the environmental impact of concurrent manufacturing, use, and disposal of the new and predicate tobacco products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The tobacco product characteristics of the new and predicate tobacco products are identical except for an increase in product quantity from 1.2 ounces to 7.2 ounces (500%).

The OS memorandum³ concludes that based on OS' experience and the currently available evidence, the increase in product quantity in SE0015566 does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

³ See memorandum on product quantity changes, dated December 7, 2017.

The predicate tobacco product in SE0015566 meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act.

FDA examined the environmental effects of finding the new tobacco product substantially equivalent and found that additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

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

1. Your SE Report lacks market volume information for the predicate tobacco product and the market volume you provided for the new tobacco product was contradictory. Specifically, the number of cans increased over time, but the corresponding pounds did not increase proportionately with the number of cans. Marketing information is used to assess the environmental impact of manufacturing, use, and disposal of the new and predicate tobacco products. Provide the current market volume for the predicate tobacco product and the first- and fifth-year market volume projections for the new and predicate tobacco products. Table 1 may be used to provide this information, or you can submit this information using an alternative approach if it provides the current, first- and fifth-year market volume projections.

Table 1. New and Predicate Tobacco Product Market Volumes				
STN	Unit	Current Year	First Year	Fifth Year
SE0015566	Cans			
	Pounds			
Predicate for SE0015566	Cans			
	Pounds			

If the applicant adequately responds to the request and an EIS or FONSI is completed, an SE order letter should be issued for the new tobacco product in SE0015566, as identified on the cover page of this review.