

Primary STN: SE0003730, SE0003731

Reviewer: Megan Schroeder Ph.D.

New Product Name: Newport Non-menthol Gold Box 100s, Newport Non-menthol Gold Box



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Center for Tobacco Products  
Office of Science

### Addiction Review of 905(j)(1)(A)(i) Report

Submission	
Primary STN	SE0003730, SE0003731
Submission Date	
Applicant	Lorillard Tobacco Company
FDA Establishment Identifier (FEI)	
Product Type	<input checked="" type="checkbox"/> Introduction of New Product <input type="checkbox"/> Modification of Existing Product
Submission Summary	Substantial Equivalence Report for "Newport Non-menthol Gold Box 100s" using "2007 Newport Lt M 100 Hard Box" as the predicate product. Substantial Equivalence Report for "Newport Non-menthol Gold Box" using "2007 Newport Lt M 80 Hard Box" as the predicate product.
Related STNs	
New Product	
Name	Newport Non-menthol Gold Box 100s, Newport Non-menthol Gold Box
Package Size	
Product ID	
Product Category	<input checked="" type="checkbox"/> Cigarette <input type="checkbox"/> Roll-Your-Own <input type="checkbox"/> Cigarette Tobacco <input type="checkbox"/> Smokeless <input type="checkbox"/> Pipe Tobacco <input type="checkbox"/> Hookah Tobacco <input type="checkbox"/> Cigars <input type="checkbox"/> Bidis <input type="checkbox"/> Kreteks <input type="checkbox"/> ENDS <input type="checkbox"/> Other
Product Sub-Category	Menthol cigarette
Product Use	<input checked="" type="checkbox"/> For Consumer Use <input type="checkbox"/> For Further Manufacturing
Product Type	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Component <input type="checkbox"/> Part <input type="checkbox"/> Accessory

Reviewer name: Megan Schroeder  
CTP/OS

Signature: (b) (6)  
Date: 6/12/13

Team Leader name: Allison Hoffman  
CTP/OS

Signature: (b) (6)  
Date: 6/12/2013

Concur  Non-concur (see separate memo)

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## Executive Summary

### Comparative Information

The applicant states that new products SE0003730 and SE0003731 have the same characteristics as their respective predicate products or do not raise different questions of public health.

We find several product characteristics related to tobacco addiction to be different between these new products and their predicate products.

**Menthol** has been eliminated in the new products as compared to their predicate products:

- SE0003730
  - (b) (4) (b) (4) mg in predicate product
  - (b) (4) (b) (4) mg in predicate product
- SE0003731
  - (b) (4) (b) (4) mg in predicate product
  - (b) (4) (b) (4) mg in predicate product

(b) (4) levels are decreased in the new products as compared to their predicate products:

- SE0003730
  - (b) (4) mg in predicate product, (b) (4) mg in new product
- SE0003731
  - (b) (4) mg in predicate product, (b) (4) mg in new product

(b) (4)

- SE0003730
  - (b) (4)
  - (b) (4)

These changes were not found to pose different questions of public health.

### Comments to be Conveyed to Applicant

#### Required Information - Deficiencies

None: The provided information associated with tobacco addiction is sufficient to support an SE determination.

## Background

### Predicate Product Information

Table 1. Predicate Products

Predicate Product	2007 Newport Lt M 100 Hard Box
New Product	Newport Non-menthol Gold Box 100s

This predicate product is a mentholated cigarette. The applicant claims that the predicate product is a grandfathered product. CTP's Office of Compliance and Enforcement (OCE) has determined that the predicate product is a grandfathered product.

Predicate Product	2007 Newport Lt M 80 Hard Box
New Product	Newport Non-menthol Gold Box

This predicate product is a mentholated cigarette. The applicant claims that the predicate product is a grandfathered product. CTP's Office of Compliance and Enforcement (OCE) has determined that the predicate product is a grandfathered product.

### Scope of Review

This review identifies issues related to nicotine addiction in SE0003730 and SE0003731. Because these applications are similar in scope, they will be discussed together in this review.

This Addiction review evaluates whether or not these new products may influence tobacco initiation, cessation, or other aspects of tobacco dependence differently than their predicate products.

## Evaluation of Submission

Nicotine yields in the new products were measured with (b) (4)

(b) (4)

However, data

(b)

(4)

was

provided in each application, and (b) (4) (and further described in SE amendments). The application provides nicotine yields for the new product (b) (4)

. The (b) (4)

nicotine yields in

the new products are within the predicate products' previously established (b) (4) of (b) (4) for nicotine. (b) (4) is not significantly different between new and predicate products and is therefore unlikely to raise different issues of public health relating to (b) (4).

**Table 2. Nicotine Yield in New Products.**

New product	(b) (4) Yield (mg/cig)	(b) (4) Yield (mg/cig)	Predicate Product (b) (4) yield (mg/cig, upper and lower limits)
SE0003730	(b) (4)	(b) (4)	(b) (4)
SE0003731	(b) (4)	(b) (4)	(b) (4)

Menthol, a characterizing flavor, was removed in the new products whereas both predicate products contain this compound. (b) (4)

and (b) (4). These characterizing flavors contribute to a tobacco product's palatability, and may influence initiation behaviors, nicotine dependence, and continued use (Villanti, Richardson, Vallone, & Rath, 2013), (Henningfield, Hatsukami, Zeller, & Peters, 2011). Furthermore, menthol as a characterizing flavor may increase the likelihood of initiation and the level/severity of dependence, and/or decrease the likelihood of cessation success (Foulds, Hooper, Pletcher, & Okuyemi, 2010; Ahijevych & Garrett, 2010; Hoffman & Simmons, 2011; Hoffman & Miceli, 2011). Thus, while the addition of menthol may pose different questions of public health as related to addiction, the removal of menthol as a characterizing flavor between the new and predicate products compared here does not.

Elimination of menthol was associated with a decrease in (b) (4) levels in both products. However, it is unlikely that this will affect issues of public health related to product initiation and tobacco addiction.

## Conclusions

Lorillard Tobacco Company submitted an SE application for two products, SE0003730 and SE0003731, for substantial equivalence status. Each new product has a different predicate product to which the company claims it is substantially equivalent. (b) (4) does not appear to be different between the new products and the predicate products, and therefore is unlikely to raise different issues of public health. Menthol has been removed (and thus ethyl

alcohol levels have been reduced), however this was not found to raise different issues related to addiction-related public health questions.

Therefore, it is concluded that both SE0003730 and SE0003731 are substantially equivalent to the predicate product.

## References

Ahijevych, K. & Garrett, B. E. (2010). The role of menthol in cigarettes as a reinforcer of smoking behavior. *Nicotine Tob Res.*, 12 Suppl 2, S110-S116.

ntq203;10.1093/ntr/ntq203

Foulds, J., Hooper, M. W., Pletcher, M. J., & Okuyemi, K. S. (2010). Do smokers of menthol cigarettes find it harder to quit smoking? *Nicotine Tob Res.*, 12 Suppl 2,

S102-S109. ntq166;10.1093/ntr/ntq166

Henningfield, J. E., Hatsukami, D. K., Zeller, M., & Peters, E. (2011). Conference on abuse liability and appeal of tobacco products: conclusions and recommendations.

*Drug and alcohol dependence*, 116, 1-7. S0376-8716(11)00030-

5;10.1016/j.drugalcdep.2010.12.009

Hoffman, A. C. & Miceli, D. (2011). Menthol cigarettes and smoking cessation behavior. *Tob Induc.Dis.*, 9 Suppl 1, S6. 1617-9625-9-S1-S6;10.1186/1617-9625-9-S1-S6

Hoffman, A. C. & Simmons, D. (2011). Menthol cigarette smoking and nicotine dependence. *Tob Induc.Dis.*, 9 Suppl 1, S5. 1617-9625-9-S1-S5;10.1186/1617-9625-9-S1-S5

Primary STN: SE0003730, SE0003731

Reviewer: Megan Schroeder Ph.D.

New Product Name: Newport Non-menthol Gold Box 100s, Newport Non-menthol Gold Box

Villanti, A. C., Richardson, A., Vallone, D. M., & Rath, J. M. (2013). Flavored tobacco product use among u.s. Young adults. *Am J Prev.Med.*, 44, 388-391. S0749-3797(12)00939-7;10.1016/j.amepre.2012.11.031

**2<sup>nd</sup> Cycle Chemistry Review of SE Reports  
Submitted by Lorillard Tobacco Company for  
Conventional Filtered Cigarettes**

<b>SE0003730: Newport Non-Menthol Gold Box 100s</b>	
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2003906 (internal) (UPC 0-26100-00661-2)
<b>SE0003731: Newport Non-Menthol Gold Box</b>	
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2003905 (internal) (UPC 0-26100-00660-5)
<b>Common Attributes of SE Reports</b>	
Applicant	Lorillard Tobacco Company
Status	Regular
Common characteristic(s)	Switch to FSC paper and removal of menthol
Product Category	Cigarette
Product Sub-Category	Conventional Filtered
Product Use	Consumer Use
Product Type	Complete Product
<b>Recommendation</b>	
Issue Substantial Equivalence (SE) orders for SE0003730 and SE0003731.	

Reviewer: Zhong Li, Ph.D.

Signature: (b) (6)

Date: March 1, 2013

Team Leader: Matthew Walters, Ph.D.

Signature: (b) (6)

Date: 3/1/2013 Concur Non-concur (see separate memo)



2<sup>nd</sup> Cycle Chemistry Review of SE Reports Submitted by  
Lorillard Tobacco Company for Conventional Filtered Cigarettes

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2<sup>nd</sup> Cycle Chemistry Review of SE Reports Submitted by  
Lorillard Tobacco Company for Conventional Filtered Cigarettes

**1. BACKGROUND**

**1.1. PREDICATE INFORMATION**

The applicant has submitted the following predicate products:

**Table 1. Predicate Products**

Newport Non-Menthol Gold Box 100s (SE0003730)	
Name	2007 Newport Lights Menthol 100s Hard Box <sup>1</sup>
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2000241 (internal) (UPC 0-26100-00572-1)
Newport Non-Menthol Gold Box (SE0003731)	
Name	2007 Newport Lights Menthol 80 Hard Box <sup>2</sup>
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2000314 (internal) (UPC 0-26100-00576-9)

Both of the predicate products are conventional filtered cigarettes. The applicant claims they are grandfathered products. The applicant stated that the predicate products are no longer on the market.

**1.2. BASIS FOR SUBSTANTIAL EQUIVALENCE CLAIM**

The applicant claims that the predicate and new products have the same characteristics (sec. 910(a)(3)(A)(i)).

**1.3. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

The applicant submitted original SE Reports on October 12, 2011. FDA's Center for Tobacco Products (CTP) sent the applicant administrative advice and information (A/I) request letters for the SE Reports. In response, the applicant submitted amendments to the SE Reports in February 2012. Following FDA review of the original and amended SE Reports, CTP sent scientific A/I letters to the applicant in October 2012 citing specific deficiencies to be addressed. The applicant responded to the scientific A/I letters by amending their SE Reports in December 2012. On February 1, 2013, additional clarifications were requested through a teleconference with the applicant. The applicant responded with an amendment dated February 8, 2013.

<sup>1</sup> This is the predicate product name provided in SE0003730, which was compared to the new product in all characteristics except HPHCs in the original SE Report. (b) (4)

The amendment SE0005253 compared the HPHCs in the new product to the predicate product, 2007 Newport Lt M 100 Hard Box.

<sup>2</sup> This is the predicate product name provided in SE0003731, which was compared to the new product in all characteristics except HPHCs in the original SE Report. (b) (4)

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**Table 2. SE Reports Considered in this Review<sup>3</sup>**

Product Name	Original SE Report	Amendments
Newport Non-Menthol Gold Box 100s	SE0003730	<b>SE0004149</b> <b>SE0005253</b> <b>SE0007185</b>
Newport Non-Menthol Gold Box	SE0003731	<b>SE0004148</b> <b>SE0005305</b> <b>SE0007186</b>

#### 1.4. SCOPE OF REVIEW

This review constitutes the 2<sup>nd</sup> cycle review of the chemistry issues identified in SE0003730 and SE0003731. This review focuses on the deficiencies identified in the scientific A/I letters sent in October 2012, amendments SE0005253, SE0005305, SE0007185, and SE0007186 (bolded in Table 2 of this review).

## 2. EVALUATION OF SUBMISSION

### 2.1. REQUIRED INFORMATION

This section of the review includes the chemistry deficiencies (required information)<sup>4</sup> identified in the A/I letter that FDA sent on October 26, 2012, as well as the evaluation of the submitted information.

#### Deficiency #1

In two parts of your SE reports (Section 4 and Appendix C), some quantities of ingredients are missing or a value was not reported. It is unclear whether these ingredients were not detected (below the detection limit) or were not present. Explain the missing values or supply the appropriate values.

#### Evaluation

The applicant has adequately addressed this deficiency. The applicant stated that the quantities of ingredients that were missing or where a value was not reported is due to the fact that these ingredients or materials were not present either in the new products or in the predicate products. The new products do not contain all ingredients that were used in the menthol (b) (4) in the predicate products and do not use FSC cigarette paper. The applicant provided revised lists of ingredient and materials with complete information requested by FDA. The revised lists have been examined and appear to be acceptable. (b) (4)

<sup>3</sup> The amendments submitted in response to our scientific A/I letters are shown in bold.

<sup>4</sup> Note that the numbering of deficiencies in this review aligns with that in the A/I letters.

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The removal of the (b) (4) from the product is not expected to have an adverse impact on the amount of (b) (4) nicotine in the product containing (b) (4) of total nicotine. Overall, there are no differences in identity or quantities of ingredients and additives between the predicate products and corresponding new products that would raise different questions of public health.

**Deficiency #2**

Your SE reports provide information about the tobacco and other ingredients in the new and predicate products. However, the information provided does not include sufficient detail to fully identify the composition of the predicate and new products. We need any other information you may have that uniquely identifies the tobacco used in the new and predicate products. This is the information that you rely on to ensure that the tobacco used in the new and predicate products provide the same consumer experience for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each tobacco used in the new and predicate products. For other ingredients, it would be helpful to know the grade of each ingredient as an example. If this information is identical for ingredients and additives in the predicate and new products, provide the information for the new product and a statement that this information is the same in the predicate product. Lastly, provide this information for all packaging materials.

**Evaluation**

The applicant has adequately addressed this deficiency.

**Tobacco**

The applicant provided information on its proprietary grading system for tobacco grades by (b) (4) within a specific tobacco type (e.g., burley, flue-cured, oriental). This portion of the applicant's response is acceptable.

The tobacco grade information provided by the applicant has been examined. For SE0003730, the new product and the predicate product contain the same percentages of (b) (4)

(b) (4), but individual grades of (b) (4) tobacco differ between the products as shown in Table 3 below. For SE0003731, individual tobacco grades and percentages (b) (4)

(b) (4). It is also noted that the (b) (4) used in the new product of SE0003730 appears to be identical to that used in the predicate and new products of SE0003731.

**Table 3. Comparison of Tobacco Grades (SE0003730)\***

Tobacco Grades	Quantity (% of tobacco filler)		Difference (%)
	New Product	Predicate Product	
(b) (4)			

(b) (4)

The burley tobacco from the upper stalk position and the flue-cured tobacco from the leaf stalk position are generally considered as flavor/modifier grades that impart a specific flavor contribution to the smoke with the desired degree of irritation<sup>5</sup>. On the other hand, the lower stalk position grades are normally used as fillers that contribute much less to the flavor of the tobacco products. Therefore, the changes in tobacco grades from flavor grades to filler grades and vice versa may have a potential impact on the flavor and taste characteristics of a tobacco product. (b) (4)

The position of the leaf on the stalk can influence the chemical levels in harvested tobacco leaves that will eventually affect the levels of chemical constituents in cigarette smoke<sup>6</sup>. It is possible that the changes in individual tobacco grades can have an effect on the HPHC composition and yield of a tobacco product. However, as discussed in section 2.2 of this review, the HPHC composition and yields resulting from the tobacco grade modification does not seem to be significant. Therefore, the changes in individual tobacco grades do not appear to raise different questions of public health.

**Ingredients other than Tobacco**

The applicant stated that all non-tobacco ingredients and materials are identical in the new and predicate products, except for the menthol (b) (4), cigarette paper, plug wrap, and tipping paper. Cigarette paper was changed from non-FSC paper to FSC paper. Tipping paper was changed from pre-perforated paper (b) (4)

<sup>5</sup> Phil Fisher, Tobacco Production, Chemistry and Technology, Chapter 11A, 1999.

<sup>6</sup> A Report of the Surgeon General, How Tobacco Smoke Causes Disease, Chapter 3, P78, 2010.

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Lorillard Tobacco Company for Conventional Filtered Cigarettes

The applicant provided information on the grades of the ingredients used in the tobacco blends, which are either food grade or U.S.P. grade. The applicant stated that (b) (4)

(b) (4). The applicant's statement about (b) (4) is consistent with what we know about these materials. Therefore, because the ingredients in the filler do not appear to differ between the new and predicate products and the identity and quantities of all ingredients and additives were included in the SE Report, the ingredients and additives do not raise different questions of public health. This portion of the applicant's response is acceptable.

#### **Packaging Materials**

The applicant stated that Lorillard uses industry standard boxes, cartons, and cases to package its products and all packaging materials are identical between the new and predicate products with the exception of the (b) (4) (b) (4) (b) (4)

(b) (4). In addition, the graphics appearing on the box, carton, and case were changed to accommodate branding of the new products and current regulatory requirements. The applicant also stated in the submission that (b) (4)

The minor differences in packaging material for the predicate products and corresponding new products do not raise different questions about public health. This portion of the applicant's response is acceptable.

Overall, there are no differences in the grades of tobacco and non-tobacco ingredients between the predicate product and corresponding new product that would raise different questions in public health.

#### **Deficiency #3**

Your SE reports provide TNCO data for the predicate and new products. However, your SE reports lack information necessary to fully evaluate the data. Provide the following information about HPHC testing so that we can fully evaluate the differences in HPHC quantities in the two products:

- a. Testing laboratory or laboratories
- b. Length of time between date(s) of manufacture and date(s) of testing
- c. Storage conditions prior to initiating testing

In addition, provide full test data (including test protocols, any deviations from test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) for all testing performed.

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**Evaluation**

The applicant has adequately addressed this deficiency. The applicant provided [REDACTED] (b) (4)

The submitted information has been examined and appears to be appropriate. The testing laboratories that were used to generate the TNCO and HPHC data are accredited as satisfying [REDACTED] (b) (4) with a scope that includes all of the testing methods used for the product analysis in the submission(s). The data provided by the applicant are discussed in section 2.2 of this review.

**2.2. REQUESTED INFORMATION**

This section of the review includes the chemistry information requested<sup>b</sup> in the AI letter that FDA sent on October 26, 2012, as well as an evaluation of the submitted information.

**Request #8**

Your SE reports provide TNCO data [REDACTED] (b) (4). However, FDA cannot fully understand the public health impact of the predicate and new products without information on the amounts of a given HPHC produced under both intense and non-intense conditions. HPHC quantities measured under an intense smoking regimen would provide the maximum expected quantity of HPHCs produced for each product. Submit test results for TNCO [REDACTED] (b) (4) regimen, providing full test data (including test protocols, deviations from test protocols, quantitative acceptance (pass/fail) criteria, complete data sets, and summaries of the results) for all testing performed.

**Evaluation**

The applicant has adequately addressed this deficiency. The applicant provided [REDACTED] (b) (4) under [REDACTED] (b) (4) for the new and predicate products in SE0003730 and the new product in SE0003731.

For the predicate product in SE0003731, the applicant only provided TNCO data [REDACTED] (b) (4)

<sup>b</sup>Note that the numbering of requested information in this review aligns to that in the AI letters.

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(b) (4)



The applicant provided TNCO data for the new and corresponding predicate products in both SE Reports, in response to the deficiency in the A/I letter. The deficiency in the A/I letter is limited to TNCO and does not include other HPHCs because (b) (4)

The differences between the new and corresponding predicate products (i.e., addition of FSC paper and removal of menthol) do not pose any unique public health concerns that would require additional HPHC data. (b) (4)

The data provided by the applicant are summarized in Appendixes 1-2 of this review. This portion of the applicant's response is acceptable. The HPHC data, including TNCO, provided by the applicant is examined and discussed below.

**HPHC Data for SE0003730**

Appendix 1 of this review summarizes the HPHC and smoke pH data (b) (4) for the predicate product<sup>9</sup> and corresponding new product (Newport Non-Menthol Gold Box 100s cigarettes). (b) (4)

The observed differences in TNCO and smoke pH between the new and predicate products do not raise different questions of public health. The toxicology review will address the other HPHC data submitted (b) (4) in this SE Report.

**HPHC Data for SE0003731**

Appendix 2 summarizes the HPHC and smoke pH data for the predicate product and corresponding new product (Newport Non-Menthol Gold Box cigarettes). (b) (4)

<sup>9</sup> (b) (4)





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(b) (4)

Hence, there are no differences in TNCO yields between the predicate and new products for SE0003731 that would raise different questions of public health.

### 3. CONCLUSIONS AND RECOMMENDATIONS

The following SE Reports contains sufficient detail to make a final determination of substantial equivalence:

1. Newport Non-Menthol Gold Box 100s (SE0003730)
2. Newport Non-Menthol Gold Box (SE0003731)

In terms of product chemistry, the new and corresponding predicate products for both SE Reports are substantially equivalent. The compositions of the new and corresponding predicate products are nearly identical with the exception of the absence of a menthol (b) (4) and use of a FSC paper in the new products and the difference in the tobacco grades between the Newport Non-Menthol Gold Box 100s (SE0003730) and its predicate product. These differences do not appear to have any significant adverse impact on the smoke compositions and/or yields of the new products based on the TNCO data provided by the applicant. Overall, the chemistry review concludes that there are no significant differences in the identity or quantities of ingredients and additives between the predicate and new products that would lead the new product to raise different questions of public health. If other disciplines also find these products to be substantially equivalent, FDA should issue Substantial Equivalence orders allowing marketing of each of these new products.

It is also recommended that the toxicology reviewer evaluate the HPHC data voluntarily submitted for SE0003730 to determine the relative risk of the new and predicate products.

### 4. APPENDIXES



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Lorillard Tobacco Company for Conventional Filtered Cigarettes

**Appendix 2. Comparison of HPHCs (SE0003731)**

Smoke Component	Unit	New Product	Predicate Product
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)
(b) (4)	mg	(b) (4)	(b) (4)

**OCE/EMC Compliance with the Act Memo for Regular 905(j) Applications**

**1. SUBMISSION INFORMATION**

**STN #:** SE0003730  
**Submission Type:** 905(j) Regular Report  
**Submission Receipt Date:** 10/13/2011

**New Tobacco Product Name:** Newport Non-Menthol Gold Box 100s  
**New Tobacco Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco

**New Tobacco Product Code:** (b) (4)

**Submitter's Name:** Lorillard Inc.  
**Company's Name (if different):**  
**Contact Information:** Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335-7656  
(336) 335-7752 (fax)  
nwilcox@lortobco.com

---

**2. DETERMINATION**

<input checked="" type="checkbox"/> Tobacco product is in compliance with applicable provisions of the FD&C Act.
<input type="checkbox"/> Tobacco product is not in compliance with applicable provisions of the FD&C Act.

3. SIGN-OFF

<b>Compliance Reviewer:</b> Dan-My Chu	Date: (b) (6) Signature: (b) (6)
<b>Team Leader:</b> Christine M. Smith	Date: 2/1/13 Signature: (b) (6)
<b>Group Leader:</b> Joanna Weitershausen	Date: 2/1/13 Signature: (b) (6)

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that the firm is in compliance with section 919 (user fees) of the FD&C Act and the brandname Newport Non-Menthol Gold Box 100s is in compliance with applicable provisions of the FD&C Act.

(b) (6)

FDY Ann Simoneau, J.D.  
Director, Office of Compliance and Enforcement  
Center for Tobacco Products

2/4/13  
Date

**4. REVIEW OF PROVISIONS**

The new tobacco product must comply with all applicable statutory and regulatory requirements. To determine whether or not the new tobacco product is in compliance with the FD & C Act, a review of the provisions below was conducted. Sections 903, 907 and 911 were evaluated by examining the brand name of the tobacco product only. Section 919 was assessed by a review of CTP's User Fee arrears listing. Tobacco product packaging, advertising, labeling or warning plan (if submitted) were not reviewed.

Provision	In Compliance?	Comments
903(a)(1)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	The name of the new tobacco product is not false or misleading.
907(a)(1)(A)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	The name of the new tobacco product does not contain a characterizing flavor.
911(b)(2)(A)(i)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	The name of the new tobacco product does not purport to have lower risk, less harm, that there is a reduced level or reduced exposure of or to a substance, or that the product or its smoke does not contain or is free of a substance.
911(b)(2)(A)(ii)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	The name of the new tobacco product does not include the descriptors "Light," "Low," or "Mild" or similar descriptors.
919	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	The firm was not found on CTP's arrears list dated January 7, 2013.

**5. CORRESPONDENCE AND SUPPORTING DOCUMENTS**

Tab	Date	From	Description

**1. SUBMISSION INFORMATION**

STN #: GF1200010  
Submission Type: GF Submission  
Submission Receipt Date: 05/04/2012

Tobacco Product Name: Newport Lights Menthol Gold Box 100s (also referred to as 2007 Newport Lights Menthol 100 Hard Box)

Tobacco Category Type:  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:

Tobacco Product Code: (b) (4)

Submitter's Name: Lorillard, Inc.  
Company's Name (if different):  
Contact Information: Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335-7656  
(225) 335-7752 (fax)  
nwilcox@lortobco.com

**2. OCE RECOMMENDATION**

**GF Status:**  
 Established Grandfathered Status  
 Cannot Establish Grandfathered Status

**Predicate Eligibility:**  
 Tobacco product is predicate eligible  
 Tobacco product is not predicate eligible

**NOTE:** This determination was not based on a review of the characteristics of the tobacco product.

**3. SIGN-OFF**

<b>Compliance Reviewer:</b> John Torcivia	Date: 5/29/2012 Signature (b) (6)
<b>Team Leader:</b> Paul Perdue, Jr. Comments:	Date: 5/29/2012 Signature (b) (6)
<b>Group Leader:</b> Joanna Weitershausen Comments:	Date: 5-31-12 Signature (b) (6)
<b>Senior Regulatory Counsel:</b> Emil Wang Comments:	Date: 6/21/12 Signature (b) (6)

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that Newport Lights Menthol Gold Box 100s was commercially marketed as of February 15, 2007 and is eligible to serve as a predicate product in a report under section 905(j) of the FD&C Act.

(b) (6)

Ann Simoneau, J.D.  
Director, Office of Compliance and Enforcement  
Center for Tobacco Products

6/22/12  
Date



**4. TOBACCO PRODUCT INFORMATION**

<b>Product Description</b>
Newport Lights Menthol Gold Box 100s is a mentholated cigarette.
<b>Product Use</b>
The cigarette is lit by the consumer and smoked.

**5. REGULATED TOBACCO PRODUCT DETERMINATION**

<b>Jurisdiction Questions</b>	<b>Yes</b>	<b>No</b>	<b>Comments/rationale, as applicable.</b>
1. Is the product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)? (FD&C Act § 201(rr)(1))	X		
2. Is the product a drug, device, or combination product? (FD&C Act § 201(rr)(2))		X	
3. Is the product marketed in combination with any other article or product regulated under the Act? (FD&C Act § 201(rr)(4))		X	
4. Is the product <i>currently</i> regulated under Chapter IX? If "yes," specify the tobacco product category. (FD&C Act § 901(b))	X		Tobacco product meets the definition of "cigarette" under the Act.
<b>Does CTP currently regulate this tobacco product? ("Yes" response to Questions 1 and 4 and "No" response to Questions 2 and 3.).</b>	X		Cigarette

**6. GF EVIDENCE REVIEW**

**Evidence Demonstrating Commercial Marketing as of February 15, 2007**

<b>Tab</b>	<b>Type of Evidence</b>	<b>Date</b>	<b>Comments</b>
1.C	Bill of Lading	2/12/2007	Bill of Lading #4500028511, Page 1; NPT LT M 100 BX (12M); UPC#00639 Material#1000094
2.C	Bill of Lading	2/16/2007	Bill of Lading #4500028613, Page 1; NPT LT M 100 BX (12M); UPC#00639 Material#1000094

**Other Evidence Submitted**

<b>Tab</b>	<b>Type of Evidence</b>	<b>Date</b>	<b>Comments</b>
	N/A		

**7. PREDICATE ELIGIBILITY EVIDENCE REVIEW**

<b>Tab</b>	<b>Type of Evidence</b>	<b>Date</b>	<b>Test Market Status</b>	<b>Comments</b>
D	Statement	5/4/2012	<input checked="" type="checkbox"/> Not in test market (Predicate Eligible) <input type="checkbox"/> In test market (Not Predicate Eligible)	"We hereby confirm that Newport Lights Menthol Gold Box 100s was not in a test market as of February 15, 2007. At that time, the product was sold nationally." – Neil Wilcox, Senior Vice President & CCO

**8. CORRESPONDENCE**

A	5/3/2012	Dan-My Chu (CTP, OCE, EMG)	Email summary of information requested for grandfathered application.
B	5/3/2012	Patricia Kovacevic (Lorillard)	Email acknowledgement of Tab A correspondence
C	5/4/2012	Patricia Kovacevic (Lorillard)	Email requested for grandfathered review for Newport Lights Menthol Gold Box 100s. Email contained (1) cover letter dated 5/4/2012 from Neil Wilcox, (2) evidence for commercial marketing of grandfathered products, and (3) statement product was not in test market as of February 15, 2007.

**OCE 905(j) Consult Memo: Cross-Reference Grandfathered (GF) Status**

**1. SUBMISSION INFORMATION**

**STN #:** SE0003730  
**Submission Type:**  905(j) Report  905(j) Exemption  
**Submission Receipt Date:** October 13, 2011

**Predicate Name:** Newport Lights Menthol Gold Box 100s (also referred to as 2007 Newport Light Menthol 100 Hard Box)

**Predicate Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:

**Predicate Product Code:** (b) (4)

**New Tobacco Product Name:** Newport Non-Menthol Gold Box 100s  
**New Tobacco Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:

**New Tobacco Product Code:** (b) (4)

**Submitter's Name:** Lorillard Inc.  
**Company's Name (if different):**  
**Contact Information:** Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335-7656  
(225) 335-7752 (fax)  
nwilcox@lortobco.com

**Related Submissions** GF Determination for GF1200010

**2. OCE RECOMMENDATION**

**GF Status 2007 Newport Light Menthol 100 Hard Box:**

- Established Grandfathered Status as per GF1200010. Please see iTRAC for Admin Record.
- Grandfathered Status was denied as per [STN]. Please see iTRAC for Admin Record.

**Predicate Eligibility 2007 Newport Light Menthol 100 Hard Box:**

- Tobacco product is predicate eligible as per GF1200010. Please see iTRAC for Admin Record.
- Tobacco product is not predicate eligible as per [STN]. Please see iTRAC for Admin Record.

**NOTE:** The original GF determination was not made based on a review of the characteristics of the tobacco product.

**3. SIGN-OFF**

<b>Compliance Reviewer:</b> Dan-My Chu Comments:	Date: 6/19/12 Sign: (b) (6)
<b>905(j) Coordinator:</b> Dina Raafat Comments:	Date: 6/19/12 Sign: (b) (6)
<b>Team Leader:</b> Paul Perdue, Jr. or <b>Group Leader:</b> Joanna Weitershausen	Date: 6-21-12 U Sign: (b) (6)

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that 2007 Newport Light Menthol 100 Hard Box was commercially marketed as of February 15, 2007 and is eligible to serve as a predicate product in a report under section 905(j) of the FD&C Act.

(b) (6)

Ann Simoneau, J.D.  
Director, Office of Compliance and Enforcement  
Center for Tobacco Products

6/22/12  
Date



## 2<sup>nd</sup> Cycle Engineering Review of SE Reports Submitted by Lorillard Tobacco Company for Conventional Filtered Cigarettes

<b>SE0003730: Newport Non-Menthol Gold Box 100s</b>	
Package Size	20 cigarettes per pack: 10 packs per carton
Product ID	0-26100-00661-2 (UPC), 2003906 (Internal)
<b>SE0003731: Newport Non-Menthol Gold Box</b>	
Package Size	20 cigarettes per pack: 10 packs per carton
Product ID	0-26100-00660-5 (UPC), 2003905 (Internal)
<b>Common Attributes of SE Reports</b>	
Applicant	Lorillard Tobacco Company
Status	Regular
Product Category	Cigarette
Product Sub-Category	Conventional Filtered
<b>Recommendation</b>	
Issue a Substantial Equivalence (SE) order	

Reviewer: Christopher Brown

Signature: 

Date: March 13, 2013

Team Leader: Sabina Reilly

Signature: 

Date: March 13, 2013

Concur

2<sup>nd</sup> Cycle Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

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## 1. BACKGROUND

### 1.1. PREDICATE INFORMATION

The applicant has submitted the following predicate products:

Table 1. Predicate Products

Newport Non-Menthol Gold Box 100s (SE0003730)	
Name	Newport Lights Menthol Gold Box 100s <sup>1</sup>
Package Size	20 cigarettes per pack; 10 packs per carton
Product ID	0-26100-00572-1 (UPC), 2000241 (Internal)
Newport Non-Menthol Gold Box (SE0003731)	
Name	Newport Lights Menthol Gold Box <sup>2</sup>
Package Size	20 cigarettes per pack; 10 packs per carton
Product ID	0-26100-00576-9 (UPC), 2000314 (Internal)

Both of the predicate products are Conventional Filtered Cigarettes. The applicant claims they are grandfathered products. CTP's Office of Compliance and Enforcement (OCE) has determined that the predicate products (i.e., those called grandfathered products by the applicant) are grandfathered products. The applicant stated that the predicate products are no longer on the market.

### 1.2. BASIS FOR SUBSTANTIAL EQUIVALENCE CLAIM

The applicant claims that the predicate products and corresponding new products have the same characteristics (sec. 910(a)(3)(A)(i)).

### 1.3. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 21, 2011, the applicant submitted the two original SE Reports listed in Table 2 of this review. The applicant was sent an 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 of this review). Following our review of the original and amended SE Reports, another scientific A/I letter was sent to the applicant dated October 26, 2012 citing specific deficiencies to be addressed. The applicant responded to the Scientific A/I letters by amending their SE Reports (see Table 2 of this review). On February 1, 2013, additional clarifications were requested through a teleconference with the applicant. The applicant responded on February 08, 2013, with amendments that were not assigned STNs prior to finalizing this review.

<sup>1</sup> This is predicate product name provided in SE0004149 (response to administrative AI letter). SE0003731 stated predicate product name as "2007 Newport Lt M 100 Hard Box." It is assumed that the predicate products identified in SE0003731 and SE0004149 are the same product.

<sup>2</sup> This is predicate product name provided in SE0004148 (response to administrative AI letter). SE0003731 stated predicate product name as "2007 Newport Lt M 80 Hard Box." It is assumed that the predicate products identified in SE0003731 and SE0004148 are the same product.

2<sup>nd</sup> Cycle Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

**Table 2. SE Reports Considered in this Review<sup>3</sup>**

Product Name	Original SE Report	Amendments
Newport Non-Menthol Gold Box 100s	SE0003730	SE0004149 <b>SE0005253</b> <b>SE0007185</b>
Newport Non-Menthol Gold Box	SE0003731	SE0004148 <b>SE0005305</b> <b>SE0007186</b>

#### 1.4. SCOPE OF REVIEW

This review is the 2<sup>nd</sup> cycle review of the engineering issues identified in SE0003730 and SE0003731. This review focuses on the deficiencies identified in the scientific A/I letter dated October 26, 2012, and the amendments to SE0005253, SE0005305, SE0007185, and SE0007186 (bolded in Table 2 of this review).

## 2. EVALUATION OF SUBMISSION

### 2.1. REQUIRED INFORMATION

This section of the review includes the engineering deficiencies (required information)<sup>4</sup> identified in the A/I letter dated October 26, 2012. This review addresses those engineering deficiencies and any other engineering issues identified in the amendments SE0005253, SE0005305, SE0007185, and SE0007186.

<sup>3</sup> The amendments submitted in response to our scientific A/I letters are shown in bold.

<sup>4</sup> Note that the numbering of deficiencies in this review aligns to that in the A/I letter. Also, note that the deficiencies addressed in this review are those identified in the October 10, 2012 engineering reviews.



**Deficiency No. 4**

Your SE [R]eport includes design features in the predicate and new products. However, your SE [R]eport does not provide sufficient detail on product design to fully identify the predicate and new products. Provide a comprehensive description of the predicate and new products including, but not limited to, the following:

- a. Schematics of the complete product;
- b. Schematics of(sub) components of the product, identify and quantitate the portions of the papers and/or components to which the porosity values apply;
- c. Cigarette nominal diameter (mm);
- d. Cigarette burn rate(s);
- e. Cigarette puff count;
- f. Tipping paper length (mm);
- g. Filter density (mg/cc);
- h. Filter efficiency (%);
- i. Tobacco rod packing density;
- j. Tobacco filler weight (mg);
- k. Tobacco filler cut width (cuts/in);
- l. Filter resistance to draw/pressure drop (mm H<sub>2</sub>O);
- m. Open cigarette resistance to draw/pressure drop (mm H<sub>2</sub>O);
- n. Units of measure for all specifications; and
- o. Porosity for both banded and non-banded sections of FSC ("LIP") paper (CU).

Provide clear identification of the changed elements, such as FSC compliant paper, and explain whether these changes raise new questions of public health. If the design is identical for the new products and respective predicate products, provide the information for the new products and a statement that the design is identical for the predicate products.

**Evaluation**

The applicant has adequately addressed this deficiency. The applicant, as shown in Table 3 of this review, provided design parameters (specifications) that addressed the deficiency with one exception (b) (4) (b) (4) (b) (4). Based on a review of puff count from (b) (4) and TNCO data, the omission does not raise different questions of public health. The applicant provided clear identification of changed elements, and schematics of the new and predicate products.

As shown in Table 3 of this review, the differences in design parameters (feature) between the new products and corresponding predicate products are (b) (4) except for FSC (LIP) cigarette paper porosity. (b) (4)

2<sup>nd</sup> Cycle Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

(b) (4) The decrease in the open cigarette draw resistance was expected due to the increased ventilation in the new products. The pressure drop across the filter shows some increase. The differences do not raise different questions of public health.

However, we identified a few discrepancies in SE0005305 (amendment to SE0003731) and SE0005253 (amendment to SE0003730). CTP communicated the findings to the applicant on February 1, 2013. The applicant submitted amendments SE0007186 and SE0007185 to address the discrepancies as summarized below:

SE0005305 (amendment to SE0003731):

**Discrepancy #1:** The "Tobacco rod packing density" from "Table 4a: Parameter Comparison" (p 00027) appears to be incorrect, since the density as calculated by CTP staff differs from that provided in the amendment.

**Applicant Response:** Lorillard submitted amended Table 4a with revised "Tobacco Rod Packing Density" values to correct "a calculation error" in SE0005305.

**Discrepancy #2:** The "Filter resistance to draw/pressure drop (mm H<sub>2</sub>O)" from "Table 4a: Parameter Comparison" (p 00028) appear to contain a typographic error, since two decimal points are included in the value provided for the draw/pressure drop in Table 4a.

**Applicant Response:** Lorillard submitted amended Table 4a with a revised "Filter Tip Pressure Drop (Measured During Smoke Analysis)" value to correct "a typographical error" in SE0005305.

**Discrepancy #3:** "Figure 4a: Subject Schematics - Product and Sub-Components" (p 00035) shows two LIP paper spacing designs for the new product: one has (b) (4) spacing and (b) (4) band width, and the other has (b) (4) spacing and (b) (4) band width. The schematic is not consistent with Table 4a, which only describes a (b) (4) spacing design, but not an (b) (4) design.

**Applicant Response:** Lorillard submitted amended Table 4a with revised "Cigarette Paper LIP Band Width and Band Spacing" values to reflect the two types of FSC cigarette paper for the new product of SE0003731. The amended Table 4a appears to be consistent with Figure 4a.

2<sup>nd</sup> Cycle Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

SE0005253 (amendment to SE0003730):

**Discrepancy #4:** "Figure 4a: Subject Schematics - Product and Sub-Components" (p 00034) shows two LIP paper spacing designs for the new product: one has (b) (4) spacing and (b) (4) band width, and the other has (b) (4) spacing and (b) (4) band width. The schematic is not consistent with Table 4a, which only describes a (b) (4) design, but not an (b) (4) design.

**Applicant Response:** Lorillard submitted amended Table 4a with revised "Cigarette Paper LIP Band Width and Band Spacing" values to reflect the two types of FSC cigarette paper for the new product of SE0003730. The amended Table 4a appears to be consistent with Figure 4a.

**Discrepancy #5:** "Figure 4c: Predicate Schematics -Product and Sub-Components" (p 00037), shows two LIP paper spacing designs for the predicate product. However, elsewhere in the SE Report, you state that predicate product uses non-LIP cigarette paper.

**Applicant Response:** Lorillard submitted new Figure 4c showing non-LIP cigarette paper to replace the original figure that had been included as a duplicate of Figure 4a in SE0005253 "in error."

After evaluating the aforementioned amendments, this reviewer determined that the applicant adequately addressed discrepancies 1-5 listed formerly identified in Deficiency No. 4 of this review.

[2<sup>nd</sup> Cycle] Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

Table 3. Comparison of Design Parameters

SE#: New Product Name	Cigarette				Tobacco				Tipping Paper		Cigarette Paper				Filter		
	Puff Count	Burn Rate	Diameter	Open Draw Resistance	Filter Weight	Cut Width (Unexpanded)	Cut Width (Expanded)	Reel Packing Density	Length (Bobbin)	Length per Cigarette	Base Paper Porosity	Band Porosity	2 <sup>nd</sup> Paper Band Width**	2 <sup>nd</sup> Paper Band Space**	Efficiency	Density	Pressure Drop (measured)
	n/a	pr/min	mm	mm H <sub>2</sub> O	mg	mg	cut/in	mg/cc	mm	mm	CU	CU	mm	mm	%	mg/cc	mm H <sub>2</sub> O
SE0003730:	<b>New</b>	(b) (4)															
Newport Non-Menthol Gold Box 100s	<b>Predicate Difference (%)</b>																
SE0003731:	<b>New</b>																
Newport Non-Menthol Gold Box	<b>Predicate Difference (%)</b>																

\* (b) (4)  
\*\* Subject of Deficiency

**Deficiency No. 5**

Your SE [R]eport provides values for some design features (e.g., porosity). In order to assess these values, additional information about product design testing and correlation studies is requested. Provide full test data (including test protocols, quantitative acceptance (pass/fail) criteria, data sets, inherent report data (i.e. sampling report) and a summary of the results) for all testing performed, or supplied by the manufacturer or supplier.

**Evaluation**

The applicant has adequately addressed this deficiency. The applicant provided product design testing information for both SE Reports.

The applicant supplies full test data and/or summaries for many of the design features listed in "Table 4a Parameter Comparison" of the amendments and described in Table 3 of this review. Table 5a of the SE Reports titled "Subject and Predicate Component Comparison" provides additional information for some design features. The applicant provided calculated values or explained when data and summaries were unavailable for a design feature.

For amendment SE0005253 design features, the full data and summaries are provided primarily in appendixes 3k (summaries), 3l (full data), 3s (summary) and 3t (full data). For amendment SE0005305 design features, the full data and summaries are provided primarily in appendixes 3k (summaries), 3l (full data), 3p (summary) and 3q (full data).

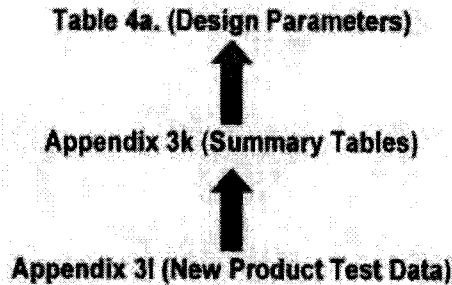
For the amendments to both SE Reports, some full data, such as puff count, is located in the smoke study appendixes. For the amendments to both SE Reports, appendixes 5a through 5j contain:

1. [REDACTED] (b) (4)

An important aspect of the review involves ensuring that design parameter data is accurate. However, when reviewing the amendments, we identified a few discrepancies that need clarification. For both SE Reports, the data in Table 4a, Appendix 3l, and Appendix 3k do not appear to be consistent with each other.

**[2<sup>nd</sup> Cycle] Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes**

For the amendments to both SE Reports, Appendix 3k contains tables that summarize the new product data from Appendix 3l. Table 4a. appears to be the compiled data from the summary tables of Appendix 3k (See Figure 1 of this review).



**Figure 1: Data Flow**

The cigarette weight and other data in Appendix 3k did not correlate with data provided in Tables 4a. For the summary tables provided in Appendix 3k, the [REDACTED] (b) (4) than the source data of Table 3l.

Accuracy of the design parameter data is integral to identification and evaluation of the new and predicate products. The data and summaries help verify the accuracy and determine if the design difference raise different questions of public health.

Therefore, a conference call was held on February 1, 2013, between the applicant and CTP staff to communicate the discrepancies of Deficiency No. 5, identified in this review, to the applicant. On February 8, 2013, the applicant submitted an amendment to address the discrepancies (SE0007185 and SE0007186).

For both SE Reports, the applicant submitted corrections for the following:

1. "Table 4a: Parameter Comparison...,"
2. Appendix 3k summary tables;
3. Appendix 3l individual sample data.

The applicant corrected a number of values in Table 4a. This resulted in the values for [REDACTED] (b) (4)

[REDACTED] The differences between values are considered minor and do not raise different questions of public health.

[2<sup>nd</sup> Cycle] Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

After reviewing the amendment, this reviewer determined that the applicant adequately addressed the discrepancies formerly identified in Deficiency No. 5 of this review.

**Deficiency No. 6**

Your SE [R]eport includes specifications describing the ventilation of the new and predicate product(s). Your SE [R]eport states that the increased ventilation is required to "maintain TNCO values" that otherwise change with the use of FSC paper technology. However, it appears that the increased ventilation levels (b) (4)

Provide additional information supporting and clarifying the need for the (b) (4) ventilation at the levels specified.

**Evaluation**

The applicant has adequately addressed this deficiency. The applicant states that the ventilation changes were necessitated by the change to FSC paper in the new products from the conventional non-FSC paper of the predicate products. In SE0003730, the ventilation increases from (b) (4) (predicate product) to (b) (4) (new product). In SE0003731, the ventilation increases from (b) (4) (predicate product) to (b) (4) (new product). The applicant stated that, for a nearly identical design product, "the filter ventilation design (b) (4)

Due to the similarity of (b) (4)

In the amendment to SE0003730, the applicant stated that the (b) (4) design process was performed for (Newport Menthol Gold Box 100's), a design product nearly identical to the new product (subject). To support the claim, the applicant presents TNCO results (b) (4)

(b) (4) for the new and predicate products and the similar design product (Newport Menthol Gold Box 100's). For SE0003730, the (b) (4) TNCO results show (b) (4) difference between the new and predicate products. Data from Tables 6a and 6b was analyzed. The (b) (4) (b) (4) TNCO values are between (b) (4) for the new product when compared to the predicate product. These differences do not raise different questions of public health and support the applicants claim.

In the amendment to SE0003731, the applicant stated that the same type of (b) (4) process described earlier was performed for (Newport Menthol Gold

[2<sup>nd</sup> Cycle] Engineering Review of SE Reports Submitted by  
Lorillard Tobacco Company For Conventional Filtered Cigarettes

Box), a design product nearly identical to the new product. The applicant presents the (b) (4) TACO results for the new product and design product (Newport Menthol Gold Box) and (b) results for the predicate product. The difference between predicate (b) and new product projected (b) is (b) (4). The projected (b) (4) data from table 8c was used, since the source of Table 6b data, as the data in Table 6b could not be verified. (b) (4)

These differences do not raise different questions of public health.

### **Deficiency No. 7**

Your SE report includes packaging schematics. However, packaging dimensions in the schematics and packaging materials were not included. In order to fully identify the predicate and new products, additional information about the packaging is being requested. Provide annotated illustrations (colored) of the packaging for the predicate and new products that includes dimensions. Provide a packaging material/list for the new and predicate products. For the packaging materials that are identical for the new products and respective predicate products, provide detailed material information for the new products and a statement that this information is identical for the predicate products. Provide a complete list of all components of packaging (film, foil, tear tape, blanks, inks, board, adhesives, etc.), provide side-by-side comparison of the packaging identifying each change.

### **Evaluation**

The applicant has adequately addressed this deficiency. For both the new and predicate products, the applicant provided (b) (4). Additionally, the applicant provided packaging materials lists for the new and predicate products.

## **2.2. REQUESTED INFORMATION**

This section of the review includes the engineering information requested<sup>5</sup> in the AI letter that FDA dated October 26, 2012. This review addresses those engineering request and any other issues related to engineering identified in the amendments SE0005253, SE0005305, SE0007185, and SE0007186.

<sup>5</sup> Note that the numbering of requested information in this review aligns to that in the Scientific AI letter. Also, note that the issues addressed in this review are those identified in the October 10, 2012 engineering reviews.



**Request No. 9**

Your SE [R]eport does not include any information about shelf life for the predicate or new products. Additional information about shelf life is needed to understand specifically how the shelf life is determined for the predicate and new products. Provide detailed shelf life testing including test protocols, quantitative acceptance criteria and a summary of results for all shelf life testing performed. Additionally, provide a description of how the shelf life is indicated on the products. If the shelf life testing is identical for the predicate products and respective new products, provide the information for the new products and a statement that this information is identical for the predicate products.

**Evaluation**

The applicant has adequately addressed this deficiency. The applicant states  
(b) (4)

**3. CONCLUSIONS AND RECOMMENDATIONS**

The following SE Reports contains sufficient detail to make a final determination of substantial equivalence:

1. Newport Non-Menthol Gold Box 100s (SE0003730)
2. Newport Non-Menthol Gold Box (SE0003731)

In terms of product design, the new and corresponding predicate products are substantially equivalent. The primary difference in product design between the new and corresponding predicate products is use of fire standard compliant (FSC) paper in the new products. With this design difference, other design parameters were modified in the new product to provide comparable (b) (4) of the mainstream smoke in the new and predicate products. The design of the new products compared to the corresponding predicate products does not raise different questions of public health. If other disciplines also find these products to be substantially equivalent, FDA should issue Substantial Equivalence orders allowing marketing of each of these new products.

**Environmental Assessment for Market  
Authorization of “Newport Non-Menthol  
Gold Box 100s” Found Substantially  
Equivalent to “2007 Newport Lights  
Menthol 100 Hard Box”**

**Prepared by Center for Tobacco Products**

**US Food and Drug Administration**

**June 4, 2013**

This environmental assessment (EA) is for "Newport Non-Menthol Gold Box 100s," which is the subject of the original SE report SE0003730. This report was amended with additional submissions and communications numbered SE0004149, SE0005253, SE0007185, SE0007199, and TC0000337. Information present in the EA is based on the submissions, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of a submission under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. **Name of Applicant:** Lorillard Tobacco Company
2. **Address:** 714 Green Valley Rd, Greensboro, NC 27408
3. **Manufacturer:** Lorillard Tobacco Company
4. **Description of the Proposed Action:**

The proposed action is to issue a market authorization under section 910(a)(2) of the FD&C Act for the introduction of a new product, "Newport Non-Menthol Gold Box 100s," into interstate commerce. The Agency has found the new product to be "Substantially Equivalent" to a product that was on the market as of February 15, 2007 ("grandfathered product"), the "2007 Newport Lights Menthol 100 Hard Box". Additionally, based on SE0003730 and SE0004149, Lorillard claims that the new product is "essentially the same" as the (b) (4) " " except for the elimination of menthol in the new product. (b) (4)

*Identification of the new tobacco product that is the subject of the proposed action:*

Type of Tobacco Product: Cigarette

Trade name of the new product: Newport Non-Menthol Gold Box 100s

Brand name: Newport

Subbrand (brand variant): Non-Menthol Gold

Size: 100 mm cigarette length (rod+ filter).

Format: Hard box pack

Quantity: 20 cigarettes in each pack, 10 packs per carton

UPC Number: 0-26100-00572-1

FDA-assigned TP number: TP-0004208

Grandfathered Product: 2007 Newport Lights Menthol 100 Hard Box

*Requested action:* An order finding "Newport Non-Menthol Gold Box 100s" substantially equivalent to a predicate tobacco product, "2007 Newport Lights Menthol 100 Hard Box."

*Need for action:* Lorillard wishes to introduce into commercial marketing the new tobacco product "Newport Non-Menthol Gold Box 100s," which is substantially equivalent to the "2007 Newport Lights Menthol 100 Hard Box".

*Location of manufacture:* The tobacco product will be manufactured at Lorillard Tobacco Company's facility in North Carolina, USA. Based on EPA's Toxics Release Inventory (TRI) Program, Lorillard's North Carolina facility is at 2525 E Market St Greensboro, NC 27401.<sup>1</sup>

*Location of use:* The tobacco product will be distributed and sold nationally to consumers for use as a cigarette. Based on the National Adult Tobacco Survey,<sup>2</sup> the distribution of cigarette users is similar to the population distribution in the US.

*Location of disposal:* The used cigarettes will be disposed of in the same manner as are other marketed cigarettes through deposit in municipal solid waste landfills or as litter. The distribution of waste from disposal should correspond to the pattern of product use (i.e. match the population distribution in the US).

*Modification identified as compared to the grandfathered product and a product currently on the market:* The modification of the grandfathered product to create the new product involves a switch to Fire Standards Compliant ("FSC") papers and the removal of menthol. Modifications related to changes in materials used are in the confidential Appendix attached to the EA.

Using information provided in (b) (4) the Agency compares the product attributes, product contents of TNCO, and product ingredients of the new product to (b) (4). The difference between the new product and the currently marketed product principally involves removal of menthol. Differences in materials used are described in the confidential Appendix attached to the EA.

Lorillard states that, "they use industry standard boxes, cartons, and cases to package its products. Each pack of cigarettes consists of twenty cigarettes wrapped in foil. The box is then constructed around the foil-wrapped cigarettes. A paperboard inner frame is added during the box construction to aid in structural support. The finished box is then wrapped with film with tear tape added to aid in the removal of the film to access the product. Ten finished packs are then inserted into a carton container. The carton containers are then inserted into a corrugated case for transportation." The packaging materials used are common in the industry. Based on Lorillard's statement it appears there are no changes in packaging materials between the grandfathered or provisional products and the new product.

## 5. Environmental Introduction due to the Proposed Actions

1

[http://iaspub.epa.gov/enviro/efsystemquery.tri?fac\\_search=primary\\_name&fac\\_value=Lorillard&fac\\_search\\_type=Beginning+With&postal\\_code=&location\\_address=&add\\_search\\_type=Beginning+With&city\\_name=&county\\_name=&state\\_code=&sic\\_type=Equal+to&sic\\_code\\_to=&naics\\_type=Equal+to&naics\\_to=&chem\\_name=&chem\\_search=Beginning+With&cas\\_num=&program\\_search=2&page\\_no=1&output\\_sql\\_switch=TRUE&report=1&database\\_type=TRIS](http://iaspub.epa.gov/enviro/efsystemquery.tri?fac_search=primary_name&fac_value=Lorillard&fac_search_type=Beginning+With&postal_code=&location_address=&add_search_type=Beginning+With&city_name=&county_name=&state_code=&sic_type=Equal+to&sic_code_to=&naics_type=Equal+to&naics_to=&chem_name=&chem_search=Beginning+With&cas_num=&program_search=2&page_no=1&output_sql_switch=TRUE&report=1&database_type=TRIS) (Accessed on 2/6/2013.)

<sup>2</sup> King B.A., Dube, S.R., and Tynan, M.A., 2012 "Current Tobacco Use Among Adults in the United States: Findings From the National Adult Tobacco Survey," American Journal of Public Health.

### 1) Environmental introduction as a result of manufacture

Existing condition- In 2007, US tobacco manufacturers produced 468.3 billion cigarettes and exported 102 billion.<sup>3</sup> Seventy-three tobacco production establishments are registered as manufacturing facilities under section 905 of the FD&C Act. Most of these establishments are located in the Southeastern region of the United States, with several in the Northeastern region, and a few in the remaining regions of the US. There are a total of thirty-eight manufacturing establishments in Florida, North Carolina, Tennessee, and Virginia registered under section 905 of the FD&C Act.<sup>4</sup> Based on the analysis done using EPA's TRI program,<sup>5</sup> in 2011, US tobacco manufacturers released 467,000 pounds of ammonia and 252,000 pounds of nicotine and salts to the air;<sup>6</sup> 46,000 pounds of ammonia to the land<sup>7</sup>; 200 pounds of ammonia and 300 pounds of nicotine and salts to the water;<sup>8</sup> 32,533 pounds of ammonia and 402,644 pounds of nicotine and salts transferred to Publicly Owned Treatment Works (POTWs) or an off-site location.<sup>9</sup>

Based on Lorillard's 2011 annual report, Lorillard's Greensboro, North Carolina manufacturing plant has a production capacity of approximately 50 billion cigarettes per year.<sup>10</sup> In 2011, based on TRI reports Lorillard submitted to EPA, Lorillard released (b) (4)

[REDACTED]

<sup>3</sup> Tobacco Outlook/TBS-263/October 24, 2007, Electronic Outlook Report from the Economic Research Service, USDA, <http://usda.mannlib.cornell.edu/usda/current/TBS/TBS-10-24-2007.pdf> (Accessed on 2/11/2013).

<sup>4</sup> <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm189469.htm>

<sup>5</sup> The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the US, including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufactures are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (2) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical (<http://www.epa.gov/tri/trichemicals/listchanges/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

<sup>6</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=air\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=air_total_release)

<sup>7</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=land\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=land_total_release)

<sup>8</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=water\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=water_total_release)

<sup>9</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=off\\_site\\_total\\_transfers](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=off_site_total_transfers)

<sup>10</sup> [http://www.lorillard.com/wp-content/uploads/2012/04/Lorillard\\_AR\\_Final\\_forWEB.pdf](http://www.lorillard.com/wp-content/uploads/2012/04/Lorillard_AR_Final_forWEB.pdf) (Accessed on 2/1/2013.)

(b) (4)

11

Environmental introduction as a result of manufacture- Waste generated as a result of manufacture of the new product is anticipated to be released to the environment, POTWs, and landfills in the same manner as the other products in the same facility and in a similar manner to other tobacco products manufactured in the US.

Lorillard states that, "Both the [2007 Newport Lights Menthol 100 Hard Box] and the new products provide [virtually] the same blend of tobaccos, virtually the same additives, [virtually] the same packaging materials, and physical characteristics that are either identical or functionally indistinguishable, including characteristics such as cigarette length, cigarette paper weight, cigarette rod length, finished tobacco blend weight, pack moisture, circumference, tipping paper width, plug wrap, filter tip length, tip pressure drop, and base paper weight." The Agency has found the new product to be substantially equivalent to the "2007 Newport Lights Menthol 100 Hard Box" from a public health point of view. Moreover, the new product has a removal of (b) (4).

, a (b) (4), and an exchange of FCS paper compared to "2007 Newport Lights Menthol 100 Hard Box". And, the new product has a removal of (b) (4), and a (b) (4)

(b) (4) compared to "Newport Menthol Gold Box 100s." Therefore, no new substances are anticipated to release into the environment as a result of manufacture of the new product.

Based on information in the confidential Appendix attached to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Therefore, the introduction of the new product is not expected to significantly affect the current manufacturing waste from non-menthol cigarette production.

Furthermore, the projected market volume for the new product is less than 1% of the total cigarettes manufactured in the US based on information from USDA's tobacco manufacture outlook in 2007,<sup>12</sup> the most recent accurate manufacture information available. Therefore, the material mass anticipated to be released into the environment as a result of manufacture due to the proposed action is negligible compared to that of all cigarettes in the US. Virtually no environmental introduction is anticipated to exist due to the manufacturing of the new product.

Therefore, the environmental introduction as a result of manufacture due to the proposed action is negligible, if any.

## 2) Environmental introduction as a result of use

<sup>11</sup>[http://oaspub.epa.gov/enviro/tri\\_formr\\_partone\\_v2.get\\_details?rpt\\_year=2011&fac\\_id=27420LRLLR2525E&ban\\_flag=Y](http://oaspub.epa.gov/enviro/tri_formr_partone_v2.get_details?rpt_year=2011&fac_id=27420LRLLR2525E&ban_flag=Y) (Accessed on 2/7/2013.)

<sup>12</sup> Tobacco Outlook/TBS-263/October 24, 2007, Electronic Outlook Report from the Economic Research Service, USDA, <http://usda.mannlib.cornell.edu/usda/current/TBS/TBS-10-24-2007.pdf> (Accessed on 2/11/2013).

Existing condition- Total cigarette use continued an 11-year downward trend with a 2.5 percent decline from 2010 to 2011.<sup>13</sup> The Centers for Disease Control estimates that 292.7 billion cigarettes were consumed in 2011.<sup>14</sup>

When consuming (using) cigarettes, the users release environmental tobacco smoke (secondhand smoke) to the environment. Secondhand smoke is classified as a Class A carcinogen by EPA, and EPA identifies it as a cause of poor indoor air quality. A study on outdoor secondhand tobacco smoke has shown that during periods of active smoking, peak and average outdoor secondhand tobacco smoke levels near smokers are equivalent to indoor secondhand tobacco smoke concentrations levels. However, outdoor secondhand tobacco smoke levels approached zero at distances greater than approximately 2 meters from a single cigarette and dropped almost instantly after smoking activity ceased.<sup>15</sup>

When using cigarettes, the users inhale the main stream smoke and they also release tobacco specific nitrosamines through excretion into the water.<sup>16</sup> The changes of (b) (4) are less than (b) (4) cigarette compared to "2007 Newport Lights Menthol 100 Hard Box." Changes of TNCO are less than (b) (4) cigarette when compared to either "2007 Newport Lights Menthol 100 Hard Box" or (b) (4). The minor difference of constituents is negligible from an environmental perspective.

Environmental introduction as a result of use- When using the new product, the users are anticipated to release secondhand smoke to the air and tobacco specific nitrosamines to the water through excretion. However, as discussed, the manufacturer states that (b) (4) to "2007 Newport Lights Menthol 100 Hard Box" and (b) (4) and the Agency has found the new product to be substantially equivalent to the "2007 Newport Lights Menthol 100 Hard Box" from a public health point of view. Moreover, the new product has a removal of (b) (4), a (b) (4), and an exchange of FSC paper compared to "2007 Newport Lights Menthol 100 Hard Box 100s." And, the new product has a removal of (b) (4), (b) (4), and a (b) (4) compared to "Newport Menthol Gold 100s." Therefore, no new substances are anticipated to be released into the environment as a result of use of the new product.

<sup>13</sup> [http://www.cdc.gov/media/releases/2012/p0802\\_tobacco\\_consumption.html](http://www.cdc.gov/media/releases/2012/p0802_tobacco_consumption.html) (Accessed on 2/1/2013.)

<sup>14</sup> <http://farmprogress.com/story-decline-cigarette-consumption-slows-2012-9-64691> (Accessed on 2/7/2013.)

<sup>15</sup> Klepels, NE, Ott, WR, & Switzer, P, Real-Time Measurement of Outdoor Tobacco Smoke Particles, *Journal of the Air & Waste Management Association*, (2007) 57:5, 522-534

<sup>16</sup> *Journal of Environmental Health*, (2011) 37:412-417.

Based on information in the confidential Appendix attached to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Therefore, the introduction of the new product is not expected to increase use of non-menthol cigarettes.

Furthermore, the projected market volume for the new product is less than 1% of the total cigarette consumption in 2011 as noted. The smoke generated as a result of use is negligible compared to that of total cigarettes anticipated in the US. Therefore, the material mass anticipated to be released into the environment as a result of use is negligible compared to that of all cigarettes in the US.

In sum, virtually no environmental introduction is anticipated to exist as a result of the use of the new product due to the proposed action. Accordingly, the environmental introduction as a result of use is negligible due to the proposed action, if any.

### 3) Introduction of cigarettes into the environment as a result of disposal after use by consumers

Existing condition- The existing environmental consequence resulting from disposal from use of cigarettes is discarded cigarette filters. Cigarette filters most commonly contain cellulose acetate<sup>17</sup> and may persist under normal environmental conditions for 18 months to 10 years.<sup>18</sup> As much as 766,571 metric tons of cigarette filters are discarded as litter worldwide per year. Discarded cigarette filters are carried as runoff from streets to drains, to rivers, and ultimately to the ocean and its beaches and are found to be the most collected item in beach clean-ups and litter surveys.<sup>19</sup> Evidence has shown that cigarette butts (smoked filter + tobacco) are the most prevalent items discarded in urban areas onto roads and streets<sup>20</sup>

Cigarette filters were found to be a point source for metal contamination litter, based on a study performed to assess the gradual release of multiple metals from the cigarette filters over a 34-day study period.<sup>21</sup> Studies on the ecotoxicity of discarded cigarette filters also have shown the potential existing environmental consequence resulting from disposal of cigarette filters. The LC<sub>50</sub> for leachate from

<sup>17</sup> US Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.)

<sup>18</sup> Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry*. (1993) A30:733-40.

<sup>19</sup> Smith, EA and Novotny, TE., 2011, Whose butt is it? Tobacco industry research about smokers and cigarette butt waste, *Tobacco Control*, 20(Sup.1):12-19.

<sup>20</sup> Department for the Environment, Food and Rural Affairs of UK. Preventing cigarette litter in England: guidelines for local authorities DEFRA 2007

<sup>21</sup> Moerman, JW; Potts, GE., 2011, Analysis of metals leached from smoked cigarette litter, *Tobacco Control*, 20(Sup.1):130-135.



smoked cigarette butts was approximately one cigarette butt/1 for both the marine topsmelt (*Atherinops affinis*) and the freshwater fathead minnow (*Pimephales promelas*).<sup>22</sup>

Environmental introduction as a result of disposal from use – After using the new product, the users may dispose the cigarette butts and ashes as municipal solid waste (MSW) or as litter. However, as discussed, the manufacturer states that the new product is “essentially identical” to “2007 Newport Lights Menthol 100 Hard Box” and “Newport Menthol Gold 100s” and the FDA has found the new product substantially equivalent to “2007 Newport Lights Menthol 100 Hard Box” from a public health point of view. Moreover, the new product has a removal of (b) (4) [REDACTED], a [REDACTED] (b) (4), and an exchange of FSC paper compared to “2007 Newport Lights Menthol 100 Hard Box.” And, the new product has a removal of (b) (4) [REDACTED], and a [REDACTED] (b) (4) [REDACTED] compared to Newport Menthol Gold. Therefore, no new substances are anticipated to be released into the environment as a result of disposal from use.

Based on information in the confidential Appendix to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Using the projected market volume for the new product, the Agency estimates the amount of waste generated from using the new product, assuming 20% of the projected market volume is disposed of as solid waste. Further calculations show the amount of solid waste generated as a result of disposal from use to be a negligible fraction of municipal solid waste (MSW) generated in 2010.<sup>23</sup> Therefore, the solid waste generated as a result of use is negligible compared to that of MSW in the US. Furthermore, as the product is anticipated to compete, replace or substitute for other non-menthol cigarettes, the new product is not expected to increase the total MSW.

The environmental introduction as a result of disposal from use by consumers is negligible, if any.

6. **Fate of new materials released into the environment due to the proposed action:** No new chemicals are anticipated to be released into the environment due to the proposed action because the new product has a removal of ingredients and an exchange of FSC paper compared to “2007 Newport Lights Menthol 100 Hard Box,” and a removal of ingredients compared to “Newport Menthol Gold 100s.”

Furthermore, the material mass released to the environment due to the proposed action is negligible, if any, as discussed.

7. **Environmental effects of the released cigarette:** Because the concentrations of materials anticipated to enter the environment due to the proposed action are minuscule, if any, the environmental effects of the materials are negligible compared to those of marketed cigarettes.

<sup>22</sup> Slaughter, E; Gersberg, RM; Watanabe, K; Rudolph, J; Stransky, C; Novotny, TE, 2011, Toxicity of cigarette butts, and their chemical components, to marine and freshwater fish, *Toxicol Control*, 20(Sup1):125-130.

<sup>23</sup> [http://www.epa.gov/osw/nonhaz/municipal/pubs/msw\\_2010\\_rev\\_factsheet.pdf](http://www.epa.gov/osw/nonhaz/municipal/pubs/msw_2010_rev_factsheet.pdf)

8. **Use of resources and energy:** The new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market as noted. Furthermore, the market volume of the new product is a negligible fraction of that of all cigarettes manufactured in the US in 2007. Accordingly, the use of resources and energy due to the proposed action is negligible.
9. **Mitigation:** No adverse environmental effects are identified based upon our review of the available data and information for the new product and its proposed use as a cigarette. Therefore, no mitigation measures are to be discussed. Furthermore, the manufacturer's facility has reported air releases under the Clean Air Act and has permits to discharge to water under the local, state, and Federal relevant environmental regulations.<sup>24</sup>

**10. Alternatives to the proposed action:**

*Alternative A (No action alternative):* the no-action alternative is to not allow the product to be marketed in the US. The environmental impact is virtually not changing the existing condition due to the manufacture, use, and disposal from use of the tobacco product.

*Alternative B (Proposed action):* There is virtually no environmental effect due to the proposed action of authorizing the new product and the associated manufacture, use, and disposal from use of the new tobacco product.

Therefore, the difference of environmental impacts of these two alternatives is negligible, if any.

**11. Confidential Appendix:**

Appendix 1: Modification of the New Product, Newport Non-Menthol Gold Box 100s, to Grandfathered Product, "2007 Newport Lights Menthol 100 Hard Box"

Appendix 2: (b) (4)

Appendix 3: Confidential business information: first and fifth year market volume projections

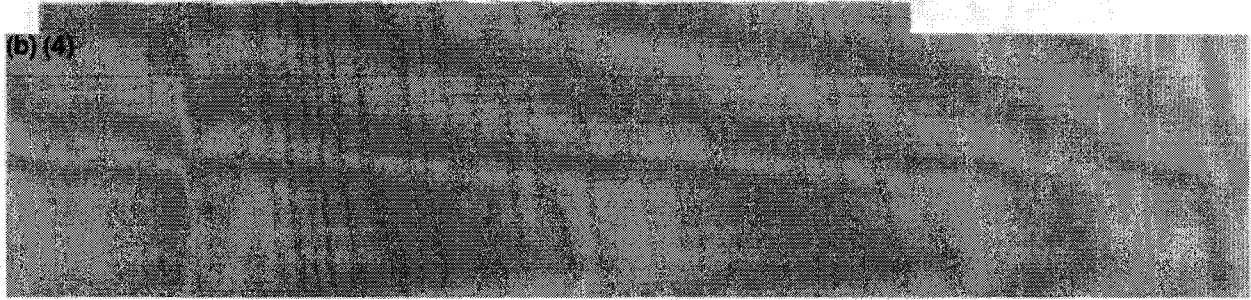
<sup>24</sup> Report based on TRI.

**Appendix 1: Modification of the New Product, Newport Non-Menthol Gold Box 100s, to Grandfathered Product, "2007 Newport Lights Menthol 100 Hard Box"**

	<b>Modification</b>
<b>Product Attributes</b>	1) [REDACTED] (b) (4) [REDACTED] 3) Exchange of Fire Standard Compliant ("FSC") 4) White tipping paper to cork-and-white and (b) (4) of (b) /cig tipping paper weight
<b>Product Constituents</b>	1) Changes of less than (b) (4) /cigarette of certain constituent 2) Changes of less than (b) /cigarette of tar, nicotine, CO (TNCO)
<b>Product Ingredients</b>	1) Decrease of (b) (4) /cigarette of (b) (4) ethyl alcohol (b) (b) (4) (l) 2) Removal of (b) (4) (b) (4) 3) Changes within 1(b) /cig of various tobacco blends

Appendix 2: (b) (4)

(b) (4)



**Appendix 3: Confidential business information: first and fifth year market volume projections**

In their response, SE0007199, dated February 12, 2013, Lorillard stated that, "Newport Non-Menthol Gold Box 100s' is intended to compete with other non-menthol cigarettes currently on the market." They also stated, "Newport Non-Menthol Gold Box 100s' is not reasonably expected to increase the total market volume for non-menthol cigarettes."

They further stated that, "Newport Non-Menthol Gold Box 100s' market volume is projected to be (b) (4) units (cigarettes) in the first year (first 12 months) and (b) (4) units (cigarettes) in the fifth year. Please note that brand volume projections are usually revised annually based on actual sales and market dynamics."

**FINDING OF NO SIGNIFICANT IMPACT  
FOR**

**Market Authorization of "Newport Non-Menthol Gold Box 100s"  
Found Substantially Equivalent to "2007 Newport Lights Menthol  
100 Hard Box"**

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required. The evidence supporting this finding is contained in the attached environmental assessment, dated June 4, 2013, which is available to the public upon request. The agency prepared the environmental assessment under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act.

(b) (6)



Date: June 4, 2013

David Ashley, PhD  
Director  
Office of Science  
Center for Tobacco Products  
Food and Drug Administration

**OCE/EMG Compliance with the Act Memo for Regular 905(j) Applications  
Addendum**

**1. SUBMISSION INFORMATION**

STN #: SE0003730  
Submission Type: 905(j) Regular Report  
Submission Receipt Date: 10/13/2011

New Tobacco Product Name: Newport Non-Menthol Gold Box 100s  
New Tobacco Category Type:  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco

New Tobacco Product Code: (b) (4)

Submitter's Name: Lorillard Inc.  
Company's Name (if different):  
Contact Information: Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335 - 7656  
(336) 335 - 7752 (fax)  
nwilcox@lortobco.com

**2. RECOMMENDATION**

<input checked="" type="checkbox"/> Tobacco product is in compliance with applicable provisions of the FD&C Act.
<input type="checkbox"/> Tobacco product is not in compliance with applicable provisions of the FD&C Act.

3. SIGN-OFF

Compliance Reviewer: Dina Raafat	Date: 6/19/13 Initials: DR
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Based on a review of the information provided, the Office of Compliance and Enforcement has determined that the firm is in compliance with section 919 (user fees) of the FD&C Act and the brand name Newport Non-Menthol Gold Box 100s is in compliance with applicable provisions of the FD&C Act.

(b) (6)

*for CMS*

*6-19-13*

Christine M. Smith  
Division Director, Office of Compliance and Enforcement  
Center for Tobacco Products

Date

4. ADDITIONAL INFORMATION

Tab	Date	From	Description
N/A	6/19/13	N/A	The firm was not found on CTP's arrears list dated 6/2/13.



Primary STN # SE0003730

Reviewer: D. Portnoy

New Product Name: Newport Non-Menthol Gold Box 100s

Submission	
Primary STN	SE0003730 amended by SE0005253
Submission Date	December 3, 2012
FDA Receipt Date	December 6, 2012
Applicant	Lorillard, Inc.
Purpose	<input checked="" type="checkbox"/> Introduction of New Product <input type="checkbox"/> Modification of Existing Product
Scope of Review	To determine whether the predicate and new product are substantially equivalent in terms of consumer perceptions.
Information Reviewed	<input type="checkbox"/> Label <input type="checkbox"/> Marketing <input type="checkbox"/> Sensory Perception Studies <input type="checkbox"/> Risk Perception Studies <input type="checkbox"/> Health Information Summary
Recommendation	Substantially Equivalent
New Product	
Name	Newport Non-Menthol Gold Box 100s
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2003906
Product Category	<input checked="" type="checkbox"/> Cigarette <input type="checkbox"/> Roll-Your-Own <input type="checkbox"/> Cigarette Tobacco <input type="checkbox"/> Smokeless <input type="checkbox"/> Pipe Tobacco <input type="checkbox"/> Hookah Tobacco <input type="checkbox"/> Cigars <input type="checkbox"/> Bidis <input type="checkbox"/> Kreteks <input type="checkbox"/> ENDS <input type="checkbox"/> Other
Product Sub-Category	Filtered (Combustion)
Product Use	<input checked="" type="checkbox"/> For Consumer Use <input type="checkbox"/> For Further Manufacturing
Product Type	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Component <input type="checkbox"/> Part <input type="checkbox"/> Accessory
Predicate Product	
Name	Newport Lights Menthol Gold Box 100s
Package Size	20 cigarettes in each pack, 10 packs per carton

Reviewer name: David Portnoy, Ph.D., MPH Signature: \_\_\_\_\_  
CTP/OS

(b) (6)

Date: 6/7/13 (b) (6)

Team Leader name: Conrad Choiniere, Ph.D. Signature: \_\_\_\_\_  
CTP/OS

(b) (6)

Date: 6/13/13

Concur                       Non-concur (see separate memo)

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Primary STN # SE0003730

Reviewer: D. Portnoy

New Product Name: Newport Non-Menthol Gold Box 100s

## EXECUTIVE SUMMARY

On October 12, 2011, Lorillard Tobacco Company submitted a report in accordance with section 905(j): Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce. On December 3, 2012 Lorillard Tobacco Company submitted an amendment in response to the AI letter dated October 26, 2012.

The applicant is seeking an order to introduce a new product, Newport Non-Menthol Gold Box 100s, as a substantially equivalent product to the grandfathered product Newport Lights Menthol Gold Box 100s, into interstate commerce.

Modifications to the product include modifications of the materials and ingredients. The new product does not have menthol as a characterizing flavor. The applicant posits that although menthol was removed between the new product and the predicate product, the products are substantially equivalent and any differences do not raise different questions of public health.

In the cover letter, dated October 12, 2011, sent with the report the applicant states that "a summary of the relevant health information for the subject product will be made available upon request pursuant to Section 910(a)(4) of the FDCA."

## EVALUATION OF CONSUMER INFORMATION

### 1.1 Scope of Review

This review assesses the substantial equivalence of Newport Non-Menthol Gold Box 100s in relation to Newport Lights Menthol Gold Box 100s (predicate product) based on the consumer information provided in the application. The review does this by examining the following parts of the application:

- Health Information Summary
- Change in characterizing flavor

### 1.2 Review of Consumer Information

#### **Health Information Summary**

On the cover sheet for the original SE submission dated October 12, 2011, and again in the amendment dated December 3, 2012 the applicant states that a summary of health information will be provided upon request.

#### **Change in characterizing flavor**

A change from the predicate product, which contains menthol, to the new product, which does not contain menthol, poses an issue from a social science perspective regarding whether the change raises different questions of public health specifically with respect to the impact of a new non-menthol product on initiation of tobacco use. This review primarily focuses on youth and young adults as initiation of established smoking occurs almost exclusively before the age of 25. In the process of addressing the issues, we reviewed the peer-reviewed literature, public documents, and FDA's internal review of menthol.

Approximately half (46%) of all current youth and young adult cigarette smokers smoke menthol cigarettes according to data from the 2004 National Youth Tobacco Survey, with similar findings in 2008 among youth smokers.<sup>1,2</sup> The appeal of menthol cigarettes, especially among youth, has been linked to their portrayal in marketing as having a smoother taste and being less harsh, which may be appealing to newer smokers or those curious about experimentation.<sup>3,4,5</sup> Direct data on the appeal of non-menthol cigarettes as compared to menthol cigarettes as it relates to initiation is less available. A review of tobacco industry documents found that menthol cigarettes were marketed as being implied to be healthier and that they were targeted to those consumers that would not otherwise progress to regular smoking, including young smokers and those that do not like regular cigarettes.<sup>6</sup> A second piece of indirect evidence on the influence of menthol on cigarette initiation comes from an economic analysis of pricing of menthol and non-menthol cigarettes. Tauras et al. used data from over 57,000 smokers from the TUS-CPS to examine preference of menthol versus non-menthol cigarettes.<sup>7</sup> That analysis suggested that from an economic point of view, smokers of non-menthol cigarettes are less likely to substitute their cigarettes for menthol cigarettes than the reverse. A survey of current adolescent and adult smokers in 2010 found that among menthol smokers, if they were no longer able to obtain menthol cigarettes, they reported that they would most likely try to quit smoking/smoke less or seek out alternative sources of menthol, such as in a smokeless tobacco product<sup>8</sup>. In that study,

New Product Name: Newport Non-Menthol Gold Box 100s

over 80% of menthol smokers reported that they would be willing to try a non-menthol cigarette, suggesting that in the absence of a menthol cigarette, current menthol smokers might be willing to switch to a non-menthol cigarette, although this study did not directly address initiation of smoking.

In sum, menthol cigarettes are used more frequently by youth and young adult smokers than adult smokers, especially youth and young adults that have smoked for less than a year, suggesting they appeal to youth and may be associated with increased initiation as compared to non-menthol cigarettes. However, there is limited data that directly compares initiation of menthol versus non-menthol cigarettes. DiFranza found that among 120 participants that initiated cigarette use during a 30-month follow-up assessment, and could remember their first cigarette, 42% reported that their first cigarette was menthol.<sup>9</sup> However it is suggested that newer tobacco users may start with a menthol product and then later switch to a non-menthol product.<sup>10,11</sup>

The evidence for initiation of menthol cigarettes, especially among youth and young adults, suggests that the new product (non-menthol) is not likely to have a negative impact on initiation rates compared to the predicate (menthol) product and does not raise different questions of public health beyond those of the predicate product. However these questions should also be referred to an addiction reviewer to evaluate the impact on the likelihood of initiation, level of dependence and cessation.

## OUTSTANDING ISSUES

### 2.1 Issues

- None identified.

### 2.2 Letter Ready Comments

- N/A

## CONCLUSIONS

Based on the inclusion of a statement that a health information summary will be made available upon request, and consideration of the public health impact of the removal of menthol as a characterizing flavor, we have resolved the questions raised by the introduction of Newport Non-Menthol Gold Box 100s into interstate commerce that would preclude an order finding Newport Non-Menthol Gold Box 100s substantially equivalent to Newport Lights Menthol Gold Box 100s from the social science perspective.

## References

- <sup>1</sup> Wackowski O, Delnevo CD. Menthol cigarettes and indicators of tobacco dependence among adolescents. *Addictive behaviors* 2007;32:1964-1969.
- <sup>2</sup> <http://www.oas.samhsa.gov/2k9/134/134MentholCigarette.htm>; Substance Abuse and Mental Health Services Administration, 2009, as cited by FDA Menthol Report
- <sup>3</sup> Hersey JC, Ng SW, Nonnemaker JM et al. Are menthol cigarettes a starter product for youth? *Nicotine Tob Res* 2006;8:403-413.
- <sup>4</sup> Klausner K. Menthol cigarettes and smoking initiation: A tobacco industry perspective. *Tobacco Control* 2011;20:ii12-ii19.
- <sup>5</sup> Henningfield JE, Benowitz NL, Ahijevych K, Garrett BE, Connolly GN, & Wayne GF. Does menthol enhance the addictiveness of cigarettes? An agenda for research *Nicotine Tob Res* 2003;5(1), 9-11.
- <sup>6</sup> Anderson SJ. Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents. *Tobacco Control* 2011; 20,ii20-ii28.
- <sup>7</sup> Tauras JA, Levy D, Chaloupka FJ, Villanti A, Niaura RS, Vallone D, & Abrams DB. Menthol and non-menthol smoking: the impact of prices and smoke-free air laws. *Addiction* 2010; 105(s1), 115-123.
- <sup>8</sup> O'Connor RJ, Bansal-Travers M, Carter LP, & Cummings KM. What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand. *Addiction* 2012; 107, 1330-1338
- <sup>9</sup> DiFranza JR, Savageau JA, Fletcher K, Ockene JK, Rigotti NA, McNeill AD, Coleman M, & Wood C. Recollections and repercussions of the first inhaled cigarette. *Addictive Behavior* 2004; 29, 261-272.
- <sup>10</sup> Rising J & Wasson-Blader W. Menthol and initiation of cigarette smoking. *Tobacco Induced Diseases* 2011; 9(Suppl 1), S4-S8.
- <sup>11</sup> The NSDUH Report: Use of Menthol Cigarettes. Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2009.

**Toxicology Review of 905(j)(1)(A)(i) Report  
Second-Cycle Review of Additional Information**

Submission			
Primary STN	SE0003730; SE0003731		
Submission Date	October 12, 2011	FDA Receipt Date	October 13, 2011
Review Number	2		
STN Amendments	SE0005253; SE0005305		
Amendment Date	December 3, 2011	FDA Receipt Date	December 6, 2011
Applicant	Lorillard Tobacco Company		
FDA Establishment Identifier (FEI)	None identified		
Product Type	<input checked="" type="checkbox"/> Introduction of New Product <input type="checkbox"/> Modification of Existing Product		
Submission Summary	SE0003730: Newport Non-Menthol Gold Box 100's is compared to Newport Lights Menthol Gold Box 100s. SE0003731: Newport Non-Menthol Gold Box is compared to Newport Lights Menthol Gold Box. Lorillard Tobacco Company claims the new product has the same characteristics.		
Related STNs	SE0003730 (b) (4), SE0004149, TC0000337, SE0005253); SE0003731 (SE0004148, SE0005305)		
New Product			
Name	SE0003730: Newport Non-Menthol Gold Box 100s SE0003731: Newport Non-Menthol Gold Box		
Package Size	SE0003730: Hard box pack, 20 cigarettes in each pack, 10 packs per carton, 99 mm cigarette length and 891.2 mg cigarette weight SE0003731: Hard box pack, 20 cigarettes per pack, 10 packs per carton, 80 mm cigarette length and 898.3 mg cigarette weight		
Product ID	SE0003730: 2003906 SE0003731: 2003905		
Product Category	<input checked="" type="checkbox"/> Cigarette <input type="checkbox"/> Roll-Your-Own <input type="checkbox"/> Cigarette Tobacco <input type="checkbox"/> Smokeless <input type="checkbox"/> Pipe Tobacco <input type="checkbox"/> Hookah Tobacco <input type="checkbox"/> Cigars <input type="checkbox"/> Bidis <input type="checkbox"/> Kreteks <input type="checkbox"/> ENDS <input type="checkbox"/> Other		
Product Sub-Category	Filtered (Combustion)		
Product Use	<input checked="" type="checkbox"/> For Consumer Use <input type="checkbox"/> For Further Manufacturing		
Product Type	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Component <input type="checkbox"/> P (b) (6)		

Reviewer name: Raymond P. Yeager, PhD  
CTP/OS

Signature: [Redacted]

Date: 06.03.2013  
(b) (6)Team Leader name: Kimberly Benson, PhD  
CTP/OS

Signature: [Redacted]

Date: 3 JUN 2013

 Concur Non-concur (see separate memo)

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## 1. Executive Summary

### 1.1 Conclusions Based on All Information Submitted By Applicant

<b>SE0003730</b>
<input checked="" type="checkbox"/> Toxicological Evidence supports a determination of SE
<input type="checkbox"/> Toxicological Evidence does not support a determination of SE
<input type="checkbox"/> Insufficient toxicological information to support a determination of SE
<b>Comments:</b> Based on the supplied HPHC information and the limited risk calculation conducted.

<b>SE0003731</b>
<input checked="" type="checkbox"/> Toxicological Evidence supports a determination of SE
<input type="checkbox"/> Toxicological Evidence does not support a determination of SE
<input type="checkbox"/> Insufficient toxicological information to support a determination of SE
<b>Comments:</b> No comment

### 1.2 Deficiencies and Information Required to Resolve Deficiencies

#### 1.2.1 Based on Initial Reviews

- No deficiencies were identified or conveyed from Toxicology



### 1.2.2 Based on Second-Cycle Reviews

- None

### 1.3 Comments to be Conveyed to the Applicant

- None

### 1.4 Overview of Product History

SE0003730	SE0003731
<p><b>A. Predicate product</b></p> <ul style="list-style-type: none"> <li>a. Trade Name: Newport Lights Menthol Gold Box 100's (2007 Newport Light Menthol 100 Hard Box)</li> <li>b. Type: Cigarette</li> <li>c. FDA-tracking #: TP-0004208</li> <li>d. Company Reference Identification Number: 2000241; UPC 0-26100-00572-1</li> <li>e. Characteristics as of February 15, 2007</li> </ul>	<p><b>B. Predicate product</b></p> <ul style="list-style-type: none"> <li>a. Trade Name: Newport Lights Menthol Gold Box (2007 Newport Lt M 80 Hard Box)</li> <li>b. Type: Cigarette</li> <li>c. FDA-tracking #: TP-0004209</li> <li>d. Company Reference Identification Number: 2000314; UPC 0-26100-00576-9</li> <li>e. Characteristics as of February 15, 2007</li> </ul>
<p><b>C. New Product</b></p> <ul style="list-style-type: none"> <li>a. Trade Name: Newport Non-Menthol Gold Box 100's</li> <li>b. Type: : Cigarette</li> <li>c. FDA-tracking #: None identified</li> <li>d. Company Reference Identification Number: 2003906; UPC 0-26100-00661-2</li> </ul>	<p><b>D. New Product</b></p> <ul style="list-style-type: none"> <li>a. Trade Name: Newport Non-Menthol Gold Box</li> <li>b. Type: : Cigarette</li> <li>c. FDA-tracking #: None identified</li> <li>d. Company Reference Identification Number: 2003905; (PIN 0-26100-00660-5)</li> </ul>

### 1.5 Significant Changes in Ingredients and Constituents Identified by Initial Toxicology/Chemistry/Engineering Review

- The new products, Newport Non-Menthol Gold Box 100's (SE0003730) and Newport Non-Menthol Gold Box (SE0003731), contain the following changes compared to the predicates, Newport Lights Menthol Gold Box 100's and Newport Lights Menthol Gold Box, respectively:
  - Removal of menthol, (b) (4);
  - Decrease in ethyl alcohol (b) (4) used for delivery of the menthol to the cigarette;
  - Lorillard cigarette paper (b) (4) LIP) to replace cigarette paper (b) (4);
  - Tipping paper (b) (4) to replace Tipping paper (b) (4);
  - A new component, (b) (4) in the cigarette paper.

### 1.6 Current Outstanding Issues

- Toxicology had no outstanding issues that needed to be addressed by the applicant during the first review of their submission.

- Toxicology has no outstanding issues from review of the supplemental information that was supplied by the applicant.

## 1.7 Overall Summary and Conclusions

The new products and predicates were described in Toxicology review number 1. The primary changes are removal of menthol, (b)(4), reduction of ethyl alcohol and the change to a new type of cigarette paper and tipping paper, including adding (b) to the cigarette paper. In addition, the new product contains (b)(4)

and the predicate product is not reported to contain (b)(4) in the component cigarette paper. Scientific publications on fire-safe paper by (Theophilus et al, 2007, Misra et al, 2005, and June et al, 2011) and literature discussing (b)(4)

were reviewed and the review noted it is reasonable to proceed with the use of the fire safe cigarette paper instead of the conventional cigarette paper.

A scientific AI letter was sent to the applicant on October 26, 2012 and the applicant replied on December 6, 2012. Smoke constituents, including some HPHCs, were voluntarily submitted by the applicant in the initial submission and the applicant's reply to FDA communication. In the applicant's reply HPHCs were reported for the new products in SE0003730 and SE0003731. This information for the predicate was only submitted in SE0003730. The Chemistry reviewer summarized the appropriate HPHC data and met with the Toxicology reviewer regarding concerns about the HPHCs. Based on the submission of this HPHC information, the Toxicology reviewer proposed a limited risk calculation could be used to compare the risk impacts to the user of the new product compared to the predicate product in submission SE0003730. The abbreviated HPHC listing provided by the applicant is comparable for the new product and predicate in SE0003730 but not in SE0003731. As such, the new product in SE0003730 can be evaluated in this risk model. The risk of new product in SE0003731 compared to its predicate, however, cannot be evaluated.

A simplified risk calculation is provided with the following assumptions:

- In the interest of protecting the public health, conservative estimates are applied;
- The complete set of HPHCs were not measured and as such, some HPHC information is missing;
- When HPHCs are measured and a value was reported as below the quantitation limit the lower limit of quantitation (LOQ) is used as a conservative estimate for the concentration (note that no HPHC measured was reported as below detection limit);
- The central tendency reported for each HPHC represents an appropriate average concentration absorbed by the consumer and represents the central tendency in a normal distribution;
- The risk estimation is based on a pack-a-day smoker who initiated at 12.5 years and continued smoking until 70 years;
- The smoker is assumed to take 9 puffs per cigarette at 2.4 seconds per puff;

- Dosimetry of each HPHC has not been estimated differently based on physicochemical properties (i.e. particle vs. gas) or target organ endpoint (i.e. portal-of-entry effects vs. systemic effects);
- The appropriate dosimetric adjustment factor for the animal to human extrapolation for the point of departure to establish an inhalation unit risk value as established by the given agency (i.e. EPA, CALEPA) is appropriate and is assumed to result in less variability than the intraspecies uncertainty factor (assumed to be 10);
- The causal modeling of exposure resulting in adverse health events is based on the health endpoints reported by the agencies vetting the dose-response relationship and resulting inhalation unit risk;
- Dose-response effects are based on the presumption that the critical toxic effect is of concern and prevention of a critical effect also prevents all other toxic events;
- In the absence of human dose-response relationships an animal model presents an appropriate paradigm for the human pathological endpoint;
- Some data is missing, for example some HPHCs lack a well-described dose-response relationship;
- Cancer and non-cancer endpoints have been separated;
- Cancer risk is assumed to be independent and additive for each HPHC;
- Carcinogenesis is assumed to be a non-threshold event and non-cancer effects are considered to be threshold events;
- Though non-cancer spans numerous endpoints and target organs, the effects are considered independent and additive for each HPHC;
- Metals are assumed to be inorganic and in a bioavailable form;
- The external concentration is a surrogate for the absorbed dose and 100 percent of each HPHC is absorbed;
- The smoking regimes means for the ISO Method and the Canadian Intense (CI) method will serve as the boundaries for risk;
- Radioactive compounds have not been evaluated in this risk analysis;
- Cancer risk and hazard quotient calculations are based on basic methodologies in EPA's RAGS Part F (EPA, 2009) with assumptions inherent in inhalation dosimetry (EPA, 1994);
  - Dose-response relationships are typically based on animal exposure which is a result of intermittent not continuous dosing and as such may be more reflective of the intermittent exposure experienced by smokers than by air constituents, as an HPHC may not be at steady-state with the chemical level in the blood of the smoker;
  - The periodic measurements in the animal studies used to derive dose-response relationships are considered to be measured at appropriate periods to reflect the cause and effect of the given chemical;
  - Pharmacokinetic and physiologically-based pharmacokinetic models appropriately measure the uptake and disposition of each chemical;
  - The extrapolation of the blood concentration of the chemical or metabolite in the animal to the blood concentration in the human is considered a surrogate for the target tissue dose which results in an adverse event;
  - Percent blood flow to any respiratory/pulmonary compartment is independent of species and metabolic parameters scale in the same way as the alveolar ventilation rate;
- The estimate of risk is based on the inhalation of mainstream smoke from the given cigarette with a range of risk reported – the collection of smoke using the ISO method

serves as the lower bound of exposure and the collection of smoke using the CI method serves as the higher bound of exposure;

- A user is assumed to initiate smoking at 12.5 years old and to smoke one pack a day (i.e. 20 cigarettes) for a lifetime (i.e. 70 years or 57.5 years of exposure) taking a 2.4 second puff from a cigarette and a total of 9 puffs (US EPA, 2009; SAMHSA, 2008; OSG, 2004; Zacny & Stitzer, 1994; Caraballo et al, 2006; US EPA, 1989; US EPA, 1997).

$$\text{ICR} = \text{IUR} \cdot \text{EC} \text{ for Cancer Risk}$$

and

$$\text{HQ} = \text{EC} / (\text{RfC} \cdot 1,000) \text{ for Noncarcinogenic Risk}$$

Where

$$\text{EC} = (\text{MSC} \cdot \text{ET} \cdot \text{EF} \cdot \text{ED}) / \text{AT}; \text{ET} = \text{CPD} \cdot \text{PC} \cdot \text{DT}$$

ICR = Inhalation Cancer Risk (probability)

RfC = Reference Concentration ( $\text{mg}/\text{m}^3$ )\*

EC = Exposure Concentration ( $\mu\text{g}/\text{m}^3$ )

\*Note: 1,000  $\mu\text{g}/\text{mg}$  unit conversion is required

MSC = Mainstream smoke concentration ( $\mu\text{g}/\text{cig}$ )

ET = Exposure time (hours/day)

EF = (days/year)

ED = Exposure Duration (years)

AT = Averaging Time (days)

CC = Cigarettes consumption (cig/day)

PPC = Puff count (puffs/cigarette)

DT = Drag time (hours/puff)

The complete equations are as follows:

$$\text{ICR} = \text{IUR} \times [(\text{MSC} \cdot \{\text{CPD} \cdot \text{PC} \cdot \text{DT}\} \cdot \text{EF} \cdot \text{ED}) / \text{AT}]$$

And

$$\text{HQ} = [(\text{MSC} \cdot \{\text{CPD} \cdot \text{PC} \cdot \text{DT}\} \cdot \text{EF} \cdot \text{ED}) / \text{AT}] / \text{RfC}$$

A risk assessment was completed comparing the Predicate Newport Lights Menthol Gold Box 100s to the New Product Non-Menthol Gold Box 100's and the carcinogenic and noncarcinogenic risks are noted below (Figures 1 and 2) – SE0003730. Smoke contains 89 HPHCs and the applicant reported concentrations for 42 of these constituents. Of the 42 constituents that are reported, some do not have dose-response data. As such 23 carcinogenic risks and 11 noncarcinogenic risks could be calculated. Risk could be calculated for HPHCs considered a greater concern (Fowles & Dybing, 2003 – i.e. 1,3-butadiene, acrylonitrile, arsenic, acetaldehyde, benzene, etc. for carcinogens and acrolein, acetaldehyde, formaldehyde, cadmium, chromium, and acrylonitrile for noncarcinogens). The World Health Organization (WHO) recommends that seven constituents are considered the 'most hazardous' in cigarette smoke and these include acetaldehyde, acrolein, benzene, benzo(a)pyrene, 1,3-butadiene, carbon monoxide, and formaldehyde (WHO, 2008) and risk could be estimated for six of these (not CO). The initial list of WHO criteria constituents also includes acrylonitrile, 4-aminobiphenyl, 2-aminonaphthalene, cadmium, catechol, crotonaldehyde, hydrogen

cyanide, hydroquinone, nitrogen oxides, NNN, and NNK (WHO, 2008) and risk could be estimated for ten of the sixteen (not CO, catechol, HCN, hydroquinone, NOx, or NNK). The WHO recommends a list to target lower concentrations and the constituents are NNK, NNN, acetaldehyde, acrolein, benzene, benzo(a)pyrene, 1,3-butadiene, carbon monoxide, and formaldehyde (WHO, 2008) and a risk could be estimated for seven of the nine constituents (not NNK or CO). While risk could not be calculated for all 89 HPHCs the coverage represented 25 percent of the total HPHCs with over 50 percent of the WHO recommended constituents. The risk could be estimated for HPHCs representative of different chemical classes and for different health effects (both carcinogenic and noncarcinogenic) which for now, is appropriate coverage representative of the public health impact of these cigarettes.

(b) (4)



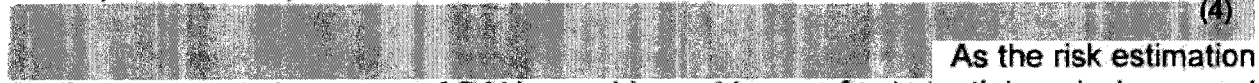
In the risk model, a linear no-threshold model, carcinogenicity is expected to be one of the most sensitive predictors for adverse health events over a lifetime. The inhalation model estimates risks for a range of different types of PAHs with 2 to 6 rings and a range of molecular weights from 128 to 278. The model incorporates the impact of

(b) (4)



which provides a representative PAH profile for the new product and the predicate. (b) (4)

(b) (4)



As the risk estimation for the representative group of PAHs provides evidence of substantial equivalence and the remaining PAHs are neither HPHCs listed by the FDA nor classified as class 1 or 2 carcinogens by IARC, the increases (and decreases) of the remaining PAHs is considered of lesser concern.

Primary STN: SE0003730-SE0003731

Reviewer: Raymond P. Yeager, PhD

New Product Name: Newport Non-Menthol Gold Box 100s & Newport Non-Menthol Gold Box

(b) (4)



Primary STN: SE0003730-SE0003731

Reviewer: Raymond P. Yeager, PhD

New Product Name: Newport Non-Menthol Gold Box 100s & Newport Non-Menthol Gold Box

(b) (4)



(b) (4)

(Figures 1 and 2). Some risk is considered low enough to be of lesser concern, based on the assumption above, and this is for carcinogenic risks below  $1 \times 10^{-6}$  and hazard quotients less than 1.0. A view of the fingerprint of HPHCs for the predicate and the new product appears to be substantially similar in the estimation of carcinogenic and noncarcinogenic risk. The sample population of HPHCs for which risk could be estimated appears to be representative of several chemical classes of HPHCs for both carcinogenic (b) (4)

) and noncarcinogenic endpoints (b) (4)

). The sample HPHC population for which risk could be calculated is representative of chemical class and health effects for the FDA HPHC list and WHO recommended constituents and the risk estimated seems reasonably representative for the impact the HPHCs could have on a user.

The toxicology reviewer considers the overlapping risk of these representative HPHCs as supportive of a determination that SE0003730, the new product Non-Menthol Gold Box 100s, is substantially equivalent to the predicate Newport Lights Menthol Gold Box 100s,

As previously discussed, there was insufficient information for HPHC levels for SE0003731; therefore a comparable risk analysis could not be conducted. Though a risk assessment could not be performed, there are minimal changes in the new product, as was discussed in the first Toxicology review, including a change to fire-safe paper and the removal of menthol and decrease in ethanol. From a toxicological perspective it is reasonable to proceed with the expectation that the use of fire safe paper and the elimination of menthol and reduction of alcohol do not raise new toxicological issues. Based on the evidence provided, Toxicology supports a determination that the new product in SE0003731, Newport Lights Non-Menthol Gold Box, is substantially equivalent to the predicate, Newport Lights Menthol Gold Box.

## 1.8 Appendices

### Appendix 1 References

(b) (4)

(b) (4)

(b) (4)



Caraballo et al, 2006. Preventing Chronic Disease: Public Health Research, Practice, and Policy, vol. 3(2):1-12.

Hall, J. R., Jr. (2008). *The smoking-material fire problem*, Retrieved from National Fire Protection Association <http://www.nfpa.org/assets/files//PDF/OS.Smoking.pdf>

(b) (4)

(b) (4)

International Agency for Research on Cancer (IARC), 2006. Preamble, Lyon, France.

IARC, 2010. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Some Non-heterocyclic Polycyclic Aromatic Hydrocarbons and Some Related Exposures, vol. 92, Lyon, France.

June KM, Hammond, D, Sjodin, A, Li, A, Romanoff L, O'Connor RJ, 2011. Cigarette ignition propensity, smoking behavior, and toxicant exposure: A natural experiment in Canada. *Tob Indu Dis*, vol. 9(1):13.

Misra M, Leverette RD, Hamm JT, Bennett MB, Heck JD, Morrissey R, Rajendran N, 2005. Toxicological evaluation of a cigarette paper with reduced ignition propensity: In vitro and In vivo tests. *The Toxicologist*, vol. 84(1-S):1186.

Office of the Surgeon General (OSG), 2004. *The Health Consequences of Smoking: A Report of the Surgeon General*. US Department of Health and Human Services.

(b) (4)

Substance Abuse and Mental Health Administration (SAMHSA), 2008. *National Survey on Drug Use and Health: National Findings*. Rockville (MD)

Theophilus EH, Keith Shreve W, Ayres PH, Gamer CD, Pence DH, Swauger JE, 2007. Comparative 13-week cigarette smoke inhalation study in Sprague-Dawley rats: Evaluation of cigarettes with two banded cigarette paper technologies. *Food Chem Toxicol.*, vol. Jun;45(6):1076-90.

(b) (4)

US Environmental Protection Agency (EPA), 2009. *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual; Part F, Supplemental Guidance for Inhalation Risk Assessment*, Office of Superfund Remediation and Technology Innovation, Washington, DC

US EPA, 2009, *Risk Assessment Guidance for Superfund, Volume I, Part F (RAGS F)*.

US EPA, 1989, *Risk Assessment Guidance for Superfund, Volume I, Part A (RAGS)*.

US EPA, 1997: *Exposure Factors Handbook, Final Report*.

(b) (4)

(b) (4)

Primary STN. SE0003730-SE0003731

Reviewer: Raymond P. Yeager, PhD

New Product Name: Newport Non-Menthol Gold Box 100s & Newport Non-Menthol Gold Box

World Health Organization (WHO), 2008. The Scientific Basis of Tobacco product Regulation, Second Rpeort of a WHO Study Group, WHO Technical Report Series 951.

(b)

(4)



**OCE/EMG Compliance with the Act Memo for Regular 905(j) Applications  
Addendum**

**1. SUBMISSION INFORMATION**

STN #: SE0003731  
Submission Type: 905(j) Regular Report  
Submission Receipt Date: 10/13/2011

New Tobacco Product Name: Newport Non-Menthol Gold Box  
New Tobacco Category Type:  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
New Tobacco Product Code: (b) (4)

Submitter's Name: Lorillard Inc.  
Company's Name (if different):  
Contact Information: Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335 - 7656  
(336) 335 - 7752 (fax)  
nwilcox@lortobco.com

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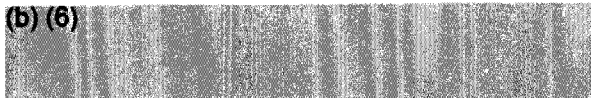
**2. RECOMMENDATION**

- |  |
|--|
| <input checked="" type="checkbox"/> Tobacco product is in compliance with applicable provisions of the FD&C Act. |
| <input type="checkbox"/> Tobacco product is not in compliance with applicable provisions of the FD&C Act.        |

3. SIGN-OFF

Compliance Reviewer: Dina Raafat	Date: 5/14/ (b) (6) Signature: 
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Based on a review of the information provided, the Office of Compliance and Enforcement has determined that the firm is in compliance with section 919 (user fees) of the FD&C Act and the brand name Newport Non-Menthol Gold Box is in compliance with applicable provisions of the FD&C Act.

(b) (6) 

5/14/2013  
Date

Christine M. Smith  
Branch Chief, Office of Compliance and Enforcement  
Center for Tobacco Products

4. ADDITIONAL INFORMATION

Tab	Date	From	Description
N/A	5/14/2013	N/A	The firm was not found on CTP's arrears list dated 5/6/2013.

## OCE 905(j) Consult Memo: Cross-Reference Grandfathered (GF) Status

### 1. SUBMISSION INFORMATION

**STN #:** SE0003731  
**Submission Type:**  905(j) Report  905(j) Exemption  
**Submission Receipt Date:** October 13, 2011

**Predicate Name:** Newport Lights Menthol Gold Box (also referred to as 2007 Newport Light Menthol 80 Hard Box)  
**Predicate Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:  
**Predicate Product Code:** (b) (4)

**New Tobacco Product Name:** Newport Non-Menthol Gold Box  
**New Tobacco Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:  
**New Tobacco Product Code:** (b) (4)

**Submitter's Name:** Lorillard Inc.  
**Company's Name (if different):**  
**Contact Information:** Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335-7656  
(225) 335-7752 (fax)  
nwilcox@lortobco.com

**Related Submissions** GF Determination for GF1200009

### 2. OCE RECOMMENDATION

**GF Status 2007 Newport Light Menthol 80 Hard Box:**

Established Grandfathered Status as per GF1200009. Please see iTRAC for Admin Record.

Grandfathered Status was denied as per [STN]. Please see iTRAC for Admin Record.

**Predicate Eligibility 2007 Newport Light Menthol 80 Hard Box:**

Tobacco product is predicate eligible as per GF1200009. Please see iTRAC for Admin Record.

Tobacco product is not predicate eligible as per [STN]. Please see iTRAC for Admin Record.

**NOTE:** The original GF determination was not made based on a review of the characteristics of the tobacco product.

**3. SIGN-OFF**

<b>Compliance Reviewer:</b> Dan-My Chu Comments:	Date: 6/19/12 Sign: (b) (6)
<b>905(j) Coordinator:</b> Dina Raafat Comments:	Date: 6/19/12 Sign: (b) (6)
<b>Team Leader:</b> Paul Perdue, Jr. or <b>Group Leader:</b> Joanna Weitershausen	Date: 6/21/12 Sign: (b) (6)

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that 2007 Newport Light Menthol 100 Hard Box was commercially marketed as of February 15, 2007 and is eligible to serve as a predicate product in a report under section 905(j) of the FD&C Act.

(b) (6)

6/22/12  
Date

Ann Simoneau, J.D.  
Director, Office of Compliance and Enforcement  
Center for Tobacco Products

**OCE 905(j) Consult Memo: Grandfathered (GF) Review Addendum**

**1. SUBMISSION INFORMATION**

**STN #:** SE0003731  
**Submission Type:**  905(j) Report  905(j) Exemption  
**Submission Receipt Date:** October 13, 2011

**Predicate Product Name:** Newport Lights Menthol Gold Box  
**Package Type/Size:** Box/80mm/20 Cigarettes per Pack  
**Predicate Product Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco

**Predicate Product Code:** (b) (4)

**New Tobacco Product Name:** Newport Non-Menthol Gold Box  
**Package Type/Size:** Box/80mm/20 Cigarettes per Pack  
**New Tobacco Product Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco

**New Tobacco Product Code:** (b) (4)

**Submitter's Name:** Lorillard Tobacco Company  
**Company's Name (if different):** Lorillard, Inc.  
**Contact Information:** Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
Phone: (336)335-7656  
Fax: (225)335-7752  
nwilcox@lortobco.com

**2. SUMMARY**

This information is an addendum to the existing OCE Review Memorandum for SE0003731. The information included provides package type and size for both the predicate and new tobacco products.

**3. SIGN-OFF**

<b>Compliance Reviewer:</b> Sarah Walinsky	Date: 5/14/2013 Signature: (b) (6)
<b>Team Leader:</b> Christine Smith	Date: 5/14/13 (b) (6)

**4. ADDITIONAL INFORMATION**

Tab	Date	From	Description
A	10/12/2011	Neil L. Wilcox, DVM, MPH Senior Vice President & Chief Compliance Officer, Lorillard, Inc.	Substantial Equivalence Product Submission for Newport Non-Menthol Gold Box providing the length of the predicate and new tobacco products.
B	2/10/2012	Neil L. Wilcox, DVM, MPH Senior Vice President & Chief Compliance Officer, Lorillard, Inc.	Response to information request by CTP/OS for Newport Non-Menthol Gold Box providing the number of cigarettes per package. (Included within SE0004148 which amends SE0003731).



**Environmental Assessment for Market  
Authorization of “Newport Non-Menthol  
Gold Box” Found Substantially Equivalent  
to “2007 Newport Lights Menthol 80 Hard  
Box”**

Prepared by Center for Tobacco Products

US Food and Drug Administration

June 4, 2013

This environmental assessment (EA) is for "Newport Non-Menthol Gold Box," which is the subject of the original SE report SE0003731. This report was amended with additional submissions and communications numbered SE0004148, SE0005305, SE0007186, SE0007199, and TC0000337. Information present in the EA is based on the submissions, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of a submission under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. **Name of Applicant:** Lorillard Tobacco Company
2. **Address:** 714 Green Valley Rd, Greensboro, NC 27408
3. **Manufacturer:** Lorillard Tobacco Company
4. **Description of the Proposed Action:**

The proposed action is to issue a market authorization under section 910(a)(2) of the FD&C Act for the introduction of a new product, "Newport Non-Menthol Gold Box," into interstate commerce. The Agency has found the new product to be "Substantially Equivalent" to a product that was on the market as of February 15, 2007 ("grandfathered product"), the "2007 Newport Lights Menthol 80 Hard Box". Additionally, based on SE0003731 and SE0004148, Lorillard claims that the new product is (b) (4) as the (b) (4) " except for the elimination of menthol in the new product. (b) (4)

*Identification of the new tobacco product that is the subject of the proposed action:*

Type of Tobacco Product: Cigarette

Trade name of the new product: Newport Non-Menthol Gold Box

Brand name: Newport

Subbrand (brand variant): Non-Menthol Gold

Size: 100 mm cigarette length (rod+ filter).

Format: Hard box pack

Quantity: 20 cigarettes in each pack, 10 packs per carton

UPC Number: 0-26100-00572-1

FDA-assigned TP number: TP-0004208

Grandfathered Product: 2007 Newport Lights Menthol 80 Hard Box

*Requested action:* An order finding "Newport Non-Menthol Gold Box" substantially equivalent to a predicate tobacco product, "2007 Newport Lights Menthol 80 Hard Box."

*Need for action:* Lorillard wishes to introduce into commercial marketing the new tobacco product "Newport Non-Menthol Gold Box," which is substantially equivalent to the "2007 Newport Lights Menthol 80 Hard Box".

*Location of manufacture:* The tobacco product will be manufactured at Lorillard Tobacco Company's facility in North Carolina, USA. Based on EPA's Toxics Release Inventory (TRI) Program, Lorillard's North Carolina facility is at 2525 E Market St Greensboro, NC 27401.<sup>1</sup>

*Location of use:* The tobacco product will be distributed and sold nationally to consumers for use as a cigarette. Based on the National Adult Tobacco Survey,<sup>2</sup> the distribution of cigarette users is similar to the population distribution in the US.

*Location of disposal:* The used cigarettes will be disposed of in the same manner as are other marketed cigarettes through deposit in municipal solid waste landfills or as litter. The distribution of waste from disposal should correspond to the pattern of product use (i.e. match the population distribution in the US).

*Modification identified as compared to the grandfathered product and a product currently on the market:* The modification of the grandfathered product to create the new product involves a switch to Fire Standards Compliant ("FSC") papers and the removal of menthol. Modifications related to changes in materials used are in the confidential Appendix attached to the EA.

Using information provided in (b) (4) [REDACTED] the Agency compares the product attributes, product contents of TNCO, and product ingredients of the new product to "(b) (4)" [REDACTED]. The difference between the new product and the currently marketed product principally involves removal of menthol. Differences in materials used are described in the confidential Appendix attached to the EA.

Lorillard states that, "they use industry standard boxes, cartons, and cases to package *its products*. Each pack of cigarettes consists of twenty cigarettes wrapped in foil. The box is then constructed around the foil-wrapped cigarettes. A paperboard inner frame is added during the box construction to aid in structural support. The finished box is then wrapped with film with tear tape added to aid in the removal of the film to access the product. Ten finished packs are then inserted into a carton container. The carton containers are then inserted into a corrugated case for transportation." The packaging materials used are common in the industry. Based on Lorillard's statement it appears there are no changes in packaging materials between the grandfathered or provisional products and the new product.

## 5. Environmental Introduction due to the Proposed Actions

1

[http://iaspub.epa.gov/enviro/efsystemquery.tri?fac\\_search=primary\\_name&fac\\_value=Lorillard&fac\\_search\\_type=Beginning+With&postal\\_code=&location\\_address=&add\\_search\\_type=Beginning+With&city\\_name=&county\\_name=&state\\_code=&sic\\_type=Equal+to&sic\\_code\\_to=&naics\\_type=Equal+to&naics\\_to=&chem\\_name=&chem\\_search=Beginning+With&cas\\_num=&program\\_search=2&page\\_no=1&output\\_sql\\_switch=TRUE&report=1&database\\_type=TRIS](http://iaspub.epa.gov/enviro/efsystemquery.tri?fac_search=primary_name&fac_value=Lorillard&fac_search_type=Beginning+With&postal_code=&location_address=&add_search_type=Beginning+With&city_name=&county_name=&state_code=&sic_type=Equal+to&sic_code_to=&naics_type=Equal+to&naics_to=&chem_name=&chem_search=Beginning+With&cas_num=&program_search=2&page_no=1&output_sql_switch=TRUE&report=1&database_type=TRIS) (Accessed on 2/6/2013.)

<sup>2</sup> King B.A., Dube S.R., and Tynan, M.A., 2012 "Current Tobacco Use Among Adults in the United States: Findings From the National Adult Tobacco Survey," American Journal of Public Health.

1) *Environmental introduction as a result of manufacture*

Existing condition- In 2007, US tobacco manufacturers produced 468.3 billion cigarettes and exported 102 billion.<sup>3</sup> Seventy-three tobacco production establishments are registered as manufacturing facilities under section 905 of the FD&C Act. Most of these establishments are located in the Southeastern region of the United States, with several in the Northeastern region, and a few in the remaining regions of the US. There are a total of thirty-eight manufacturing establishments in Florida, North Carolina, Tennessee, and Virginia registered under section 905 of the FD&C Act.<sup>4</sup> Based on the analysis done using EPA's TRI program,<sup>5</sup> in 2011, US tobacco manufacturers released 467,000 pounds of ammonia and 252,000 pounds of nicotine and salts to the air;<sup>6</sup> 46,000 pounds of ammonia to the land<sup>7</sup>; 200 pounds of ammonia and 300 pounds of nicotine and salts to the water;<sup>8</sup> 32,533 pounds of ammonia and 402,644 pounds of nicotine and salts transferred to Publicly Owned Treatment Works (POTWs) or an off-site location.<sup>9</sup>

Based on Lorillard's 2011 annual report, Lorillard's Greensboro, North Carolina manufacturing plant has a production capacity of approximately 50 billion cigarettes per year.<sup>10</sup> In 2011, based on TRI reports Lorillard submitted to EPA, Lorillard released (b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

<sup>3</sup> Tobacco Outlook/TBS-263/October 24, 2007, Electronic Outlook Report from the Economic Research Service, USDA, <http://usda.mannlib.cornell.edu/usda/current/TBS/TBS-10-24-2007.pdf> (Accessed on 2/11/2013).

<sup>4</sup> <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm189469.htm>

<sup>5</sup> The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the US, including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufactures are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (2) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical (<http://www.epa.gov/tri/trichemicals/listchanges/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

<sup>6</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=air\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=air_total_release)

<sup>7</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=land\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=land_total_release)

<sup>8</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=water\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=water_total_release)

<sup>9</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=off\\_site\\_total\\_transfers](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=off_site_total_transfers)

<sup>10</sup> [http://www.lorillard.com/wp-content/uploads/2012/04/Lorillard\\_AR\\_Final\\_forWEB.pdf](http://www.lorillard.com/wp-content/uploads/2012/04/Lorillard_AR_Final_forWEB.pdf) (Accessed on 2/1/2013.)

(b) (4)

**Environmental introduction as a result of manufacture-** Waste generated as a result of manufacture of the new product is anticipated to be released to the environment, POTWs, and landfills in the same manner as the other products in the same facility and in a similar manner to other tobacco products manufactured in the US.

Lorillard states that, "Both the [2007 Newport Lights Menthol 80 Hard Box] and the new products provide [virtually] the same blend of tobaccos, virtually the same additives, [virtually] the same packaging materials, and physical characteristics that are either identical or functionally indistinguishable, including characteristics such as cigarette length, cigarette paper weight, cigarette rod length, finished tobacco blend weight, pack moisture, circumference, tipping paper width, plug wrap, filter tip length, tip pressure drop, and base paper weight." The Agency has found the new product to be substantially equivalent to the "2007 Newport Lights Menthol 80 Hard Box" from a public health point of view. Moreover, the new product has a removal of (b) (4) , a (b) (4) and an exchange of FCS paper compared to "2007 Newport Lights Menthol 80 Hard Box". And, the new product has a removal of (b) (4) , and a (b) (4) compared to "Newport Menthol Gold Box." Therefore, no new substances are anticipated to release into the environment as a result of manufacture of the new product.

Based on information in the confidential Appendix attached to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Therefore, the introduction of the new product is not expected to significantly affect the current manufacturing waste from non-menthol cigarette production.

Furthermore, the projected market volume for the new product is less than 1% of the total cigarettes manufactured in the US based on information from USDA's tobacco manufacture outlook in 2007,<sup>12</sup> the most recent accurate manufacture information available. Therefore, the material mass anticipated to be released into the environment as a result of manufacture due to the proposed action is negligible compared to that of all cigarettes in the US. Virtually no environmental introduction is anticipated to exist due to the manufacturing of the new product.

Therefore, the environmental introduction as a result of manufacture due to the proposed action is negligible, if any.

## 2) Environmental introduction as a result of use

<sup>11</sup>[http://oaspub.epa.gov/enviro/tri\\_formr\\_partone\\_v2.get\\_details?rpt\\_year=2011&fac\\_id=27420LRLLR2525E&ban\\_flag=Y](http://oaspub.epa.gov/enviro/tri_formr_partone_v2.get_details?rpt_year=2011&fac_id=27420LRLLR2525E&ban_flag=Y) (Accessed on 2/7/2013.)

<sup>12</sup> Tobacco Outlook/TBS-263/October 24, 2007, Electronic Outlook Report from the Economic Research Service, USDA, <http://usda.mannlib.cornell.edu/usda/current/TBS/TBS-10-24-2007.pdf> (Accessed on 2/11/2013).

Existing condition- Total cigarette use continued an 11-year downward trend with a 2.5 percent decline from 2010 to 2011.<sup>13</sup> The Centers for Disease Control estimates that 292.7 billion cigarettes were consumed in 2011.<sup>14</sup>

When consuming (using) cigarettes, the users release environmental tobacco smoke (secondhand smoke) to the environment. Secondhand smoke is classified as a Class A carcinogen by EPA, and EPA identifies it as a cause of poor indoor air quality. A study on outdoor secondhand tobacco smoke has shown that during periods of active smoking, peak and average outdoor secondhand tobacco smoke levels near smokers are equivalent to indoor secondhand tobacco smoke concentrations levels. However, outdoor secondhand tobacco smoke levels approached zero at distances greater than approximately 2 meters from a single cigarette and dropped almost instantly after smoking activity ceased.<sup>15</sup>

When using cigarettes, the users inhale the main stream smoke and they also release tobacco specific nitrosamines through excretion into the water.<sup>16</sup> The changes of (b) (4) are less than (b) (4) cigarette compared to "2007 Newport Lights Menthol 80 Hard Box." Changes of TNCO are less than (b) (4) cigarette when compared to either "2007 Newport Lights Menthol 80 Hard Box" or (b) (4). The minor difference of constituents is negligible from an environmental perspective.

Environmental introduction as a result of use- When using the new product, the users are anticipated to release secondhand smoke to the air and tobacco specific nitrosamines to the water through excretion. However, as discussed, the manufacturer states that (b) (4) to "2007 Newport Lights Menthol 80 Hard Box" and (b) (4) and the Agency has found the new product to be substantially equivalent to the "2007 Newport Lights Menthol 80 Hard Box" from a public health point of view. Moreover, the new product has a removal of (b) (4) a (b) (4) and an exchange of FSC paper compared to "2007 Newport Lights Menthol 80 Hard Box." And, the new product has a removal of (b) (4) and a (b) (4) compared to "Newport Menthol Gold." Therefore, no new substances are anticipated to be released into the environment as a result of use of the new product.

<sup>13</sup> [http://www.cdc.gov/media/releases/2012/p0802\\_tobacco\\_consumption.html](http://www.cdc.gov/media/releases/2012/p0802_tobacco_consumption.html) (Accessed on 2/1/2013.)

<sup>14</sup> <http://farmprogress.com/story-decline-cigarette-consumption-slows-2012-9-64691> (Accessed on 2/7/2013.)

<sup>15</sup> Klepeis, NE, Ott, WR, & Switzer, P, Real-Time Measurement of Outdoor Tobacco Smoke Particles, *Journal of the Air & Waste Management Association*, (2007) 57:5, 522-534

<sup>16</sup> Andra and Makris, Tobacco-specific nitrosamines in water: An unexplored environmental health risk, *Environmental International*, (2011) 37:412-417.

Based on information in the confidential Appendix attached to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Therefore, the introduction of the new product is not expected to increase use of non-menthol cigarettes.

Furthermore, the projected market volume for the new product is less than 1% of the total cigarette consumption in 2011 as noted. The smoke generated as a result of use is negligible compared to that of total cigarettes anticipated in the US. Therefore, the material mass anticipated to be released into the environment as a result of use is negligible compared to that of all cigarettes in the US.

In sum, virtually no environmental introduction is anticipated to exist as a result of the use of the new product due to the proposed action. Accordingly, the environmental introduction as a result of use is negligible due to the proposed action, if any.

### 3) Introduction of cigarettes into the environment as a result of disposal after use by consumers

Existing condition: The existing environmental consequence resulting from disposal from use of cigarettes is discarded cigarette filters. Cigarette filters most commonly contain cellulose acetate<sup>17</sup> and may persist under normal environmental conditions for 18 months to 10 years.<sup>18</sup> As much as 766,571 metric tons of cigarette filters are discarded as litter worldwide per year. Discarded cigarette filters are carried as runoff from streets to drains, to rivers, and ultimately to the ocean and its beaches and are found to be the most collected item in beach clean-ups and litter surveys.<sup>19</sup> Evidence has shown that cigarette butts (smoked filter + tobacco) are the most prevalent items discarded in urban areas onto roads and streets<sup>20</sup>

Cigarette filters were found to be a point source for metal contamination litter, based on a study performed to assess the gradual release of multiple metals from the cigarette filters over a 34-day study period.<sup>21</sup> Studies on the ecotoxicity of discarded cigarette filters also have shown the potential existing environmental consequence resulting from disposal of cigarette filters. The LC<sub>50</sub> for leachate from

<sup>17</sup> US Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.)

<sup>18</sup> Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry*. (1993) A30:733-40.

<sup>19</sup> Smith, EA and Novotny, TE., 2011, Whose butt is it? Tobacco industry research about smokers and cigarette butt waste, *Tobacco Control*, 20(Sup.1):12-19.

<sup>20</sup> Department for the Environment, Food and Rural Affairs of UK. Preventing cigarette litter in England: guidelines for local authorities DEFRA 2007

<sup>21</sup> Moerman, JW; Potts, GE., 2011, Analysis of metals leached from smoked cigarette litter, *Tobacco Control*, 20(Sup.1):130-135.

smoked cigarette butts was approximately one cigarette butt/l for both the marine topsmelt (*Atherinops affinis*) and the freshwater fathead minnow (*Pimephales promelas*).<sup>22</sup>

Environmental introduction as a result of disposal from use – After using the new product, the users may dispose the cigarette butts and ashes as municipal solid waste (MSW) or as litter. However, as discussed, the manufacturer states that the new product is “essentially identical” to “2007 Newport Lights Menthol 80 Hard Box” and “Newport Menthol Gold” and the FDA has found the new product substantially equivalent to “2007 Newport Lights Menthol 80 Hard Box” from a public health point of view. Moreover, the new product has a removal of (b) (4) [REDACTED] and an exchange of FCS paper compared to “2007 Newport Lights Menthol 80 Hard Box.” And, the new product has a removal of (b) (4) [REDACTED] and a [REDACTED] (b) (4) [REDACTED] compared to Newport Menthol Gold. Therefore, no new substances are anticipated to be released into the environment as a result of disposal from use.

Based on information in the confidential Appendix to this EA, the new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market. Using the projected market volume for the new product, the Agency estimates the amount of waste generated from using the new product, assuming 20% of the projected market volume is disposed of as solid waste. Further calculations show the amount of solid waste generated as a result of disposal from use to be a negligible fraction of municipal solid waste (MSW) generated in 2010.<sup>23</sup> Therefore, the solid waste generated as a result of use is negligible compared to that of MSW in the US. Furthermore, as the product is anticipated to compete, replace or substitute for other non-menthol cigarettes, the new product is not expected to increase the total MSW.

The environmental introduction as a result of disposal from use by consumers is negligible, if any.

- 6. Fate of new materials released into the environment due to the proposed action:** No new chemicals are anticipated to be released into the environment due to the proposed action because the new product has a removal of ingredients and an exchange of FSC paper compared to “2007 Newport Lights Menthol 80 Hard Box;” and a removal of ingredients compared to “Newport Menthol Gold.”

Furthermore, the material mass released to the environment due to the proposed action is negligible, if any, as discussed.

- 7. Environmental effects of the released cigarette:** Because the concentrations of materials anticipated to enter the environment due to the proposed action are minuscule, if any, the environmental effects of the materials are negligible compared to those of marketed cigarettes.

<sup>22</sup> Slaughter, E; Gersberg, RM; Watanabe, K; Rudolph, J; Stransky, C; Novotny, TE, 2011, Toxicity of cigarette butts, and their chemical components, to marine and freshwater fish, *Tobacco Control*, 20(Sup1),125-129.

<sup>23</sup> [http://www.epa.gov/osw/nonhaz/municipal/pubs/msw\\_2010\\_rev\\_factsheet.pdf](http://www.epa.gov/osw/nonhaz/municipal/pubs/msw_2010_rev_factsheet.pdf)



- 8. Use of resources and energy:** The new product is anticipated to compete, replace, or substitute with non-menthol cigarettes currently on the market as noted. Furthermore, the market volume of the new product is a negligible fraction of that of all cigarettes manufactured in the US in 2007. Accordingly, the use of resources and energy due to the proposed action is negligible.
- 9. Mitigation:** No adverse environmental effects are identified based upon our review of the available data and information for the new product and its proposed use as a cigarette. Therefore, no mitigation measures are to be discussed. Furthermore, the manufacturer's facility has reported air releases under the Clean Air Act and has permits to discharge to water under the local, state, and Federal relevant environmental regulations.<sup>24</sup>

**10. Alternatives to the proposed action:**

*Alternative A (No action alternative):* the no-action alternative is to not allow the product to be marketed in the US. The environmental impact is virtually not changing the existing condition due to the manufacture, use, and disposal from use of the tobacco product.

*Alternative B (Proposed action):* There is virtually no environmental effect due to the proposed action of authorizing the new product and the associated manufacture, use, and disposal from use of the new tobacco product.

Therefore, the difference of environmental impacts of these two alternatives is negligible, if any.

**11. Confidential Appendix:**

Appendix 1: Modification of the New Product, Newport Non-Menthol Gold Box, to Grandfathered Product, "2007 Newport Lights Menthol 80 Hard Box"

Appendix 2: (b) (4)

Appendix 3: Confidential business information: first and fifth year market volume projections

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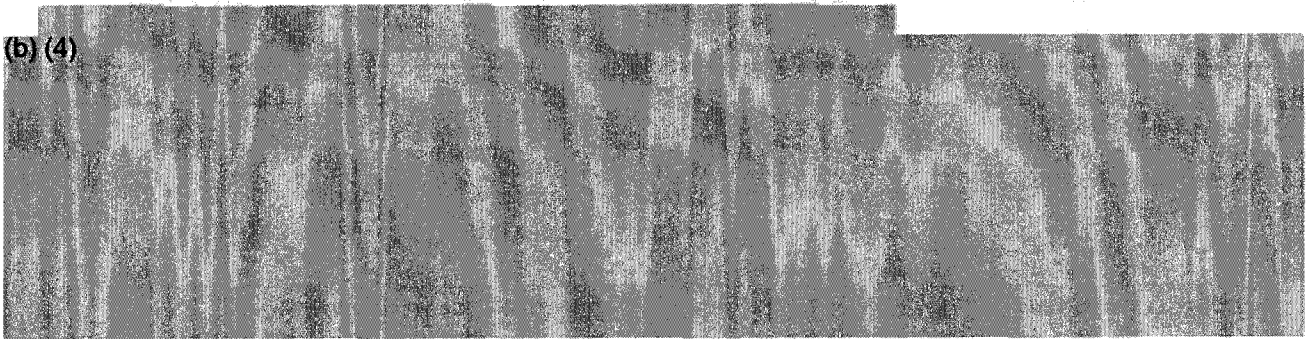
<sup>24</sup> Report based on TRI.

**Appendix 1: Modification of the New Product, Newport Non-Menthol Gold Box, to Grandfathered Product, "2007 Newport Lights Menthol 80 Hard Box"**

	<b>Modification</b>
<b>Product Attributes</b>	1) (b) (4) (b) (4) (b) (4) (b) (4) 3) Exchange of Fire Standards Compliant ("FSC") paper 4) White tipping paper to cork-and-white and decrease of (b) (4) /cig tipping paper weight
<b>Product Constituents</b>	1) Changes of less than (b) (4) /cigarette of certain constituent 2) Changes of less than (b) (4) cigarette of tar, nicotine, CO (TNCO)
<b>Product Ingredients</b>	1) (b) (4) of (b) (4) mg/cigarette of (b) (4) ethyl alcohol (b) (4) (b) (4) 2) Removal of (b) (4) (b) (4) 3) Changes within (b) (4) cig of various tobacco blends

Appendix 2: (b) (4)

(b) (4)



**Appendix 3: Confidential business information: first and fifth year market volume projections**

In their response, SE0007199, dated February 12, 2013, Lorillard stated that, "Newport Non-Menthol Gold Box' is intended to compete with other non-menthol cigarettes currently on the market." They also stated, "Newport Non-Menthol Gold Box' is not reasonably expected to increase the total market volume for non-menthol cigarettes."

They further stated that, "Newport Non-Menthol Gold Box' market volume is projected to be (b) (4) units (cigarettes) in the first year (first 12 months) and (b) (4) (cigarettes) in the fifth year. Please note that brand volume projections are usually revised annually based on actual sales and market dynamics."

**FINDING OF NO SIGNIFICANT IMPACT  
FOR**

**Market Authorization of "Newport Non-Menthol Gold Box"  
Found Substantially Equivalent to "2007 Newport Lights Menthol  
80 Hard Box"**

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required. The evidence supporting this finding is contained in the attached environmental assessment, dated June 4, 2013, which is available to the public upon request. The agency prepared the environmental assessment under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act.

(b) (6)



Date: June 4, 2013

David Ashley, PhD  
Director  
Office of Science  
Center for Tobacco Products  
Food and Drug Administration

## OCE Grandfathered (GF) Product Review Memo

### 1. SUBMISSION INFORMATION

**STN #:** GF1200009  
**Submission Type:** GF Submission  
**Submission Receipt Date:** 05/04/2012

**Tobacco Product Name:** Newport Lights Menthol Gold Box (also referred to as 2007 Newport Light Menthol 80 Hard Box)

**Tobacco Category Type:**  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
 Other:

**Tobacco Product Code:** (b) (4)

**Submitter's Name:** Lorillard, Inc.  
**Company's Name (if different):**  
**Contact Information:** Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335-7656  
(225) 335-7752 (fax)  
nwilcox@lortobco.com

### 2. OCE RECOMMENDATION

**GF Status:**

- Established Grandfathered Status  
 Cannot Establish Grandfathered Status

**Predicate Eligibility:**

- Tobacco product is predicate eligible  
 Tobacco product is not predicate eligible

**NOTE:** This determination was not based on a review of the characteristics of the tobacco product.

3. SIGN-OFF

<b>Compliance Reviewer:</b> John Torcivia	Date: 5/29/2012 Signature: (b) (6)
<b>Team Leader:</b> Paul Perdue, Jr. Comments:	Date: 5/29/2012 Signature: (b) (6)
<b>Group Leader:</b> Joanna Weitershausen Comments:	Date: 5-31-12 Signature: (b) (6)
<b>Senior Regulatory Counsel:</b> Emil Wang Comments:	Date: 6/21/12 Signature: (b) (6)

*[Handwritten signature]*

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that Newport Lights Menthol Gold Box was commercially marketed as of February 15, 2007 and is eligible to serve as a predicate product in a report under section 905(j) of the FD&C Act.

(b) (6)

6/22/12

Ann Simoneau, J.D.  
Director, Office of Compliance and Enforcement  
Center for Tobacco Products

Date

**4. TOBACCO PRODUCT INFORMATION**

<b>Product Description</b>
Newport Lights Menthol Gold Box are mentholated cigarettes.
<b>Product Use</b>
The cigarette is lit by the consumer and smoked.

**5. REGULATED TOBACCO PRODUCT DETERMINATION**

Jurisdiction Questions	Yes	No	Comments/rationale, as applicable.
1. Is the product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)? (FD&C Act § 201(rr)(1))	X		
2. Is the product a drug, device, or combination product? (FD&C Act § 201(rr)(2))		X	
3. Is the product marketed in combination with any other article or product regulated under the Act? (FD&C Act § 201(rr)(4))		X	
4. Is the product <i>currently</i> regulated under Chapter IX? If "yes," specify the tobacco product category. (FD&C Act § 901(b))	X		Tobacco product meets the definition of "cigarette" under the Act.
Does CTP currently regulate this tobacco product? ("Yes" response to Questions 1 and 4 and "No" response to Questions 2 and 3.)	X		Cigarette

**6. GF EVIDENCE REVIEW**

**Evidence Demonstrating Commercial Marketing as of February 15, 2007**

Tab	Type of Evidence	Date	Comments
1.C	Bill of Lading	2/12/2007	Bill of Lading #4500028517, Page 1; NPT LT M 80 BX (12M); UPC#00349 Material#1000072
2.C	Bill of Lading	2/16/2007	Bill of Lading #4500028613, Page 1; NPT LT M 80 BX (12M); UPC#00349 Material#1000072

**Other Evidence Submitted**

Tab	Type of Evidence	Date	Comments
	N/A		

**7. PREDICATE ELIGIBILITY EVIDENCE REVIEW**

Tab	Type of Evidence	Date	Test Market Status	Comments
D	Statement	5/4/2012	<input checked="" type="checkbox"/> Not in test market (Predicate Eligible)  <input type="checkbox"/> In test market (Not Predicate Eligible)	"We hereby confirm that Newport Lights Menthol Gold Box was not in a test market as of February 15, 2007. At that time, the product was sold nationally." – Neil Wilcox, Senior Vice President & CCO. Newport



				Lights Menthol Gold Box is also known as NPL LT M 80 BX and is a hard box.
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**8. CORRESPONDENCE**

<b>Tab</b>	<b>Date</b>	<b>From</b>	<b>Description</b>
A	5/3/2012	Dan-My Chu (CTP, OCE, EMG)	Email summary of information requested for grandfathered application.
B	5/3/2012	Patricia Kovacevic (Lorillard)	Email acknowledgement of Tab A correspondence
C	5/4/2012	Patricia Kovacevic (Lorillard)	Email requested for grandfathered review for Newport Lights Menthol Gold Box. Email contained (1) cover letter dated 5/4/2012 from Neil Wilcox, (2) evidence for commercial marketing of grandfathered products, and (3) statement product was not in test market as of February 15, 2007.

**OCE/EMG Compliance with the Act Memo for Regular 905(j) Applications  
Addendum**

**1. SUBMISSION INFORMATION**

STN #: SE0003731  
Submission Type: 905(j) Regular Report  
Submission Receipt Date: 10/13/2011

New Tobacco Product Name: Newport Non-Menthol Gold Box  
New Tobacco Category Type:  Cigarette  Smokeless Tobacco  
 RYO Tobacco  Cigarette Tobacco  
New Tobacco Product Code: (b) (4)

Submitter's Name: Lorillard Inc.  
Company's Name (if different):  
Contact Information: Neil L. Wilcox, DVM, MPH  
Senior Vice President & Chief Compliance Officer  
714 Green Valley Road  
Greensboro, NC 27408  
(336) 335 - 7656  
(336) 335 - 7752 (fax)  
nwilcox@lortobco.com

**2. RECOMMENDATION**

- |  |
|--|
| <input checked="" type="checkbox"/> Tobacco product is in compliance with applicable provisions of the FD&C Act. |
| <input type="checkbox"/> Tobacco product is not in compliance with applicable provisions of the FD&C Act.        |

3. SIGN-OFF

Compliance Reviewer: Dina Raafat	Date: 6/19/13 Initials: DR
----------------------------------	-------------------------------

Based on a review of the information provided, the Office of Compliance and Enforcement has determined that the firm is in compliance with section 919 (user fees) of the FD&C Act and the brand name Newport Non-Menthol Gold Box is in compliance with applicable provisions of the FD&C Act.

(b) (6)

*for CMS*

*6.19.13*

Christine M. Smith  
Division Director, Office of Compliance and Enforcement  
Center for Tobacco Products

Date

4. ADDITIONAL INFORMATION

Tab	Date	From	Description
N/A	6/19/13	N/A	The firm was not found on CTP's arrears list dated 6/2/13.

Primary STN # SE0003731

Reviewer: D. Portnoy

New Product Name: Newport Non-Menthol Gold Box

Submission	
Primary STN	SE0003731 amended by SE0005305
Submission Date	December 3, 2012   FDA Receipt Date   December 10, 2012
Applicant	Lorillard, Inc.
Purpose	<input checked="" type="checkbox"/> Introduction of New Product <input type="checkbox"/> Modification of Existing Product
Scope of Review	To determine whether the predicate and new product are substantially equivalent in terms of consumer perceptions.
Information Reviewed	<input type="checkbox"/> Label <input type="checkbox"/> Marketing <input type="checkbox"/> Sensory Perception Studies <input type="checkbox"/> Risk Perception Studies <input type="checkbox"/> Health Information Summary
Recommendation	Substantially Equivalent
New Product	
Name	Newport Non-Menthol Gold Box
Package Size	Hard box pack, 20 cigarettes in each pack, 10 packs per carton
Product ID	2000314 (reference ID # internal)/ TP-0004209
Product Category	<input checked="" type="checkbox"/> Cigarette <input type="checkbox"/> Roll-Your-Own <input type="checkbox"/> Cigarette Tobacco <input type="checkbox"/> Smokeless <input type="checkbox"/> Pipe Tobacco <input type="checkbox"/> Hookah Tobacco <input type="checkbox"/> Cigars <input type="checkbox"/> Bidis <input type="checkbox"/> Kreteks <input type="checkbox"/> ENDS <input type="checkbox"/> Other
Product Sub-Category	Filtered (Combustion)
Product Use	<input checked="" type="checkbox"/> For Consumer Use <input type="checkbox"/> For Further Manufacturing
Product Type	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Component <input type="checkbox"/> Part <input type="checkbox"/> Accessory
Predicate Product	
Name	Newport Lights Menthol Gold Box
Package Size	20 cigarettes in each pack, 10 packs per carton

Reviewer name: David Portnoy, Ph.D., MPH Signature: \_\_\_\_\_  
CTP/OS

Date: 6/13/13  
(b) (6)

Team Leader name: Conrad Choiniere, Ph.D. Signature: \_\_\_\_\_  
CTP/OS

Concur

Non-concur (see separate memo)

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Primary STN # SE0003731  
New Product Name: Newport Non-Menthol Gold Box

Reviewer: D. Portnoy

## EXECUTIVE SUMMARY

On October 12, 2011, Lorillard Tobacco Company submitted a report in accordance with section 905(j): Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce. On December 3, 2012 Lorillard Tobacco Company submitted an amendment in response to the AI letter dated October 26, 2012.

The applicant is seeking an order to introduce a new product, Newport Non-Menthol Gold Box, as a substantially equivalent product to the grandfathered product Newport Lights Menthol Gold Box, into interstate commerce.

Modifications to the product include modifications of the The applicant posits that although menthol was removed between the new product and the predicate product, the products are substantially equivalent and any differences do not raise different questions of public health

In the cover letter dated October 12, 2011, sent with the report, the applicant states that "a summary of the relevant health information for the subject product will be made available upon request pursuant to Section 910(a)(4) of the FDCA."

## EVALUATION OF CONSUMER INFORMATION

### 1.1 Scope of Review

This review assesses the substantial equivalence of Newport Non-Menthol Gold Box in relation to Newport Lights Menthol Gold Box (predicate product) based on the consumer information provided in the application. The review does this by examining the following parts of the application:

- Health Information Summary
- Change in characterizing flavor

### 1.2 Review of Consumer Information

#### **Health Information Summary**

On the cover sheet for the original SE submission dated October 12, 2011, and again in the amendment dated December 3, 2012 the applicant states that a summary of health information will be provided upon request.

#### **Change in characterizing flavor**

A change from the predicate product, which contains menthol, to the new product, which does not contain menthol, poses an issue from a social science perspective regarding whether the change raises different questions of public health specifically with respect to the impact of a new non-menthol product on initiation of tobacco use. This review primarily focuses on youth and young adults as initiation of established smoking occurs almost exclusively before the age of 25. In the process of addressing the issues, we reviewed the peer-reviewed literature, public documents, and FDA's internal review of menthol.

Approximately half (46%) of all current youth and young adult cigarette smokers smoke menthol cigarettes according to data from the 2004 National Youth Tobacco Survey, with similar findings in 2008 among youth smokers.<sup>1,2</sup> The appeal of menthol cigarettes, especially among youth, has been linked to their portrayal in marketing as having a smoother taste and being less harsh, which may be appealing to newer smokers or those curious about experimentation.<sup>3,4,5</sup> Direct data on the appeal of non-menthol cigarettes as compared to menthol cigarettes as it relates to initiation is less available. A review of tobacco industry documents found that menthol cigarettes were marketed as being implied to be healthier and that they were targeted to those consumers that would not otherwise progress to regular smoking, including young smokers and those that do not like regular cigarettes.<sup>6</sup> A second piece of indirect evidence on the influence of menthol on cigarette initiation comes from an economic analysis of pricing of menthol and non-menthol cigarettes. Tauras et al. used data from over 57,000 smokers from the TUS-CPS to examine preference of menthol versus non-menthol cigarettes.<sup>7</sup> That analysis suggested that from an economic point of view, smokers of non-menthol cigarettes are less likely to substitute their cigarettes for menthol cigarettes than the reverse. A survey of current adolescent and adult smokers in 2010 found that among menthol smokers, if they were no longer able to obtain menthol cigarettes, they reported that they would most likely try to quit smoking/smoke less or

New Product Name: Newport Non-Menthol Gold Box

seek out alternative sources of menthol, such as in a smokeless tobacco product<sup>8</sup>. In that study, over 80% of menthol smokers reported that they would be willing to try a non-menthol cigarette, suggesting that in the absence of a menthol cigarette, current menthol smokers might be willing to switch to a non-menthol cigarette, although this study did not directly address initiation of smoking.

In sum, menthol cigarettes are used more frequently by youth and young adult smokers than adult smokers, especially youth and young adults that have smoked for less than a year, suggesting they appeal to youth and may be associated with increased initiation as compared to non-menthol cigarettes. However, there is limited data that directly compares initiation of menthol versus non-menthol cigarettes. DiFranza found that among 120 participants that initiated cigarette use during a 30-month follow-up assessment, and could remember their first cigarette, 42% reported that their first cigarette was menthol.<sup>9</sup> However it is suggested that newer tobacco users may start with a menthol product and then later switch to a non-menthol product.<sup>10,11</sup>

The evidence for initiation of menthol cigarettes, especially among youth and young adults, suggests that the new product (non-menthol) is not likely to have a negative impact on initiation rates compared to the predicate (menthol) product and does not raise different questions of public health beyond those of the predicate product. However these questions should also be referred to an addiction reviewer to evaluate the impact on the likelihood of initiation, level of dependence and cessation.

## OUTSTANDING ISSUES

### 2.1 Issues

- None identified.

### 2.2 Letter Ready Comments

- N/A

## CONCLUSIONS

Based on the inclusion of a statement that a health information summary will be made available upon request, and consideration of the public health impact of the removal of menthol as a characterizing flavor, we have resolved the questions raised by the introduction of Newport Non-Menthol Gold Box into interstate commerce that would preclude an order finding Newport Non-Menthol Gold Box substantially equivalent Newport Lights Menthol Gold Box from the social science perspective.



New Product Name: Newport Non-Menthol Gold Box

## References

- <sup>1</sup> Wackowski O, Delnevo CD. Menthol cigarettes and indicators of tobacco dependence among adolescents. *Addictive behaviors* 2007;32:1964-1969.
- <sup>2</sup> <http://www.oas.samhsa.gov/2k9/134/134MentholCigarette.htm>; Substance Abuse and Mental Health Services Administration, 2009, as cited by FDA Menthol Report
- <sup>3</sup> Hersey JC, Ng SW, Nonnemaker JM et al. Are menthol cigarettes a starter product for youth? *Nicotine Tob Res* 2006;8:403-413.
- <sup>4</sup> Klausner K. Menthol cigarettes and smoking initiation: A tobacco industry perspective. *Tobacco Control* 2011;20:ii12-ii19.
- <sup>5</sup> Henningfield JE, Benowitz NL, Ahijevych K, Garrett BE, Connolly GN, & Wayne GF. Does menthol enhance the addictiveness of cigarettes? An agenda for research *Nicotine Tob Res* 2003;5(1), 9-11.
- <sup>6</sup> Anderson SJ. Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents. *Tobacco Control* 2011; 20,ii20-ii28.
- <sup>7</sup> Tauras JA, Levy D, Chaloupka FJ, Villanti A, Niaura RS, Vallone D, & Abrams DB. Menthol and non-menthol smoking: the impact of prices and smoke-free air laws. *Addiction* 2010; 105(s1), 115-123.
- <sup>8</sup> O'Connor RJ, Bansal-Travers M, Carter LP, & Cummings KM. What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand. *Addiction* 2012; 107, 1330-1338
- <sup>9</sup> DiFranza JR, Savageau JA, Fletcher K, Ockene JK, Rigotti NA, McNeill AD, Coleman M, & Wood C. Recollections and repercussions of the first inhaled cigarette. *Addictive Behavior* 2004; 29, 261-272.
- <sup>10</sup> Rising J & Wasson-Blader W. Menthol and initiation of cigarette smoking. *Tobacco Induced Diseases* 2011; 9(Suppl 1), S4-S8.
- <sup>11</sup> The NSDUH Report: Use of Menthol Cigarettes. Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2009.