FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015707

SE0015707: Grizzly Premium Natural Fine Cut	
Package Type	Plastic Can with Metal Lid
Package Quantity	7.2 ounces
Tobacco Cut Size	(b) (4) CPI[1]
Characterizing Flavor	None[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. The applicant indicates that two cutters are used: (b) (4) CPI and (b) (4) CPI.

[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: 2020.05.04 11:56:40 -04'00'

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: 2020.05.04 12:04:35 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015707: Grizzly Premium Natural Fine Cut	
Product Name	Grizzly Premium Natural Fine Cut
Package Type	Plastic Can with Metal Lid
Package Quantity	1.2 ounces
Tobacco Cut Size	(b) (4) CPI[1]
Characterizing Flavor	None[2]

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 10, 2020, FDA received one Product Quantity Change SE Report (SE0015707) from RAI Services Company on behalf of American Snuff Company, LLC. On February 13, 2020, FDA issued an Acceptance letter to the applicant.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Nikole Ayala-Agosto on February 13, 2020, and April 22, 2020.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015707 was determined to be substantially equivalent by FDA under SE0015250. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 April 9, 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 memorandum[3] 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 William Brenner on March 19, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 21, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 20, 2020.

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 memorandum[3] concludes that based on OS' experience and the currently available evidence, the increase in product quantity in SE0015707 does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0015250.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015707 was previously determined to be substantially equivalent by FDA under SE0015250. Comparison of the new tobacco product to the grandfathered tobacco product (Grizzly Premium Natural Fine Cut [GF1200414]) reveals that the new tobacco

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

product has the following differences in characteristics from Grizzly Premium Natural Fine Cut, the grandfathered tobacco product:

- 500% increase in product quantity (1.2 ounces to 7.2 ounces)
- Change in container closure system (replacement of plastic lid with metal lid)
- Increase in free nicotine
- Increase in small cut size tobacco particles in the tobacco blend
- 45-55% decrease in N'-nitrosonornicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and total tobacco-specific nitrosamines (TSNAs) over 6 months of product storage (i.e., shelf life)

The differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0015250. A change in free nicotine values suggests that the nicotine release rates may differ between the new and grandfathered tobacco products. In addition, there is an increase in small cut size tobacco particles in the tobacco blend in the new tobacco product. A smaller tobacco particle size has a greater surface area, which may result in an increase in the release rate of nicotine. Changes in the nicotine release rate may result in changes in user behavior. However, the increase in small cut size tobacco particles in the tobacco blend and free nicotine do not cause the new tobacco product to raise different questions of public health because a nicotine dissolution study indicated that the dissolution profiles of the predicate and grandfathered tobacco products are equivalent, and the new tobacco product differs from the predicate tobacco product only in product quantity. Therefore, the differences in the tobacco cut size and free nicotine do not cause the new tobacco product to raise different questions of public health. The change in container closure system could potentially affect the moisture content of the product, which, in turn, could impact microbial growth and product stability. However, the change in container closure system does not cause the new tobacco product to raise different questions of public health because the quantities of several carcinogens (NNN, NNK, and total TSNAs) decrease compared to the grandfathered tobacco product. Therefore, these differences do not cause the new tobacco product in SE0015707 to raise different questions of public health. Additionally, for the same reasons as discussed above, the difference in product quantity between the new tobacco product in SE0015707 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015707 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

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 made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015707, as identified on the cover page of this review.