



Technical Project Lead (TPL) Memorandum:

SE Reports SE0003503-SE0003524 & SE0010338-SE0010359

SE0003503: Riverside Blue 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003504: Riverside Blue Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003505: Riverside Blue Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper
SE0003506: Riverside Filter 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003507: Riverside Filter Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper
SE0003508: Riverside Filter Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper

SE0003509: Riverside Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003510: Riverside Menthol Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003511: Riverside Menthol Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper
SE0003512: Riverside Silver 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003513: Riverside Silver Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003514: Riverside Teal Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003515: Riverside Teal Menthol Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper

SE0003516: Valu Time Filter 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003517: Valu Time Filter Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003518: Valu Time Filter Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper
SE0003519: Valu Time Gold 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003520: Valu Time Gold Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper
SE0003521: Valu Time Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003522: Valu Time Menthol Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper

SE0003523: Valu Time Silver 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0003524: Valu Time Teal Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper
SE0010338: Riverside Blue 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010339: Riverside Blue Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010340: Riverside Blue Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010341: Riverside Filter 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010342: Riverside Filter Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)

SE0010343: Riverside Filter Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010344: Riverside Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010345: Riverside Menthol Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010346: Riverside Menthol Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010347: Riverside Silver 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010348: Riverside Silver Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010349: Riverside Teal Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)

SE0010350: Riverside Teal Menthol Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010351: Valu Time Filter 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010352: Valu Time Filter Kings	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010353: Valu Time Filter Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010354: Valu Time Gold 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010355: Valu Time Gold Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010356: Valu Time Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)

SE0010357: Valu Time Menthol Kings Box	
Length	85 mm
Package Size	20 cigarettes per pack
Package Type	Box
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010358: Valu Time Silver 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
SE0010359: Valu Time Teal Menthol 100's	
Length	100 mm
Package Size	20 cigarettes per pack
Package Type	Soft pack
Additional Tobacco Product Identification	Cigarette paper – (b) (4)
Common Attributes of SE Reports	
Applicant	S&M Brands, Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combustible filtered
Recommendation	
Issue Substantial Equivalence (SE) orders	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S

Date: 2014.06.25 20:00:45 -04'00'

Matthew R. Holman, Ph.D.
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 David Ashley -S

Date: 2014.06.26 06:41:44 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

Table 1. Predicate Tobacco Products

Riverside Blue 100's (SE0003503 & SE0010338)	
Length	100 mm
Product Name	Tahoe Light 100's
Package Size	20 cigarettes per pack
Riverside Blue Kings (SE0003504 & SE0010339)	
Length	85 mm
Product Name	Tahoe Light Kings
Package Size	20 cigarettes per pack
Riverside Blue Kings Box (SE0003505 & SE0010340)	
Length	85 mm
Product Name	Tahoe Light Kings Box
Package Size	20 cigarettes per pack
Riverside Filter 100's (SE0003506 & SE0010341)	
Length	100 mm
Product Name	Tahoe Full Flavor 100's
Package Size	20 cigarettes per pack
Riverside Filter Kings Box (SE0003507 & SE0010342)	
Length	85 mm
Product Name	Tahoe Full Flavor Kings Box
Package Size	20 cigarettes per pack
Riverside Filter Kings (SE0003508 & SE0010343)	
Length	85 mm
Product Name	Tahoe Full Flavor Kings
Package Size	20 cigarettes per pack
Riverside Menthol 100's (SE0003509 & SE0010344)	
Length	100 mm
Product Name	Tahoe Menthol 100's
Package Size	20 cigarettes per pack
Riverside Menthol Kings (SE0003510 & SE0010345)	
Length	85 mm
Product Name	Tahoe Menthol Kings
Package Size	20 cigarettes per pack
Riverside Menthol Kings Box (SE0003511 & SE0010346)	
Length	85 mm
Product Name	Tahoe Menthol Kings
Package Size	20 cigarettes per pack

Riverside Silver 100's (SE0003512 & SE0010347)	
Length	100 mm
Product Name	Tahoe Ultra Light 100's
Package Size	20 cigarettes per pack
Riverside Silver Kings (SE0003513 & SE0010348)	
Length	85 mm
Product Name	Tahoe Ultra Light Kings
Package Size	20 cigarettes per pack
Riverside Teal Menthol 100's (SE0003514 & SE0010349)	
Length	100 mm
Product Name	Tahoe Menthol Light 100's
Package Size	20 cigarettes per pack
Riverside Teal Menthol Kings (SE0003515 & SE0010350)	
Length	85 mm
Product Name	Tahoe Menthol Light Kings
Package Size	20 cigarettes per pack
Valu Time Filter 100's (SE0003516 & SE0010351)	
Length	100 mm
Product Name	Tahoe Full Flavor 100's
Package Size	20 cigarettes per pack
Valu Time Filter Kings (SE0003517 & SE0010352)	
Length	85 mm
Product Name	Tahoe Full Flavor Kings
Package Size	20 cigarettes per pack
Valu Time Filter Kings Box (SE0003518 & SE0010353)	
Length	85 mm
Product Name	Tahoe Full Flavor Kings Box
Package Size	20 cigarettes per pack
Valu Time Gold 100's (SE0003519 & SE0010354)	
Length	100 mm
Product Name	Tahoe Light 100's
Package Size	20 cigarettes per pack
Valu Time Gold Kings Box (SE0003520 & SE0010355)	
Length	85 mm
Product Name	Tahoe Light Kings Box
Package Size	20 cigarettes per pack
Valu Time Menthol 100's (SE0003521 & SE0010356)	
Length	100 mm
Product Name	Tahoe Menthol 100's
Package Size	20 cigarettes per pack
Valu Time Menthol Kings Box (SE0003522 & SE0010357)	
Length	85 mm
Product Name	Tahoe Menthol Kings
Package Size	20 cigarettes per pack

Valu Time Silver 100's (SE0003523 & SE0010358)	
Length	100 mm
Product Name	Tahoe Ultra Light 100's
Package Size	20 cigarettes per pack
Valu Time Teal Menthol 100's (SE0003524 & SE0010359)	
Length	100 mm
Product Name	Tahoe Menthol Light 100's
Package Size	20 cigarettes per pack

All of the predicate tobacco products are manufactured by S&M Brands, Inc. They are all combustible filtered cigarettes.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted 22 original SE Reports listed in Table 2 of this review. FDA sent the applicant administrative advice and information (A/I) request letters for these SE Reports. In response, the applicant submitted amendments to the original SE Reports (see Table 2). Following our review of the original and amended SE Reports, we sent scientific A/I letters to the applicant in August 2012 for SE0003503 – SE0003508, SE0003510, and SE0003511, in October 2012 for SE0003509, and in November 2012 for SE0003512-SE0003524. The applicant responded to the scientific A/I letters by amending their SE Reports (see Table 2). On April 3, 2013 FDA sent an email and on August 27, 2013, FDA called the applicant to clarify some pending issues. In response, the applicant submitted amendments SE0008151 and SE0009623 on April 3, 2013, and August 27, 2013, respectively. Following review of the amended SE Reports, FDA sent a Preliminary Finding letter to the applicant in November 2013. The applicant responded to the Preliminary Finding letter by amending their SE Reports (see Table 2). In response, the applicant submitted additional amendments (SE00010201 and SE0010286). FDA held a face-to-face meeting with the applicant on March 26, 2014, to address the applicant's questions regarding the Preliminary Finding letter. The applicant did not amend its SE Reports following the meeting. On April 4, 2014, FDA initiated a teleconference with the applicant to clarify some pending issues. In response, the applicant submitted amendment SE0010378 on April 11, 2014.

On April 15, 2014, FDA sent acknowledgement correction letters for SE0003503-SE0003524 to identify "Cigarette paper" as the "additional tobacco product identification." On April 14, 2014, FDA sent acknowledgement letters for SE0010338-SE0010359, identifying the (b) (4) (b) (4) as the "additional tobacco product identification." The administrative record for the (b) (4) (b) (4) has been copied from the original STNs to the corresponding new STNs. On May 29, 2014, FDA initiated a teleconference with the applicant to clarify which materials were present in the predicate tobacco products on or around February 15, 2007 (i.e., were present in the grandfathered products). In response, the applicant submitted amendment SE0010517

clarifying that (b) (4)

(b) (4) for the new and predicate products for SE0003503-SE0003524. Further, the applicant wishes to maintain the SE Reports for SE0003503-SE0003524 (b) (4) and SE0010338-SE0010359 for (b) (4). For all 44 SE Reports, the applicant will (b) (4)

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
Riverside Blue 100's	SE0003503	SE0004152 SE0004185 SE0004377 SE0004975 SE0004997 SE0005332 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Blue Kings	SE0003504	SE0004152 SE0004377 SE0004975 SE0004997 SE0005335 SE0008151 SE0009605 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Riverside Blue Kings Box	SE0003505	SE0004127 SE0004152 SE0004377 SE0004975 SE0004997 SE0005346 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Filter 100's	SE0003506	SE0004078 SE0004152 SE0004377 SE0004975 SE0004997 SE0005333 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Riverside Filter Kings Box	SE0003507	SE0004152 SE0004184 SE0004377 SE0004975 SE0004997 SE0005341 SE0007808 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Filter Kings	SE0003508	SE0004152 SE0004182 SE0004377 SE0004975 SE0004997 SE0005336 SE0007809 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Riverside Menthol 100's	SE0003509	SE0004152 SE0004160 SE0004377 SE0004997 SE0005018 SE0005331 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Menthol Kings	SE0003510	SE0004152 SE0004161 SE0004377 SE0004975 SE0004997 SE0005339 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Riverside Menthol Kings Box	SE0003511	SE0004152 SE0004181 SE0004377 SE0004975 SE0004997 SE0005334 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Silver 100's	SE0003512	SE0004152 SE0004377 SE0004553 SE0005329 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Riverside Silver Kings	SE0003513	SE0004152 SE0004377 SE0004551 SE0005345 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Teal Menthol 100's	SE0003514	SE0004152 SE0004377 SE0004552 SE0005330 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Riverside Teal Menthol Kings	SE0003515	SE0004152 SE0004377 SE0004555 SE0005340 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Valu Time Filter 100's	SE0003516	SE0004152 SE0004377 SE0004554 SE0005338 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Valu Time Filter Kings	SE0003517	SE0004152 SE0004377 SE0004556 SE0005354 SE0007810 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Valu Time Filter Kings Box	SE0003518	SE0004151 SE0004152 SE0004377 SE0005353 SE0007811 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Valu Time Gold 100's	SE0003519	SE0004079 SE0004152 SE0004377 SE0005342 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Valu Time Gold Kings Box	SE0003520	SE0004080 SE0004152 SE0004377 SE0005352 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Valu Time Menthol 100's	SE0003521	SE0004129 SE0004152 SE0004377 SE0005356 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Valu Time Menthol Kings Box	SE0003522	SE0004126 SE0004152 SE0004377 SE0005355 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

Product Name	SE Report	Amendments
Valu Time Silver 100's	SE0003523	SE0004128 SE0004152 SE0004377 SE0005343 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517
Valu Time Teal Menthol 100's	SE0003524	SE0004150 SE0004152 SE0004183 SE0004377 SE0005344 SE0008151 SE0009623 SE0010012 SE0010084 SE0010166 SE0010201 SE0010286 SE0010378 SE0010478 SE0010504 SE0010517

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0003503-SE0003524 and SE0010338-SE0010359. It should be noted that SE0010338-SE0010359 were not created until April 14, 2014, so the reviews discussed in this memo only discuss SE0003503-SE0003524 (see section 1.2 of this review). However, because SE0010338-SE0010359 are identical to SE0003503-SE0003524, the conclusions regarding SE0003503-SE0003524 in all of the reviews also apply to SE0010338-SE0010359.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

Cigarette paper change from non-FSC to FSC

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by the following reviewers on the following dates:

- SE0003503: Devin Thomas, M.P.H., on February 29, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003504, SE0003507, SE0003508, SE0003511: Devin Thomas, M.P.H., on March 1, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003505: Nathan Hurley on February 29, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003506, SE0003519, SE0003520: Sarah Lee, M.P.H., on December 27, 2011, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003509, SE0003510: Devin Thomas, M.P.H., on February 17, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003512, SE0003513, SE0003514: Devin Thomas, M.P.H., on May 23, 2012, and Stephanie Durkin, M.S., on September 24, 2013
- SE0003515, SE0003516: Devin Thomas, M.P.H., on May 24, 2012, and Stephanie Durkin, M.S., on September 24, 2013
- SE0003517: Devin Thomas, M.P.H., on May 24, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003518: Theodore Riley, M.S., on February 2, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003521, SE0003522, SE0003523: Idara Udoh, M.S., on January 24, 2012, and Stephanie Durkin, M.S., on June 7, 2013
- SE0003524: Theodore Riley, M.S., on February 6, 2012, and Stephanie Durkin, M.S., on September 24, 2013

The final administrative completeness reviews concluded that these 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 April 9, 2012, for SE0003503-SE0003511, June 22, 2012, for SE0003512-SE0003515, SE0003523-SE0003524 and June 19, 2012 for

SE0003516-SE0003522 conclude that the predicate tobacco products are eligible predicate tobacco products, as the applicant has established that the predicate tobacco products are grandfathered.¹

The Office of Compliance and Enforcement (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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE reviews dated May 23, 2014 and June 25, 2014, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews² were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews for SE0003503-SE0003511 were completed by Matthew Walters, Ph.D. on June 26, 2012, Kimberly Agnew-Heard, Ph.D. on May 16, 2013, and Kimberly Agnew-Heard, Ph.D. on April 30, 2014.

Chemistry reviews for SE0003512-SE0003524 were completed by Kimberly Agnew-Heard, Ph.D. on September 25, 2012, Kimberly Agnew-Heard, Ph.D. on May 16, 2013, and Kimberly Agnew-Heard, Ph.D. on April 30, 2014.

The final chemistry review concludes that the new tobacco products do not raise different questions of public health with regard to product composition or TNCO yields. Initially, the new and predicate tobacco products could not be adequately characterized since the applicant did not provide all complete and accurate information about the ingredients in the new and predicate tobacco products. However, the applicant amended its SE Reports to provide this information; there were not significant differences in product composition between the new and corresponding predicate tobacco products other than the change from non-FSC to FSC cigarette paper. Tobacco blends for the new and corresponding predicate tobacco products are identical, and most ingredients are identical or similar between the new and corresponding predicate products. (b) (4)

[REDACTED]

¹ Addendum reviews were completed in 2013 to include the package type, package count, and cigarette length for the predicate tobacco products; the conclusions in these addendum reviews did not differ from that in the original 2012 reviews.

² As noted in section 1.2 of this memo, the scientific reviews were completed for SE0003503-SE0003524. However, the scientific reviews evaluated (b) (4) [REDACTED], so the conclusions for SE0003503-SE0003524 also apply to SE0010338-SE0010359.

(b) (4) . Therefore, the product composition of the new tobacco products does not raise different questions of public health.

4.2. ENGINEERING

Engineering reviews for SE0003503-SE0003511 were completed by Chris Brown³ on June 26, 2012, Chris Brown on May 23, 2013, and Chris Brown on April 30, 2014.

Engineering reviews for SE0003512-SE0003524 were completed by Chris Brown on October 2, 2012, Chris Brown on May 23, 2013, and Chris Brown on April 30, 2014.

The final engineering review concludes that the new tobacco products do not raise different questions of public health with regard to product design. Initially, the new and predicate tobacco products could not be adequately characterized since the applicant did not provide all the design parameters specifications or test data. Additionally, numerous design specifications or test data were inconsistent or contained typographical errors. Complete design parameter specifications and test data are used to accurately evaluate the substantial equivalence of the new and corresponding predicate products. The omitted design specifications, test data, and typographical errors were all sufficiently addressed by the applicant. (b) (4)

Therefore, the product design of the new tobacco products does not raise different questions of public health.

4.3. TOXICOLOGY

A toxicology review for SE0003503-SE0003511 was completed by Michael Orr, Ph.D., DABT, on July 26, 2012.

A toxicology review for SE0003512-SE0003524 was completed by Michael Orr, Ph.D., DABT, on October 4, 2012

The final toxicology review concludes that the new tobacco products do not raise different questions of public health with regard to product toxicity. The toxicology review focused on the toxicity of non-FSC compared to FSC cigarette paper.

³ Except the review for SE0003503 was completed by Sabina Reilly.

(b) (4)



However, based on the literature and information provided to CTP to date, the toxicological weight of evidence does not support that these new products using FSC cigarette paper are more toxic to consumers than the predicate products using non-FSC cigarette paper. A change to FSC cigarette paper in the new tobacco products can reduce the number of deaths of smokers and non-smokers due to fatal house fires. Therefore, the toxicology review concludes that the new tobacco products do not raise different questions of public health.


It should be noted that the toxicology review did not evaluate HPHC data. The toxicology review also noted errors or incomplete information regarding ingredient listings. These issues were addressed by the chemistry reviewer (see section 4.1 of this memo).

4.4. SOCIAL SCIENCE

A social science review for SE0003503-SE0003524 was completed by Sarah Johnson on April 19, 2013. A revised social science review for SE0003503-SE0003524 was conducted by Sarah Johnson on June 17, 2014 to revise the STNs used to identify the products in the April 19, 2013 review since amendment STNs had been used.

The social science review evaluated the health information summary to determine its compliance with section 910(a)(4) of the FD&C Act. The review concludes that the health information summary is acceptable.

⁴ (b) (4)



5. ENVIRONMENTAL DECISION

An environmental assessment was provided by the applicant. A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 24, 2014. The FONSI was supported by an environmental assessment prepared by Rudaina Alrefai-Kirkpatrick, Ph.D. dated June 24, 2014.

6. CONCLUSION AND RECOMMENDATION

The new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

Cigarette paper change from non-FSC to FSC

Initially, the new and predicate tobacco products could not be adequately characterized since the applicant did not provide all complete and accurate information about the ingredients in the new and predicate tobacco products. However, the applicant amended its SE Reports to provide this information; there were not significant differences between the new and corresponding predicate tobacco products other than the change from non-FSC to FSC cigarette paper. Based on the literature and information provided to CTP to date, the toxicological weight of evidence does not support that these new products using FSC cigarette paper are more harmful to consumers than the predicate products using non-FSC cigarette paper. A change to FSC cigarette paper in the new tobacco products can reduce the number of deaths of smokers and non-smokers due to fatal house fires.

(b) (4)

Therefore, the new tobacco products do not raise different questions of public health.

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. 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.

In addition, order letters can be issued because 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 SE0003503-SE0003524 and SE0010338-SE0010359, as identified on the cover pages of this memo.