



Technical Project Lead (TPL) Review: Exemption Request EX0000026

New Tobacco Product	
Product Name	Grizzly Long Cut Mint
Package Quantity	1.2 oz.
Package Type	Can
Applicant	American Snuff Company, LLC
Tobacco Particle Size	Long cut ¹
Characterizing Flavor	Mint
Additional Properties	(b) (4) water; (b)(4)/sodium chloride
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Modification	(b)(4) in sodium chloride and (b)(4) in water
Recommendation	
Issue an Exempt order letter	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.04.09 07:06:34 -04'00'

Matthew R. Holman, Ph.D.
Director
Division of Product 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 David Ashley -S
Date: 2015.04.09 07:33:45 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

¹ As provided by applicant. For purposes of an Exemption Request, a numerical value is not necessary as the tobacco itself cannot be modified since the exemption is limited to additives.

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

Manufacturer	American Snuff Company, LLC
Product Name	Grizzly Long Cut Mint
Package Quantity	1.2 oz.
Package Type	Can
Tobacco Particle Size	Long cut ¹
Characterizing Flavor	Mint
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Claimed Status	Grandfathered product

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Request EX0000026 on June 27, 2012. FDA sent the applicant an acknowledgement letter for this Exemption Request on December 7, 2012. The initial Exemption Request did not uniquely identify the new tobacco product nor the original tobacco product being modified. The unique identification of the original and new tobacco products should be identical or the new tobacco product is not eligible for the Exemption Request pathway. However, the Exemption Requests and subsequent amendments differed as to the identification of the new product and were likewise unclear as to the original tobacco product being modified in the Exemption Request. As such, until December 4, 2014, FDA was unclear what product was submitted for review under EX0000026. FDA communicated with the applicant on the following dates to request information needed to fully identify the new and original tobacco products, including the product name:

- December 20, 2012: FDA requested information (including the name on all materials) to determine if the original tobacco product was commercially marketed in the United States as of February 15, 2007
- December 22, 2012: FDA received an email from the applicant that conveyed that there was a difference in the unique identification between of the original and new tobacco products.²
- July 26, 2013: FDA requested identification for both the original and new tobacco products by brand, sub-brand, size, quantity, and packaging in a formal submission to FDA's Document Control Center (DCC)³. In

² The original tobacco product was noted as "Grizzly Long Cut Mint," while the new tobacco product was noted with an intent to market as "Grizzly (b) (4) Long Cut Mint."

³ Emails do not count as regulatory correspondence, and a formal submission must be received through the DCC to be reviewed as part of the application.

response to the July 26, 2013 request, on August 1, 2013, FDA received an amendment EX0000053 (dated July 31, 2013) which clarified both the original and new products by brand, sub-brand, size, quantity, and packaging⁴.

- September 16, 2013: In a teleconference, FDA inquired about the inconsistent use of nomenclature in the July 31, 2013, amendment that described the new tobacco product when compared to the name stated in the original submission in EX0000026 (The Exemption Request for EX0000026 stated that the name of the new product was “Grizzly Long Cut Mint” while the August 2013 amendment stated it was “Grizzly (b) (4) Mint Long Cut”). During this communication, FDA asked if the company intended that the July 31, 2013, amendment serve to modify the new tobacco product name from that which was stated in the original submission, and as such, would be different from the name of the original tobacco product⁵.
- November 13, 2013: In a teleconference, FDA inquired again about the July 31, 2013, amendment and referenced the September 16, 2013, teleconference. The applicant noted that the use of (b) (4) may appear on the product packaging but is not part of the tobacco product name and considered the name of the new tobacco product to be “Grizzly Long Cut Mint”⁶.
- December 12, 2013: Because the previous teleconference did not resolve the outstanding issues regarding product identification, FDA held another teleconference with the applicant to inquire again about the identification of the new tobacco product and referenced the November 13, 2013, teleconference. During the teleconference, FDA requested that the applicant submit an amendment to clarify the discrepancies around the product identification.
 - In response to the November and December teleconferences, on December 20, 2013, FDA received an amendment EX0000088 (dated December 19, 2013) from the applicant to clarify the product name. Within this amendment, the applicant referred to the new tobacco product as “Grizzly Mint”⁷ and noted that there are no descriptors associated with the new tobacco product. However, the amendment did not uniquely identify the new tobacco product (e.g., missing size, quantity, packaging).

⁴ The new tobacco product was noted as: Brand: Grizzly, Sub-brand: Grizzly (b) (4) Long Cut Mint, Category: Smokeless, Subcategory: Moist Snuff, Size: Non-portioned product, Quantity: 1.2 oz (net weight per package), Packaging: Can

⁵ A product that contained a change in tobacco product name as compared to the original tobacco product would not be eligible for the Exemption Request pathway.

⁶ However, this statement by the company does not match the August 1, 2013, amendment, as the amendment noted the inclusion of the term (b) (4) under the subcategory and does not include the term (b) (4) in any other field.

⁷ The name/identification of the new tobacco product in this amendment does not match any of the prior submissions to FDA.

- In response to the discrepancies in product naming on January 24, 2014, FDA received a meeting request (dated January 23, 2014) to discuss issues around the review of EX0000026 and related submissions.
- January 30, 2014: FDA confirmed receipt of the January 23, 2014, meeting request (and other similar requests) and requested that a single meeting be held to handle all outstanding requests/issues; the applicant agreed.
- January 31, 2014: FDA received an amendment EX0000090 (dated January 30, 2014) containing an email to the Office of Compliance and Enforcement dated January 24, 2014, that noted EX0000026 was for a new tobacco product named “Grizzly Mint” and identified a pending provisional SE Report as well as a GF submission for the original tobacco product in EX0000026. The amendment did not clarify if one of these was the original tobacco product being modified on its own, or if both of these were intended to be used as the original tobacco product being modified.⁸
- April 2, 2014: FDA and the applicant met and discussed the naming convention issues with respect to EX0000026 and other tobacco products as well as the Exemption Request process in general.
- November 20, 2014: FDA issued a letter to the applicant in response to correspondence received on August 22, 2014 (dated August 22, 2014) and October 20, 2014 (dated October 17, 2014). The letter from FDA requested clarification on (1) unique identification of the original tobacco product being modified, (2) unique identification of the new tobacco product, and (3) if the applicant would like to withdraw the Exemption Request
 - In response to the November 20, 2014 letter, on December 4, 2014, FDA received an amendment EX0000104 (dated December 4, 2014) in response to the November 20, 2014, letter. The amendment noted the new tobacco product as Grizzly Long Cut Mint, 1.2 oz can and that it was a modification to an original tobacco product found grandfathered under GF1200410 named Grizzly Long Cut Mint. The unique identification for both the original and new tobacco products was the same.

As part of the unique identification for a smokeless tobacco product, the following properties are required: manufacturer, product name, package quantity, package type, tobacco particle size, characterizing flavor, product category, product sub-category, and any additional items that would be applicable (e.g., descriptors). For all items except tobacco particle size, the applicant clearly labeled each property. For the tobacco particle size, a call was made on February 11, 2015, to the applicant to confirm that the tobacco particle size was captured within the name and should be noted as “Long Cut.” The applicant confirmed the tobacco particle size should be labeled as “Long Cut” for this request. It is noted that the

⁸ Additionally, on May 7, 2014, the applicant requested withdrawal of the pending provisional SE Report mentioned in the amendment.

tobacco particle size for any smokeless tobacco product should be captured by a numerical value. FDA needs to assess tobacco particle size of new smokeless tobacco products because changes to particle size cause changes to the relative amount of surface area of the product that is exposed. Accordingly, changes to the surface area of the particles influence the diffusion and release of nicotine and other harmful and potentially harmful constituents (HPHCs) from the product. However, for purposes of review under an Exemption Request, the pathway is only limited to modifications to tobacco additives⁹. As such it is not necessary to require a numerical value for scientific review as there would be no change to the tobacco particle size. If this smokeless tobacco product was reviewed under a substantial equivalence report¹⁰ or premarket tobacco application¹¹, the use of the term “long cut” would not be acceptable and a numerical value would be required.

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modification compared to the original tobacco product:

Substitution of (b) (4) water ((b)(4) from (b) (4) with (b) (4) sodium chloride ((b)(4) from (b) (4))

2. ADMINISTRATIVE REVIEW

A jurisdiction review was completed by Rosanna Beltre, M.P.H., C.P.H. on December 7, 2012. An acceptance review was not conducted as this was one of the first Exemption Requests received and the process was not formalized to require an acceptance review that included administrative completeness. It is noted that the application was accepted, nonetheless, with the issuance of the acknowledgement letter. As there were many questions around the unique identification of the original and new tobacco products, the review of the application progressed only after communications with the applicant revealed that the new and original tobacco products were the same. Additionally, only after the original product was found to be grandfathered, scientific review commenced to determine if the modifications were minor.

⁹ A change in the tobacco blend, amount, or particle size would not be eligible under this pathway.

¹⁰ The tobacco particle size is a characteristic captured within the design and must be compared to the tobacco particle size of the predicate tobacco product to see if there is a difference and if so, if the difference would cause the new product to raise different questions of public health.

¹¹ The tobacco particle size is a design parameter that contributes to the decision that the new smokeless product would or would not be appropriate for the protection of public health.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated February 7, 2013, concluded that the original tobacco product is an eligible original tobacco product, as the applicant has established that the tobacco product is grandfathered.

4. SCIENTIFIC REVIEW

A scientific review was completed by Changyu (Jake) Chae on March 27, 2015. The review concludes that the modification is a minor modification of tobacco additives in accordance with section 905(j)(3)(a)(i) of the FD&C Act. The review indicates that water and sodium chloride are both tobacco additives. Furthermore, the changes to the ingredient quantities are small when considering the total amounts of these two ingredients. The modification is not expected to impact the mint characterizing flavor.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 8, 2015. The FONSI was supported by an environmental assessment prepared by FDA on April 8, 2015.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modification compared to the original tobacco product:

Substitution of (b) (4) water ((b)(4) from (b) (4)) with (b) (4) sodium chloride ((b)(4) from (b) (4))

I concur with the conclusion of the chemistry review that this modification is a minor modification of tobacco additives in accordance with section 905(j)(3)(a)(i) of the FD&C Act. In addition, consistent with section 905(j)(3)(a)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco product to be marketed would be appropriate for protection of the public health. Although the modification results in different characteristics for the original and new tobacco products, the changes to water and sodium chloride quantities are insignificant and do not require data to determine whether they impact public health. There are no toxicological concerns with such small quantities of these ingredient (i.e., (b)(4) change in quantities). Likewise, there are no concerns about the impact of such a minor modification on initiation, cessation, or consumer behavior. Lastly, nothing contained in the Exemption Request nor from CTP's scientific understanding suggests that an exemption for this modification is not otherwise appropriate as

required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

FDA has examined the environmental effects of finding this new tobacco product exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco product in EX0000026 as identified on the cover page of this review.