

Technical Project Lead (TPL) Review: SE0011172 – SE0011177 and SE0011179 – SE0011181

SE0011172: TOP GOLD 0.6 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.6 oz
Filler Characterizing Flavor ¹	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011173: TOP REGULAR PLAIN-VU 0.65 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.65 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011174: TOP REGULAR 0.6 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.6 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011175: TOP MENTHOL 0.6 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.6 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper	None

¹ 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.

SE0011176: TOP MENTHOL PLAIN-VU 0.65 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.65 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011177: GAMBLER FULL FLAVOR 0.6 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.6 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011179: GAMBLER MENTHOL 0.6 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	0.6 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011180: DRUM HALFZWARE SHAG 5 oz CANISTER	
Filler Package Type	Canister
Filler Package Quantity	5 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	200 papers
Rolling Paper Length	69 mm
Rolling Paper Width	36 mm
Rolling Paper Characterizing Flavor	None
SE0011181: DRUM HALFZWARE SHAG 1.14 oz POUCH	
Filler Package Type	Pouch
Filler Package Quantity	1.14 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	50 papers
Rolling Paper Length	69 mm
Rolling Paper Width	36 mm
Rolling Paper Characterizing Flavor	None

Common Attributes	
Applicant	Top Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Roll-Your-Own Co-Package
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.10.19 15:00:04 -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: 2017.10.19 16:17:17 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND	6
1.1. PREDICATE TOBACCO PRODUCT	6
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	8
1.3. SCOPE OF REVIEW	10
2. REGULATORY REVIEW	10
3. COMPLIANCE REVIEW	10
4. SCIENTIFIC REVIEW	11
4.1. SOCIAL SCIENCE	11
5. ENVIRONMENTAL DECISION.....	11
6. CONCLUSION AND RECOMMENDATION	12

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products²:

SE0011172: TOP GOLD 0.6 oz POUCH	
Product Name	TOP LITE POUCH
Filler Package Type	Pouch
Filler Package Quantity	0.75 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011173: TOP REGULAR PLAIN-VU 0.65 oz POUCH	
Product Name	REG-PLAIN VIEW
Filler Package Type	Pouch
Filler Package Quantity	0.75 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011174: TOP REGULAR 0.6 oz POUCH	
Product Name	TOP REG. POUCH
Filler Package Type	Pouch
Filler Package Quantity	0.75 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None

² In amendment SE0014028, the applicant amended the predicate tobacco product names included in the original submissions. The table reflects the amended predicate tobacco product names. All reviews conducted prior to receipt of amendment SE0014028 captured the predicate tobacco product names included in the original submissions.

SE0011175: TOP MENTHOL 0.6 oz POUCH	
Product Name	TOP MENTHOL POUCH 12
Filler Package Type	Pouch
Filler Package Quantity	0.75 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011176: TOP MENTHOL PLAIN-VU 0.65 oz POUCH	
Product Name	MENTHOL-PLAIN VIEW
Filler Package Type	Pouch
Filler Package Quantity	0.75 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011177: GAMBLER FULL FLAVOR 0.6 oz POUCH	
Product Name	GAMBLER. POUCH REG.
Filler Package Type	Pouch
Filler Package Quantity	0.65 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None
SE0011179: GAMBLER MENTHOL 0.6 oz POUCH	
Product Name	GAMBLER. POUCH MEN.
Filler Package Type	Pouch
Filler Package Quantity	0.65 oz
Filler Characterizing Flavor	Menthol
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	32 papers
Rolling Paper Length	70 mm
Rolling Paper Width	39 mm
Rolling Paper Characterizing Flavor	None

SE0011180: DRUM HALFWARE SHAG 5 oz CANISTER	
Product Name	DRUM CAN
Filler Package Type	Canister
Filler Package Quantity	5.29 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	200 papers
Rolling Paper Length	69 mm
Rolling Paper Width	36 mm
Rolling Paper Characterizing Flavor	None
SE0011181: DRUM HALFWARE SHAG 1.14 oz POUCH	
Product Name	DRUM POUCH
Filler Package Type	Pouch
Filler Package Quantity	1.41 oz
Filler Characterizing Flavor	None
Rolling Paper Package Type	Booklet
Rolling Paper Package Quantity	50 papers
Rolling Paper Length	69 mm
Rolling Paper Width	36 mm
Rolling Paper Characterizing Flavor	None

The predicate tobacco products are manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2015, FDA received 9 Product Quantity Change SE Reports from Top Tobacco, LP. FDA issued Acknowledgment letters to the applicant on April 23, 2015. On May 4, 2015, FDA received solicited amendments (SE0011713 - SE0011714, SE0011716 - SE0011718, and SE0011721 - SE0011724) containing a response to the Office of Compliance and Enforcement (OCE) information request dated April 27, 2015, to demonstrate that the predicate tobacco products were commercially marketed in the United States as of February 15, 2007. On May 11, 2015, FDA received an amendment (SE0011752) containing a response to the OCE information request to clarify the predicate tobacco product names. On May 12, 2015, FDA received an amendment (SE0011759) containing a response to the Office of Science (OS) information request dated May 6, 2015, for tobacco product unique identification information. On May 29, 2015, FDA received an amendment (SE0011895) containing a response to the OS information request dated May 15, 2015, for additional tobacco product unique identification information. On April 14, 2016, FDA issued Correction letters for the Acknowledgment letters to capture the additional properties for the new and predicate products. On March 21, 2017, FDA issued a Preliminary Finding letter to convey OCE's deficiencies to establish Grandfathered status and predicate eligibility for all the SE Reports. In response, the applicant submitted an amendment (SE0014028) on April 11, 2017. After an environmental review was conducted, FDA issued a Preliminary Finding letter on July 5, 2017. The Preliminary Finding letter identified environmental deficiencies in the applicant's SE Reports. The applicant submitted a response (SE0014220) on July 28, 2017.

Product Name	SE Report	Amendment
TOP GOLD 0.6 oz POUCH	SE0011172	SE0011721 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
TOP REGULAR PLAIN-VU 0.65 oz POUCH	SE0011173	SE0011722 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
TOP REGULAR 0.6 oz POUCH	SE0011174	SE0011723 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
TOP MENTHOL 0.6 oz POUCH	SE0011175	SE0011724 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
TOP MENTHOL PLAIN-VU 0.65 oz POUCH	SE0011176	SE0011713 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
GAMBLER FULL FLAVOR 0.6 oz POUCH	SE0011177	SE0011714 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
GAMBLER MENTHOL 0.6 oz POUCH	SE0011179	SE0011716 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220

DRUM HALFZWARE SHAG 5 oz CANISTER	SE0011180	SE0011717 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
DRUM HALFZWARE SHAG 1.14 oz POUCH	SE0011181	SE0011718 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

The acceptance reviews were completed by Kendric Neely on April 22, 2015, and the regulatory review was completed by Samuel Motto on March 21, 2017.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews on June 4, 2015; March 10, 2016; January 13, 2017; and May 17, 2017, to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated May 17, 2017³, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are 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 reviews dated August 6, 2015, and October 17, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

³ An addendum was completed on July 27, 2017, to correct the predicate tobacco product size for SE0011176.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Joelle Robinson on June 2, 2015⁴.

The social science review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but that the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following differences between the new and predicate tobacco products:

- SE0011172, SE0011174, SE0011175: Decrease in product quantity of RYO tobacco filler from 0.75 oz to 0.6 oz (20%)
- SE0011173, SE0011176: Decrease in product quantity of RYO tobacco filler from 0.75 oz to 0.65 oz (13%)
- SE0011177, SE0011179: Decrease in product quantity of RYO tobacco filler from 0.65 oz to 0.6 oz (8%)
- SE0011180: Decrease in product quantity of RYO tobacco filler from 5.29 oz to 5 oz (5%)
- SE0011181: Decrease in product quantity of RYO tobacco filler from 1.41 oz to 1.14 oz (19%)

The social science reviewer states that in the context that all other product characteristics between the new and predicate tobacco products in these SE Reports are the same, the specific differences in package quantity are not expected to adversely affect consumer perception or use. Therefore, from a social science perspective, the differences in product quantity between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

I agree with the social science review's conclusion, since, given the small magnitude of the changes in package quantity (a decrease ranging from 5% to 20%), the differences in package quantity do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 29, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 29, 2017.

⁴ An addendum was completed on September 2, 2015, solely to correct SE Report STNs and revise the word "amendments" in section 2.2 to "technical updates."

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity of RYO tobacco filler:

- SE0011172, SE0011174, SE0011175: Decrease in product quantity of RYO tobacco filler from 0.75 oz to 0.6 oz (20%)
- SE0011173, SE0011176: Decrease in product quantity of RYO tobacco filler from 0.75 oz to 0.65 oz (13%)
- SE0011177, SE0011179: Decrease in product quantity of RYO tobacco filler from 0.65 oz to 0.6 oz (8%)
- SE0011180: Decrease in product quantity of RYO tobacco filler from 5.29 oz to 5 oz (5%)
- SE0011181: Decrease in product quantity of RYO tobacco filler from 1.41 oz to 1.14 oz (19%)

The social science review concludes that these differences in product quantity do not cause the new tobacco products to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act.

FDA examined the environmental effects of finding the new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0011172 – SE0011177 and SE0011179 – SE0011181, as identified on the cover page of this review.