

Technical Project Lead (TPL) Review: SE0015321, SE0015325, SE0015326, SE0015328, SE0015330, SE0015332, SE0015333, and SE0015334

SE0015321: Chesterfield Menthol 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015325: Chesterfield Blue Pack Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	None
SE0015326: Chesterfield Blue Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015328: Chesterfield 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
SE0015330: Benson & Hedges Deluxe 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	55%
Characterizing Flavor	None

SE0015332: Benson & Hedges Luxury 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	30%
Characterizing Flavor	None
SE0015333: Benson & Hedges 100's Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	Menthol
SE0015334: Benson & Hedges 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Philip Morris, USA
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2019.09.25 14:35:40 -04'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering Branch Chief
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 Glen D. Jones -S
Date: 2019.09.26 09:17:19 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND	5
1.1. PREDICATE TOBACCO PRODUCTS	5
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	7
1.3. SCOPE OF REVIEW	7
2. REGULATORY REVIEW	7
3. COMPLIANCE REVIEW	7
4. SCIENTIFIC REVIEW	8
4.1. CHEMISTRY.....	8
4.2. TOXICOLOGY.....	8
5. ENVIRONMENTAL DECISION.....	9
6. CONCLUSION AND RECOMMENDATION	9

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015321: Chesterfield Menthol 100's Box	
Product Name	Chesterfield Menthol 100's Box
Package Type	Hard Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015325: Chesterfield Blue Pack Box	
Product Name	Chesterfield Blue Pack Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	None
SE0015326: Chesterfield Blue Pack 100's Box	
Product Name	Chesterfield Blue Pack 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015328: Chesterfield 100's Box	
Product Name	Chesterfield 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None

SE0015330: Benson & Hedges Deluxe 100's Box	
Product Name	Bensons & Hedges 100's Deluxe Ultra Lights Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	55%
Characterizing Flavor	None
SE0015332: Benson & Hedges Luxury 100's Box	
Product Name	Benson & Hedges 100's Lights Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	30%
Characterizing Flavor	None
SE0015333: Benson & Hedges 100's Menthol Box	
Product Name	Benson & Hedges 100's Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	Menthol
SE0015334: Benson & Hedges 100's Box	
Product Name	Benson & Hedges 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None

The predicate tobacco products are combusted filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received eight Substantial Equivalence (SE) Reports from Philip Morris USA Inc. on June 28, 2019. FDA issued Acknowledgement letters on July 8, 2019 for SE00015321, SE00015325, SE00015326, and SE00015328, and on July 9, 2019 for SE00015330, and SE00015332- SE00015334.

Product Name	SE Report	Amendments
Chesterfield Menthol 100's Box	SE0015321	None
Chesterfield Blue Pack Box	SE0015325	
Chesterfield Blue Pack 100's Box	SE0015326	
Chesterfield 100's Box	SE0015328	
Benson & Hedges Deluxe 100's Box	SE0015330	
Benson & Hedges Luxury 100's Box	SE0015332	
Benson & Hedges 100's Menthol Box	SE0015333	
Benson & Hedges 100's Box	SE0015334	

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 Ryan Nguy on July 7, 2019 for SE00015321, SE00015325, SE00015326, SE00015328, SE00015330, SE00015332, SE00015333 and on July 9, 2019 for SE0015334.

The final reviews conclude that 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 in SE0015321, SE0015325, SE0015326, SE0015328, SE0015330, SE0015332, SE0015333 and SE0015334 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated July 28, 2019, for SE0015330, SE0015332, SE0015333, and SE0015334 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.

The predicate tobacco products in SE0015321, SE0015325, SE0015326, and SE0015328 were determined to be substantially equivalent by FDA under SE0014817, SE0015059, SE0015058, and SE0014818, respectively. Therefore, these products 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 review dated September 6, 2019, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

A chemistry review was completed by Lida Oum on August 15, 2019.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015321, SE0015325, SE0015328, SE0015333, and SE0015334)
- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015326, SE0015330, and SE0015332)
- Change from soft pack to hard pack (SE0015332)

The applicant provided certification statements for all SE Reports, certifying that the new and predicate tobacco products have identical characteristics and that no other modifications to the materials, ingredients, design features, heating source, or any other feature were made to the new tobacco products except for minor differences in the tipping adhesive composition. The applicant stated that the only modification is the addition of (b) (4) in the tipping adhesive of the new tobacco products, which is not in the predicate tobacco products. However, the amount of (b) (4) added to the tipping adhesive of the new tobacco products is 0.0080%-0.0099% of the total cigarette weight. Because the tipping adhesive is not combusted and not expected to affect mainstream smoke chemistry, the addition of the (b) (4) does not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The change of the soft pack to a hard pack is also not anticipated to have a measurable impact on smoke constituents.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. TOXICOLOGY

A toxicology review was completed by Luis M. Dasilva on August 19, 2019.

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

- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015321, SE0015325, SE0015328, SE0015333, and SE0015334)
- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015326, SE0015330, and SE0015332)

For all SE Reports, (b) (4) is added to the tipping adhesive of the new tobacco products as compared to the corresponding predicate tobacco products, and it is expected to evaporate during the (b) (4) process. The components of the tipping adhesive are not expected to be burned, volatilized, or be a potential source of thermal degradation resulting in the release of harmful and potentially harmful constituents (HPHCs).

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental science review was completed by Thomas Creaven on September 4, 2019.

The environmental review found that SE0015321, SE0015328, SE0015330, SE0015333, and SE0015334 do not provide the following necessary information for an Environmental Assessment for the new tobacco products as required in 21 CFR 25.40:

- Current year market volumes for the predicate tobacco products

Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI) for SE0015321, SE0015328, SE0015330, SE0015333, and SE0015334.

Regarding SE0015325, SE0015326, and SE0015332, a FONSI was signed by Kimberly Benson, Ph.D. on September 4, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 4, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015321, SE0015325, SE0015328, SE0015333, and SE0015334)
- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015326, SE0015330, and SE0015332)
- Change from soft pack to hard pack (SE0015332)

The addition of (b) (4) in the tipping adhesive of the new tobacco products, which is not present in the predicate tobacco products, is small when compared to the total cigarette weight. This ingredient is expected to evaporate during the (b) (4) process and is not expected to be burned, volatilized, or be a potential source of thermal degradation resulting in the release of HPHCs. Therefore, this ingredient change does not cause the new tobacco products to raise different questions of public health. The change of the soft pack to a hard pack is also not anticipated to have a measurable impact on smoke constituents. Therefore, the applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). The new tobacco products in SE0015321, SE0015325, SE0015326, and SE0015328 have the following key differences in product composition compared to the grandfathered predicate tobacco products (GF1200076, GF1200074, GF1200072, GF1200070) of the previously SE predicate tobacco products in SE0014817, SE0015059, SE0015058, and SE0014818:

- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015321, SE0015325, SE0015328)
- Addition of (b) (4) /cigarette) in the tipping adhesive (SE0015326)
- Minor changes in base tipping paper, tipping ink, and tipping ink extender ingredients
- Addition of a lip release (b) (4) /cigarette) (SE0015325-SE0015326)
- Change from soft pack to hard pack (SE0015321)

When the new tobacco products in SE0015321, SE0015325, SE0015326, and SE0015328 were compared to the corresponding grandfathered tobacco products, the key differences were in base tipping paper, tipping ink, tipping ink extender, change from a soft pack to hard pack, and tipping adhesive composition. Additionally, the new tobacco products in SE001525 and SE0015326 also contain the addition of a lip release. All ingredients that were added to or increased in the new tobacco products compared to the corresponding grandfathered tobacco products are less than (b) (4) /cigarette and are therefore unlikely to impact smoke chemistry. Additionally, base tipping papers, tipping inks, tipping ink extenders, and lip releases are not combusted during normal cigarette use and, therefore, changes to their compositions are not expected to affect smoke chemistry, including HPHCs. Therefore, the changes in ingredients and packaging in the new tobacco products in SE0015321, SE0015325, SE0015326, and SE0015328 do not cause the new tobacco product to raise different questions of public health when compared to the grandfathered tobacco products.

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued for SE0015325, SE0015326, and SE0015332.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact for SE0015325, SE0015326, and SE0015332.

SE order letters should be issued for the new tobacco products in SE0015325, SE0015326, and SE0015332, as identified on the cover page of this review.

FDA examined the environmental effects of finding the new tobacco products substantially equivalent and found additional information is necessary for SE0015321, SE0015328, SE0015330, SE0015333, and SE0015334 to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order. An Advice/Information Request letter should be issued requesting the following information:

1. All of your SE Reports lack the current year market volumes of the predicate products that you stated are currently marketed. Marketing information is used to quantitatively assess the environmental impacts of manufacturing, use, and disposal of the new products as compared to the corresponding predicate products. Provide the current year market volume in number of cigarettes for the products listed in Table 1.

Table 1. Current Market Volume of Predicate Products				
New Product STN	Predicate Product STN	Predicate Product Name	Number of Cigarettes	Current Year Market Volume
SE0015321	SE0014817	Chesterfield Menthol 100's Box		
SE0015328	SE0014818	Chesterfield 100's Box		
SE0015330	GF1200122	Benson & Hedges 100's Deluxe Ultra Lights Box		
SE0015333	GF1200128	Benson & Hedges 100's Menthol Box		
SE0015334	GF1200121	Benson & Hedges 100's Box		