FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0000602

SE0000602: Lark White Pack 100's Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	40%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Philip Morris USA, Inc.
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.27 09:43:04 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy 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: 2018.07.27 09:58:53 -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:

SE0000602: Lark White Pack 100's Soft Pack	
Product Name	Lark Lights 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	40%
Characterizing Flavor	None

The predicate tobacco product is a combusted filtered cigarette manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Report (SE0000602) for Lark White Pack 100's Soft Pack on March 18, 2011, which was submitted by Altria Client Services Inc. (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA acknowledged the SE Report on September 1, 2011. FDA issued an Advice/Information Request (A/I) letter on October 25, 2012. On November 19, 2012, FDA received the response to the A/I letter (SE0005129)[1]. On December 16, 2012, FDA assigned these products to PHI Tier 3. On January 24, 2013, FDA received an amendment (SE0006705) to correct previously submitted data. On May 30, 2013, FDA received their environmental assessment in response to the October 25, 2012, A/I letter (SE0008792). On March 28, 2014, FDA requested that the applicant provide the number of cigarettes per pack for the new tobacco product. On March 30, 2014, FDA received the response to the information request (SE0010332). FDA issued a Notification letter on April 4, 2014, indicating scientific review was expected to begin on May 20, 2014. On May 16, 2014, FDA received an amendment (SE0010492) to update information previously submitted. On September 18, 2015, FDA received an amendment (SE0012370) to correct the ingredient table in the previous submissions. The scientific review resulted in a finding of new information regarding the use of (b) (4) filters. This prompted a second PHI review on December 19, 2016, in which FDA reassigned SE0000602 to PHI Tier 2. Therefore, as explained in the March 14, 2017 memo, FDA continued with scientific review. FDA issued an A/I letter on March 16, 2017. On March 23, 2017, FDA received an email from the applicant requesting a clarification of Deficiency 9 within the A/I letter. FDA provided the response to the applicant's clarification questions on March 27, 2017. On March 30, 2017, FDA received an extension request (SE0014011). On April 7, 2017, FDA conducted a telecon to request additional information concerning the harmful or potentially harmful constituents (HPHCs) and products that will be tested pertaining to the extension request. On April 12, 2017, FDA received the response to the information request

[1] FDA completed an administrative review on March 28, 2013, and incorrectly entered the first commercial market date. The first commercial market date entered did not meet the criteria necessary for provisional SE Report status. After commencement of scientific review, FDA identified that the first commercial market dates noted in our records were incorrect. On December 29, 2015, a review corrected this error.

(SE0014029). FDA issued an Extension Granted letter on April 13, 2017. On June 27, 2017, FDA received a request (SE0014186) to the Extension Granted letter dated April 13, 2017, which stated that, due to a manufacturing issue with the laboratory, the applicant needed additional time to remanufacture the predicate tobacco products. To address the manufacturing issue with the laboratory and obtain the data needed to respond to the March 16, 2017, A/I letter, the applicant requested an additional two-week extension and proposed a new response due date of July 31, 2017. On July 6, 2017, FDA contacted the applicant for the details of the manufacturing issue. The applicant explained that the cigarette making system did not make the cigarettes with the correct weight; specifically, the filler weight did not meet their specifications. On July 12, 2017, FDA issued a second Extension Granted letter. On August 15, 2017, FDA received an amendment (SE0014238) in response to the A/I letter dated March 16, 2017. On October 23, 2017, FDA issued a Preliminary Finding (PFind) letter. On November 21, 2017, FDA received the response to the PFind letter (SE0014406), which included a claim of categorical exclusion.

Product Name	Original SE Report	Amendments
Lark White Pack 100's Soft Pack	SE0000602	SE0005129 SE0006705 SE0008792 SE0010332 SE0010492 SE0012370 SE0014011 SE0014029 SE0014186 SE0014238 SE0014406

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 Jennifer German on October 25, 2012, Jonathan Kwan on March 28, 2013, and Grace Kaiyuan on December 29, 2015.

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

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review 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 April 24, 2014, 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[2].

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Katherine Lovejoy on July 30, 2014, by Stephanie Daniels on October 13, 2017, and by Caroline Agarabi on January 22, 2018.

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 identified the following differences:

- Increase in (b) (4)
- Increase in (b) (4)
- Increase in small (b) (4)
- Decrease in expanded (b) (4) .
- Addition of (b) (4)
- Decrease in (b) (4)

The predicate tobacco product identified by the applicant was unavailable for HPHC testing. As a result, the applicant remanufactured the predicate tobacco product, which is referred to as a surrogate predicate tobacco product because not all materials used were identical during the remanufacture. The review determined the surrogate predicate product to be suitable as the tobacco blends, ingredients, and product design parameters were identical or nearly identical to these characteristics in the predicate product, allowing extrapolation of HPHC data to the predicate product. The provided HPHC data demonstrate that there were reductions or minimal increases in the HPHC yields between the new and surrogate predicate tobacco products, indicating that the changes in ingredients and tobacco blends do not cause the new tobacco product to raise different questions of public health. Given the updated ingredient information for the new and predicate tobacco products, the differences in the new and predicate tobacco product are confined to the non-combustible portions of the cigarette. The ingredients that are different are either present in lesser amounts in the new tobacco product than in the predicate tobacco product or not present in the new 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 chemistry perspective.

[2] An addendum review was completed on February 16, 2018, to clarify that the characterizing flavor of the predicate tobacco product is “none.” The addendum review does not change the conclusion of the initial determination.

4.2. ENGINEERING

Engineering reviews were completed by Julie Morabito on July 30, 2014, and by Michael Morschauser on October 6, 2017, and January 23, 2018.

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 differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Decrease in filler mass
- Decrease in the cigarette length

The new and predicate tobacco products use (b) (4) in the filters. The distribution of the (b) (4) as well as the lengths of each filter subsection, are identical for the new and predicate tobacco products, and therefore do not cause the new tobacco product to raise different questions of public health. The new tobacco product has a tobacco filler mass that is lower than the predicate tobacco product, but this change is minimal (5%). In addition, a decrease in the tobacco filler mass reduces smoke constituent yields. Furthermore, the HPHC data submitted by the applicant confirms that smoke constituent yields decreased in the new tobacco product compared to the predicate tobacco product. Therefore, this change does not cause the new tobacco product to raise different questions of public health. The applicant initially submitted multiple materials for filter tow, plug wrap, and tipping paper in the new and predicate tobacco products. However, the multiple materials have since been withdrawn and only a single filter tow, plug wrap, and tippling paper was identified. 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 Prabha Kc on November 23, 2016, and October 13, 2017, and by Eric Beier on January 19, 2018.

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:

- Multiple ingredients whose levels were increased, or newly added such as (b) (4) with other (b) (4)

The applicant provided extensive HPHC and smoke constituent data (including acetaldehyde, acetone, acrolein, benzene, 1,3-butadiene, carbon monoxide, formaldehyde, nicotine, phenol, propylene glycol, propylene oxide, toluene, and vinyl acetate) to address the toxicological concerns regarding ingredient increases and additions. No significant differences were observed in the comparison of HPHCs between the new and predicate tobacco products. To the extent

that there were differences in HPHC yields, they were within the analytical variation of the constituent measurements. 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.

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 (SE0000602) 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 differences in characteristics between the new and predicate tobacco products:

- Increase in (b) (4)
- Increase in (b) (4)
- Increase in (b) (4)
- Decrease in expanded (b) (4)
- Addition of (b) (4)
- Decrease in (b) (4)
- Multiple ingredients whose levels were increased, or newly added such as (b) (4)
- Decrease in tobacco filler mass
- Decrease in the cigarette length

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The predicate tobacco product was not available for HPHC testing; however, the applicant remanufactured the predicate tobacco product with only a few differences as compared to the original predicate product, and CTP thus treated it as a surrogate predicate tobacco product. Adequate information was submitted to show that the surrogate predicate tobacco product was a suitable surrogate for the predicate tobacco product as the tobacco blends, ingredients, and design parameters were identical or nearly identical to these characteristics in the predict product. The applicant provided HPHC data from the new and surrogate predicate products to address the differences in characteristics such as ingredient and tobacco blend differences. The differences observed resulted in minimal increases or a decrease in the HPHC yields in the comparison of the measured HPHCs and smoke constituents between the new and predicate tobacco products. To the extent that there were differences in HPHC yields, they were within the analytical variation of the constituent measurements and, thus, not significant. The decrease in tobacco filler mass is minimal and is anticipated to reduce smoke constituent yields. The HPHC data submitted by the applicant confirms that smoke constituent yields decreased in the new tobacco product compared to the surrogate predicate tobacco product. Therefore, the differences

in characteristics between the new and predicate products do not cause the new tobacco 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 other than exclusively in test markets as of February 15, 2007).

Because the proposed action is issuing an SE order for this 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 SE0000602, as identified on the cover page of this review.