FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0000225

SE0000225	
Product Name	Gambler Turkish Style 0.65 oz Pouch
Package Type	Pouch
Package Quantity	0.65 oz
Tobacco Cut Size	(b)(4) cpi
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Top Tobacco, LP
Report Type	Provisional
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Roll-Your-Own Tobacco Filler (as part of Roll Your Own tobacco co-package)
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Todd L. Cecil -S
Digitally signed by Todd L. Cecil -S
Date: 2018.09.18 09:11:02 -04'00'

Todd L. Cecil, Ph.D.
Associate 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 Matthew R. Holman -S
Date: 2018.09.18 09:58:06 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0000225: Gambler Turkish Style 0.65 oz Pouch	
Product Name	TOP REG. POUCH
Package Type	Pouch
Package Quantity	0.60 oz
Tobacco Cut Size	(b)(4) cpi
Characterizing Flavor	None
Additional Properties	Regular

The predicate tobacco product is a roll-your-own (RYO) tobacco filler (as part of RYO co-package) manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 16, 2011, Top Tobacco LP submitted an SE Report for a RYO tobacco filler/rolling paper co-package (initially designated as SE0000225). Because the RYO tobacco filler and rolling papers are each a new tobacco product and the co-packaging does not result in a new tobacco

product (as the co-packaging does not modify the products, including their respective container closure systems), a separate STN was generated for the rolling papers (SE0014688)..[1] An Acknowledgement letter was issued on September 21, 2011. FDA issued an Advice/Information Request (A/I) letter on November 29, 2012. On December 26, 2012, FDA received an amendment (SE0005502) containing a response to the A/I letter. FDA issued a Notification letter on July 10, 2015, indicating scientific review was expected to begin on August 24, 2015. FDA issued a Preliminary Finding (PFind) letter on December 16, 2015, requesting additional information to uniquely identify the new and predicate products. On January 12, 2016, FDA received an amendment (SE0012790) containing a response to the PFind letter dated December 16, 2015. On January 27, 2016, FDA received an amendment (SE0012822) containing a response to FDA's Office of Compliance and Enforcement (OCE) request for clarification of the predicate product name. FDA issued an A/I letter on June 14, 2016. On August 11, 2016, FDA received an amendment (SE0013574) containing a response to the A/I letter. FDA issued a PFind letter on November 22, 2016. On December 21, 2016, FDA received an amendment (SE0013793) containing a response to the PFind letter. FDA issued a PFind letter on May 26, 2017 with environmental requests. On June 12, 2017, FDA received an amendment (SE0014144), containing a response to the PFind letter. On June 16, 2017, FDA received an amendment (SE0014156), containing a clarification of response in the PFind letter. Within each of these amendments responding to FDA's May 26, 2017, PFind letter, the applicant notes that FDA issued these requests for environmental information in error as issuance of SE under section 910(a) of the FD&C Act for provisional SE Reports are categorically excluded under 21 CFR 25.35(a). FDA agrees that these letters were issued in error.

Product Name	SE Report	Amendments
Gambler Turkish Style 0.65 oz Pouch	SE0000225	SE0005502 SE0012790 SE0012822 SE0013574 SE0013793 SE0014144 SE0014156

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 Idara Udoh on September 22, 2011, Marcella White on November 29, 2012, La'Shelle Tatum on March 8, 2013, and Sarah Webster on December 16, 2015.

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

[1] The scientific evaluation in this TPL review is limited to the new RYO tobacco filler (SE0000225).

3. COMPLIANCE REVIEW

OCE completed reviews 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 February 8, 2016, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product (submitted as part of a co-package of two products: tobacco filler and rolling papers) is grandfathered and, therefore, is an eligible predicate tobacco product.[2]

4. SCIENTIFIC REVIEW

The evaluation detailed in this TPL review is limited to the new RYO tobacco filler. Evaluation of the new rolling paper is found in the TPL review for SE0014688. Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Todd Cecil on May 20, 2016, and Tianrong Cheng on September 28, 2016, and February 2, 2017.

The final chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review identifies the following differences:

- Tobacco blend
- Ingredients other than tobacco
- Tobacco filler HPHCs (e.g., nicotine, arsenic, cadmium, and nitrosonornicotine)

The differences in tobacco blends and ingredients between the new and predicate products may cause an increase in HPHC smoke yields in the new tobacco product. The applicant, however, submitted evidence that the HPHCs (tar, nicotine, carbon monoxide, benzo[a]pyrene, nitrosonornicotine, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, arsenic, and cadmium) in smoke are similar to or decreased in the new and predicate tobacco products. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Madison Rohrbaugh, on May 16, 2016, and September 21, 2016.

[2] Addendum reviews were completed in September 2016 to include the package type and size for the predicate and new tobacco products, and June 2018 to clarify that the characterizing flavor of the predicate tobacco product is “none.”; these addendum reviews do not change the conclusions of in the original February 2016 reviews.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product but the difference does not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- 8% increase in filler mass

The new and predicate products are identical from an engineering standpoint except for the 8% increase in filler mass, which is a result of an increase in package size and was evaluated by the social science discipline. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Maocheng Yang on May 27, 2016, November 1, 2016, and on February 17, 2017.

The final toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition of (b) (4) [redacted]
- Addition of (b) (4) [redacted] and (b) (4) [redacted]
- Increased levels of (b) (4) [redacted] and (b) (4) [redacted]

Although several ingredients which may lead to increases in HPHCs were either added to or increased in the new tobacco product, HPHC levels were either similar to or decreased relative to the predicate tobacco product. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

4.4. SOCIAL SCIENCE

A social science review was completed by Joelle Robinson on September 29, 2016.

The social science review concludes that the new tobacco product has different characteristics related to consumer perception compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- 8.3% increased quantity of tobacco filler

The review states that it is possible that changes from smaller to larger package quantities of RYO tobacco filler might affect consumer perceptions and/or use of the product; however, there is no direct scientific evidence correlating an increased quantity of RYO tobacco filler with a

change in consumer perception. Therefore, the review concludes that the differences in characteristics between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[3] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco product to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for this provisional SE Report (SE0000225) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- Tobacco blend
- Ingredients other than tobacco
- HPHCs in tobacco filler (nicotine, arsenic, cadmium, and nitrosonornicotine)
- Increase in filler mass (8%)
- Addition of (b) (4) [redacted]
- Addition of (b) (4) [redacted] and (b) (4) [redacted]
- Increased levels of (b) (4) [redacted] and (b) (4) [redacted]

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The applicant stated that there were differences in the tobacco blend, ingredients other than tobacco, and measured HPHCs in the tobacco filler between the new and predicate tobacco products. The applicant produced and tested cigarettes using their tobacco filler in the new and predicate tobacco products and identical rolling papers. The measured HPHC values in the smoke were comparable between the new and predicate tobacco product and therefore the differences in tobacco blends and ingredients other than tobacco do not cause the new tobacco product to raise different questions of public health. The applicant also states that the new tobacco product was produced using a larger package size. The social science review and the finalized memorandum[3] conclude that based on OS's experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion. Therefore, the

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

differences in characteristics between the new and corresponding predicate product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because 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).

Because the proposed action is issuing SE orders for these provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

An SE order letter should be issued for the new tobacco product in SE0000225 as identified on the cover page of this review.