FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0000243

SE0000243: Gambler Gold 0.65 oz. Pouch	
Package Type	Pouch
Package Quantity	0.65 oz
Tobacco Cut Size	Not Provided
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 a Roll Your Own tobacco co-package)
Recommendation	
Issue a Substantially Equivalent (SE) Order.	

Technical Project Lead (TPL):

Todd L. Cecil -S
Digitally signed by Todd L. Cecil -S
Date: 2018.09.17 07:25:03 -04'00'

Todd L. Cecil, Ph.D.
DPS 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 10:00:16 -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:

SE0000243: Gambler Gold 0.65 oz. Pouch	
Product Name	GAM/LITE, 36BAGS/CASE
Package Type	Bag
Package Quantity	6 oz
Tobacco Cut Size	Not Provided
Characterizing Flavor	None

The predicate tobacco product is roll-your-own tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted an SE Report on March 16, 2011. FDA issued an Acknowledgment letter on September 21, 2011. FDA issued an Advice/Information Request letter on December 13, 2012. In response, the applicant submitted amendment SE0005867, which FDA received on January 11, 2013. On July 10, 2015, FDA issued a Notification letter, indicating that substantive scientific review was expected to begin on August 24, 2015. On December 16, 2015, FDA issued a Preliminary Finding (PFind) letter. FDA received the applicant's response (SE0012790) to the PFind letter on January 12, 2016. In response to a request from FDA's Office of Compliance and Enforcement (OCE), FDA received an amendment (SE0012822) on January 27, 2016, amending the predicate tobacco product name.

Product Name	Original SE Report	Amendments
Gambler Gold 0.65 oz. Pouch	SE0000243	SE0005867 SE0012790 SE0012822

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 Marcella White on December 13, 2012, and Kristen Jackson on March 8, 2013.

The final reviews conclude that the SE Report is administratively complete.

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 is grandfathered and, therefore, is an eligible predicate tobacco product.[1]

4. SCIENTIFIC REVIEW

According to the applicant, the tobacco filler described in this SE Report is co-packaged with a booklet of rolling papers. Specifically, the applicant describes the packaging for the new product as containing "0.65oz of tobacco packaged inside a resealable pouch…inserted into a cardboard box. Each cardboard box contains a booklet of cigarette rolling papers." Because the tobacco filler and the booklet of rolling papers are not co-packaged in the same container closure system, the co-packaging does not result in a new, co-packaged product. The individual scientific reviews, however, identified the new product as a roll-your-own tobacco co-package product; the reviews should have identified the tobacco filler as a new tobacco product and compared it to the filler predicate product. When comparing the new tobacco filler product to the predicate tobacco filler product, the SE Report demonstrates that there are no differences in characteristics between the new and predicate tobacco filler products other than a change in product quantity and the container closure system. Although the individual scientific reviews did not directly address these differences in characteristics, the TPL evaluates them below.
Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Todd Cecil on May 20, 2016.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product and that the SE Report lacks adequate evidence to demonstrate that the differences do not cause the new tobacco product to raise different questions of public health. The review identifies the following deficiencies that have *not* been adequately resolved:

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the predicate and new products. However, your SE Report does not include sufficient detail to fully identify the composition of the predicate and new products. We need any other information you may have that uniquely identifies the tobacco used in the predicate and new products. This is the information that you rely on to ensure that the tobacco used in the predicate and new products is identical[2] for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in

[1] An addendum review was completed on April 21, 2017, to clarify that the characterizing flavor of the predicate tobacco product is "none." The addendum review does not change the conclusion of the initial grandfather determination dated February 8, 2016.
[2] The new and predicate tobacco products do not need to demonstrate identical characteristics. This text is in error.

the predicate and new products. Similarly, for other ingredients, it would be helpful to know the grade of each ingredient. Provide a detailed list including:

a. Ingredients for all components
b. Uniquely identifying information for all tobacco (e.g., tobacco grading system, curing, and fermentation)
c. Uniquely identifying information for all ingredients (e.g., grade/purity)

If a difference exists between the new and corresponding predicate products, provide a rationale for each difference with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.

2. Your SE Report lists "cigar" tobacco in the tobacco blend. It is unclear how the constituents and other properties of cigar tobacco differ from other tobacco types in the tobacco blend. In order for us to fully assess the characteristics of the products, we need to know more about the constituents and other properties of this type of tobacco (i.e., curing or fermentation conditions employed prior to leaf processing). Provide information on ingredient composition that distinguishes between the different types of tobacco. If this tobacco is known to have a different HPHC profile relative to other tobacco types in the tobacco blend, provide details and scientific rationale as to why this does not raise different questions of public health.

3. Your SE Report lacks information about complex ingredients. For example, your SE Report lacks the names, functions, or quantities of the single ingredients in the flavoring mixture (b) (4) [redacted], and (b) (4) [redacted] Distinguish between complex ingredients made to your specifications and those that are not. For all complex ingredients made to your specifications, provide complete information according to FDA's Guidance for Industry Listing of Ingredients in Tobacco Products.

4. SE0000243 provides a listing of all of the ingredients in the new and predicate products. SE0000243 also indicates that the new product is packaged with a container of cigarette papers. The predicate product does not include cigarette papers. It is not possible to determine the equivalence between the new and predicate products where the major component (cigarette papers) of the new product is absent in the predicate product. Provide a rationale with evidence and a scientific discussion as to why this significant difference in product composition (addition of cigarette papers) does not cause the new product to raise different questions of public health.[3]

The review concludes that the applicant did not demonstrate that 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.

[3] As indicated below, this deficiency will not be communicated to the applicant because the review should have identified the tobacco filler, not a co-packaged tobacco filler and rolling paper product, as a new tobacco product and compared it to the filler predicate product. In addition, the statement that "It is not possible to determine the equivalence between the new and predicate products where the major component (cigarette papers) of the new product is absent in the predicate product" was included in error. The statutory standard is substantial equivalence, not equivalence. Moreover, under certain circumstances, it may be possible to determine that a co-packaged tobacco filler and RYO new tobacco product is substantially equivalent to a tobacco filler predicate product.

However, the fourth deficiency identified in the review is driven by the Reviewer's comparison of the tobacco filler predicate product to a co-packaged tobacco filler and rolling paper product, which, as explained above, is incorrect. Moreover, in comparing the new tobacco filler product to the predicate tobacco filler product, the applicant's SE Report demonstrates that there are no differences in characteristics between the new and predicate tobacco products other than differences in the container closure systems (pouch vs. bag) and product quantity. As explained in section 6 of this TPL review, these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Therefore, all four deficiencies identified in this review should not be conveyed to the applicant.

4.2. ENGINEERING

An engineering review was completed by Madison Rohrbaugh on May 16, 2016.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product and that the SE Report lacks adequate evidence to demonstrate the differences do not cause the new tobacco product to raise different questions of public health. The review identifies the following deficiencies that have *not* been adequately resolved:

1. SE0000243 provides information on the design parameters for the predicate and new products. However, your SE Report does not include all of the design parameters necessary to fully characterize the predicate and new products. In order to adequately characterize the products, it is necessary to compare key design parameters. Provide the **target specification and upper and lower range limits** for *all* of the following design parameters for the new product:

    a. Total mass per rolling paper (mg)
    b. Cigarette paper base paper basis weight (g/m2) (range limits only)
    c. Cigarette paper base paper porosity (CU)
    d. Cigarette paper band width (mm) (if applicable)
    e. Cigarette paper band space (mm) (applicable)
    f. Cigarette paper length (mm) (range limits only)
    g. Cigarette paper width (mm) (range limits only)

    Provide the **target specification and upper and lower range limits** for *all* of the following design parameters for the new and predicate products:

    h. Tobacco filler mass (mg)
    i. Tobacco filler cut width (cpi)
    j. Tobacco moisture (%)

    For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., paper length should be reported in mm per rolling paper). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

2. SE0000243 includes design parameter specifications but does not include data confirming that specifications are met. Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for *all* of the following design parameters for the new product:

    a. Total mass per rolling paper (mg)
    b. Cigarette paper base paper basis weight (g/m2)
    c. Cigarette paper base paper porosity (CU)
    d. Cigarette paper band porosity (CU) (if applicable)

    Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for *all* of the following design parameters for the new and predicate products:

    e. Tobacco filler mass (mg)
    f. Tobacco filler cut width (cpi)
    g. Tobacco moisture (%)

    For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., paper length should be reported in mm per rolling paper). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

    Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include a target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. The certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

    Additionally, for the design parameters listed above that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

3. SE0000243 lacks adequate information to illustrate that the differences in design characteristics between the new and predicate products (loose tobacco bundled with rolling paper versus loose tobacco) make it appropriate and valid to perform a comparison of substantial equivalence between these product categories. The design differences between the new and predicate products prevent a meaningful scientific and regulatory review. Consequently, there is inadequate information to determine that these differences in characteristics do not cause the new products to raise different questions of public health. Provide a rationale with evidence and a scientific discussion as to why these significant dissimilarities in the design characteristics of the new and predicate products do not cause the new product to raise different questions of public

health. In your response, address each of the design characteristic differences between the new and predicate products.[4]

The review concludes that the applicant did not demonstrate that 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. However, I disagree with the Engineering Reviewer. The applicant's SE Report demonstrates that there are no differences in characteristics between the new and predicate tobacco products other than the differences in the container closure system (pouch vs. bag) and product quantity. Additionally, deficiencies 1 items a-g, 2 items a-d, and 3 in the review are driven by the Reviewer's comparison of the tobacco filler predicate product to a co-packaged tobacco filler and rolling paper product, which, as explained above, is incorrect. As explained in section 6 of this TPL review, these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Therefore, the deficiencies identified in this review should not be conveyed to the applicant.

4.3. TOXICOLOGY

A toxicology review was completed by Tony Yang on May 27, 2016.

The toxicology review evaluated the HPHCs between the new and predicate tobacco product (tobacco filler) and because there is no change in the levels of six HPHCs (ammonia, nicotine, arsenic, cadmium, NNN, and NNK) measured in tobacco filler of the new product compared to the predicate product, the review did not identify any deficiencies related to the tobacco filler. The toxicology review, however concludes that the SE Report lacks sufficient information to determine the differences in characteristics from a toxicology perspective between the new and predicate tobacco products. This determination was based on an incorrect comparison of a co-packaged tobacco filler and rolling paper product to the predicate tobacco filler. The review identifies the same deficiency related to inclusion of rolling papers in the new product that was identified in the chemistry review.

However, as stated in section 4.1 with respect to the deficiencies identified in the chemistry review, I disagree with the Chemistry Reviewer. The applicant's SE Report demonstrates that there are no differences in characteristics between the new and predicate tobacco products other than differences in the container closure system (pouch vs. bag) and product quantity. As explained in section 6 of this TPL review, these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Additionally, the fourth deficiency identified in the chemistry review is driven by the Reviewer's comparison of the tobacco filler predicate product to a co-packaged tobacco filler and rolling paper product, which, as explained above, is incorrect. Therefore, the deficiencies identified in the chemistry review should not be conveyed to the applicant.

[4] As indicated below, this deficiency will not be communicated to the applicant because the review should have identified the tobacco filler, not a co-packaged tobacco filler and rolling paper product, as a new tobacco product and compared it to the filler predicate product. In addition, the first two sentences should be clarified and corrected. As also stated in footnote 2, under certain circumstances, it may be possible to determine that a co-packaged tobacco filler and RYO new tobacco product is substantially equivalent to a tobacco filler predicate product.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of an SE order under section 910(a) of the FD&C Act for this provisional SE Report (SE0000243) 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 individual scientific reviews identified the new product as a roll-your-own tobacco co-package product. The reviews, however, should have identified the tobacco filler as the new tobacco product and compared it to the filler predicate product. When comparing the new and predicate tobacco products, the only differences in characteristics are a difference in the container closure system (pouch v. bag) and product quantity. Specifically, the new tobacco product has an aluminum foil pouch while the predicate product has a polyethylene bag and there is an 89.2% decrease in tobacco filler. FDA finalized a memorandum[5] which concludes that, based on FDA's experience and the currently available evidence, at this time, differences in product quantity do not cause the new tobacco product to raise different questions of public health. Furthermore, although the chemistry review discipline did not review the change in the container closure system, I conclude that the these differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Given the likelihood that the change to the container closure system would not alter product stability (e.g., TSNA formation) because roll-your-own tobacco filler is low in moisture with limited microbial growth and given the likelihood that the differences in the container closure system materials would not impact leaching, these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Therefore, I conclude that the differences in characteristics between the new and predicate tobacco products do not cause the new product to raise different questions of public health.

The predicate tobacco product 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).

Because the proposed action is issuing SE orders for the provisional SE Report, 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 SE0000243, as identified on the cover page of this review.

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