FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0011190, SE0011191, and SE0011196

SE0011190: Smoking Master Double Cigarette Papers	
Package Type	Booklet
Package Quantity	120 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor[1]	None
Additional Property	Interleave booklet
SE0011191: Smoking Red Double Cigarette Papers (120 Ct.)	
Package Type	Booklet
Package Quantity	120 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Interleave booklet
SE0011196: Smoking Orange Double Cigarette Papers (120 Ct.)	
Package Type	Booklet
Package Quantity	120 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Interleave booklet
Common Attributes	
Applicant	Miquel y Costas & Miquel, S.A.
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Papers
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[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.

Technical Project Lead (TPL):

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Date: 2017.11.24 06:33:45 -05'00'

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: 2017.11.27 08:17:40 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

According to the applicant's certification statement, the predicate tobacco product in SE0011190 is identical to the new tobacco product except for product quantity, brand name, label graphics and ink colors[2]. According to the applicant's certification statement, the predicate tobacco products in SE0011191 and SE0011196 are identical to the corresponding new tobacco products except for product quantity. According to the applicant, the predicate tobacco products have the following characteristics:

SE0011190: Smoking Master Double Cigarette Papers	
Product Name	Smoking Blue Cigarette Papers
Package Type	Booklet
Package Quantity	60 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor[3]	None
Additional Property	Interleave booklet
SE0011191: Smoking Red Double Cigarette Papers (120 Ct.)	
Product Name	Smoking Red Cigarette Papers (60 Ct.)
Package Type	Booklet
Package Quantity	60 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Interleave booklet
SE0011196: Smoking Orange Double Cigarette Papers (120 Ct.)	
Product Name	Smoking Orange Cigarette Papers (60 Ct.)
Package Type	Booklet
Package Quantity	60 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Interleave booklet

The predicate tobacco products are Roll-Your-Own rolling papers manufactured by the applicant.

[2] In response to FDA's inquiry, the applicant clarified in an email dated May 20, 2015, that the change in ink color differences between the new and predicate tobacco products referenced in the certification statement of Smoking Masters refers to ink color differences in graphics, but not in the tobacco product itself. The email is archived as a telecon dated May 15, 2015.
[3] 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.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 3, 2015, FDA received three Product Quantity Change SE Reports from Miquel y Costas & Miquel, S.A. FDA issued Acknowledgment letters on April 22, 2015. On May 15, 2015, FDA conducted a telecon requesting product identifying properties and adequate certification statements. FDA received the applicant's response to this request on May 27, 2015 (SE0011890). On January 17, 2017, FDA issued a Preliminary Finding letter related to predicate eligibility and the certification statement for SE0011190. FDA received the applicant's response to the Preliminary Finding letter on February 15, 2017 (SE0013938). On April 27, 2017, FDA issued a Preliminary Finding letter related to environmental deficiencies in the applicant's SE Reports. The applicant responded with partial information on May 26, 2017 (SE0014122). Additional information in response to the April 27, 2017, Preliminary Finding letter was submitted on May 26, 2017, and received on May 30, 2017 (SE0014125).

Product Name	SE Report	Amendments
Smoking Master Double Cigarette Papers	SE0011190	SE0011890 SE0013938 SE0014122 SE0014125
Smoking Red Double Cigarette Papers (120 Ct.)	SE0011191	SE0011890 SE0013938 SE0014122 SE0014125
Smoking Orange Double Cigarette Papers (120 Ct.)	SE0011196	SE0011890 SE0013938 SE0014122 SE0014125

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Charmaine Flotildes on April 22, 2015, and Arielle Schindler on January 13, 2017. The January 13, 2017, review identified that the applicant did not provide an adequate certification statement for SE0011190. The applicant provided an adequate certification statement in response to the Preliminary Finding letter (SE0011890).

The SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews 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 March 16, 2017, 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 reviews 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 June 9, 2015, and November 21, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were 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, 2015.

The social science review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but 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:

- An increase in product quantity from 60 to 120 rolling papers (100%)

The social science reviewer states that there is currently no available scientific evidence that this change in the number of cigarette rolling papers influences consumer perceptions of harm or use intentions. Therefore, from a social science perspective, the difference in product quantity between the new and predicate tobacco products does not cause the new product to raise different questions of public health.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), increasing product quantity can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of the evidence provided in these SE Reports, as well as other scientific literature and FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the class of products at issue here—cigarette rolling papers—an increase in product quantity would not cause a new tobacco product to raise different questions of public health. Although not evaluated in the social science review, for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), increasing the product quantity generally would not impact consumer use. Relatedly, scientific literature suggests that for consumer products that are "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), increasing the product quantity also generally would not impact

consumer use.[4] Given the likelihood that rolling papers are usage-invariant (since there is no benefit of using an increased number of rolling papers per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space), I find that, based on the current state of the evidence, an increase of product quantity from 60 to 120 rolling papers does 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 October 30, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 30, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from 60 to 120 RYO rolling papers.

The social science review concludes that, from a social science perspective, this difference in product quantity does 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 it was determined that 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 these 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 SE0011190, SE0011191, and SE0011196, as identified on the cover page of this review.

[4] Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. Journal of Marketing Research, 321-335.