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Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

October 12, 2011

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

**BY CERTIFIED MAIL/
RETURN RECEIPT REQUESTED**

**Re: Lorillard Tobacco Company Section 905(j)
Report for Newport Non-Menthol Gold Box 100s**

Dear Dr. Deyton:

As required by section 905(j) of the Federal Food, Drug and Cosmetic Act (FDCA), Lorillard Tobacco Company (Lorillard) submits this report and supporting information (the "905(j) Report") to demonstrate that Newport Non-Menthol Gold Box 100s is substantially equivalent to the 2007 Newport Lt M 100 Hard Box.

The 2007 Newport Lt M 100 Hard Box was commercially marketed in the United States as of February 15, 2007. Comparisons of the characteristics (including materials, ingredients, design, composition, heating source, etc.) between the subject of this submission, the Newport Non-Menthol Gold Box 100s cigarette, and the predicate product, the 2007 Newport Lt M 100 Hard Box, demonstrate that the subject product has the same characteristics as the predicate product or does not raise different questions of public health. The products are, therefore, substantially equivalent as defined in Section 910 of the FDCA. 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.

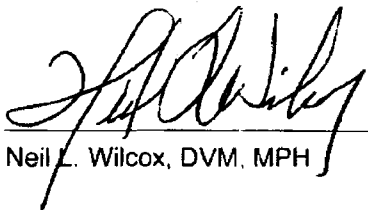
As stated in Section 905(j)(1) of the FDCA, Lorillard is required to file this 905(j) Report at least 90 days prior to introducing the subject product into interstate commerce for commercial distribution. Moreover, Lorillard understands that this product may not be commercially distributed in the United States until FDA has issued an order authorizing such distribution. To this end, and understanding that there is no mandatory time-frame under which FDA must issue an order in response to this 905(j) Report, Lorillard respectfully requests that FDA give this non-provisional product 905(j) Report high priority. Lorillard reasonably expects that FDA will act in the spirit of the FDCA, within the 90 days recommended, and further believes that the FDA is bound to issue an order within a predictable and reasonable time-frame. Lorillard has expended extensive resources to prepare for the manufacturing and distribution of this product; delaying the market launch of this product would have a substantial impact on Lorillard's business. To expedite this process, Lorillard remains ready to provide any additional information as may be requested by FDA.

Substantial Equivalence Submission
Newport Non-Menthol Gold Box 100s
Lorillard Tobacco Company
Page 2

Please note that Lorillard considers the information contained in this letter to constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter and its contents are exempt from public disclosure under 5 U.S.C. § 552(b) (4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j). Please let us know if you require additional information or clarification of these matters.

Should you have any questions regarding this submission, please do not hesitate to contact me at 336-335-7656 or nwilcox@lortobco.com.

Sincerely,



Neil L. Wilcox, DVM, MPH

Enclosure



Substantial Equivalence Product Submission

Lorillard Tobacco Company

Newport Non-Menthol Gold Box 100s

Submitted: October 12, 2011

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2. Summary Section

2.1 Submitter Name & Address

Lorillard Tobacco Company
714 Green Valley RD.
Greensboro, NC 27408

2.2 Submitter Contact Information

Neil L. Wilcox, DVM, MPH
Senior Vice President & Chief Compliance Officer
Lorillard Tobacco Company
Phone: 336-335-7656
Fax: 336-335-7752
Email: nwilcox@lortobco.com

2.3 Submission Date

October 12, 2011

2.4 Subject Product Information

Trade Name: Newport Non-Menthol Gold Box 100s
Reference Identification Number (internal): 2003906
Product Identification Number 0-26100-00661-2
Owner / Registrant: Lorillard Tobacco Company (LTC)

2.5 Predicate Product Information

Trade Name: 2007 Newport Lt M 100 Hard Box
Reference Identification Number (internal): 2000241
Owner / Registrant: Lorillard Tobacco Company (LTC)

2.6 Summary Section Narrative

Comparisons of the characteristics (including tar, nicotine and carbon monoxide smoke yields, design, materials, ingredients, heating source and composition) between the subject of this submission, the Newport Non-Menthol Gold Box 100s cigarette, and the predicate product 2007 Newport Lt M 100 Hard Box demonstrate that the subject product has the same characteristics

as the predicate product or does not raise different questions of public health. The products are, therefore, substantially equivalent as defined in Section 910 of the Federal Food, Drug and Cosmetic Act, (FDCA).

The subject product contains two categories of modifications as compared to the predicate product. First, the subject product contains no menthol and a lower level of ethyl alcohol, whereas the predicate product contained menthol as a flavoring. Second, Lorillard implemented several minor changes to the subject product as compared to the predicate in order to comply with the Fire Standard Compliant (FSC) requirements imposed by most states. Compliance with the FSC Regulations necessitates use of a special paper for the tobacco column called Low Ignition Propensity (LIP) paper. As a result of the use of the LIP paper, the Newport Non-Menthol Gold Box 100s product required a slight modification of certain ingredients and commonly used design elements to maintain equivalence with the 2007 Newport Lt M 100 Hard Box predicate product, which was non-FSC. The modifications related to LIP paper use and other modifications are discussed in the sections to follow.

Based on the information set forth in the following sections, the Newport Non-Menthol Gold Box 100s cigarette is substantially equivalent to the 2007 Newport Lt M 100 Hard Box predicate tobacco product that was commercially available in the U.S. marketplace on or before February 15, 2007 and does not raise different questions of public health.

2.7 Supporting Data for Substantial Equivalence Determination

Substantial equivalence for the Newport Non-Menthol Gold Box 100s cigarette relative to the 2007 Newport Lt M 100 Hard Box predicate product is based upon comparisons of their tar, nicotine and carbon monoxide smoke yields, design, materials, ingredients, heating source and compositions. Detailed comparisons of smoke yields, and product attributes are provided in the sections to follow.

2.8 Tar, Nicotine and Carbon Monoxide (TNCO) Comparisons

For more than 50 years, measurements of tar and nicotine smoke deliveries have been used as representative constituents of particulate phase yields from cigarettes (1, 2). Similarly, for almost 30 years, carbon monoxide has been used as a representative component of the vapor phase constituents of cigarette smoke (3). Standardized smoking regimens are typically used in the laboratory to measure smoke constituent yields including tar, nicotine, and carbon

monoxide. (b) (4) Using the (b) (4) resulted in tar, nicotine and carbon monoxide (TNCO) yields which were slightly lower than the results generated using the (b) (4). However, the parameters of the two regimes are relatively similar and it is therefore reasonable to compare data collected from the two regimes (Table 1 in Appendix A describes the differences in parameters between the (b) (4) smoking methods).

The major differences in the two smoking regimes are the butt length (or smoking endpoint) and the smoking machine air velocity. These changes result in different main stream yields for the (b) (4) relative to the (b) (4). However, (b) (4) are standard test items used for laboratory research as a basis for comparing data collected in different laboratories or different analytical test methodologies. They were chosen because their TNCO yields span a range typical of commercial cigarettes.

Over 2300 data points for the (b) (4) and details are shown in Table 2 in Appendix A. (b) (4) (Figure 1 in Appendix A). Therefore, utilizing this (b) (4) for the comparison of the subject yields, generated using the (b) (4), and the predicate yields, generated using the (b) (4), is a valid approach to demonstrate that two products are substantially equivalent.

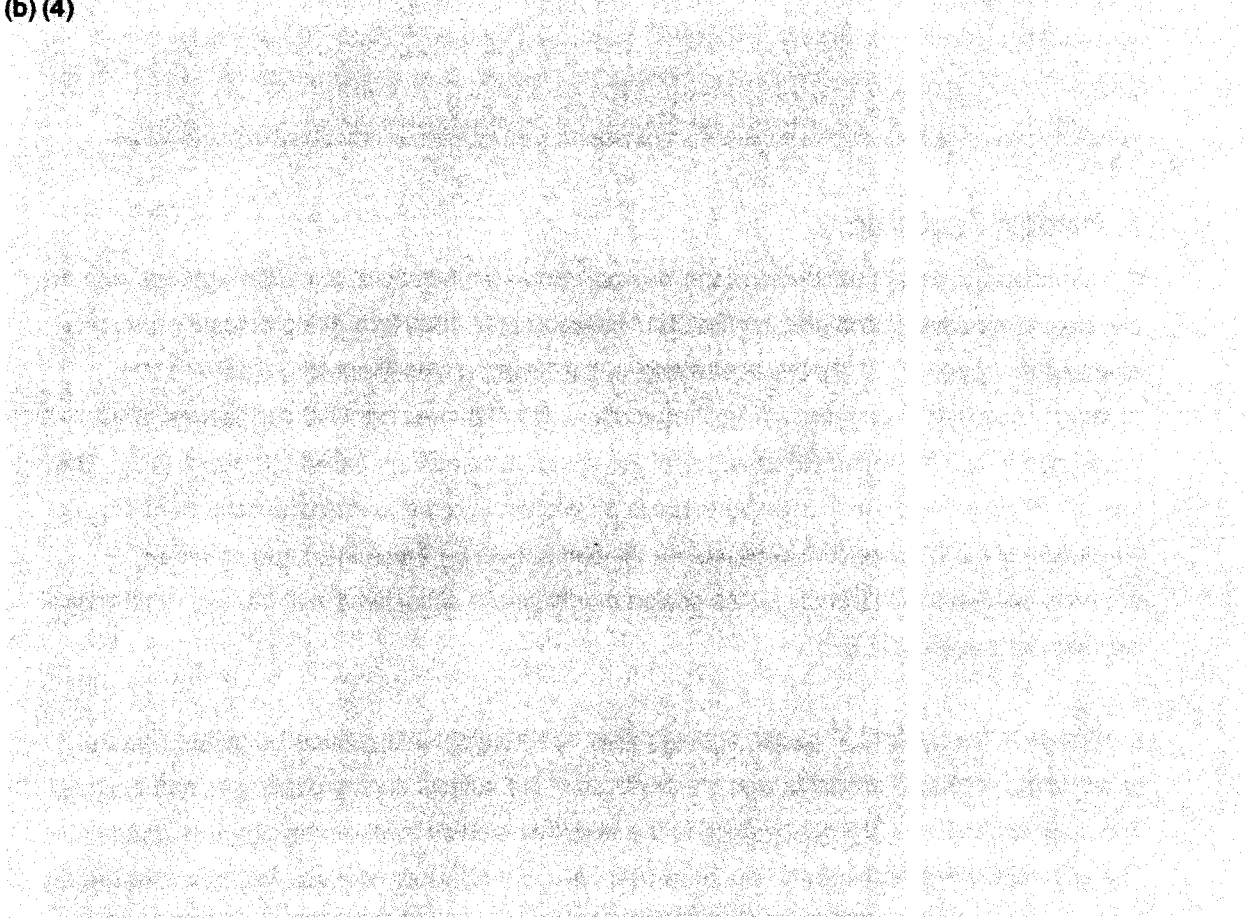
2.9 Comparison of the Subject (Newport Non-Menthol Gold Box 100s) and Predicate (2007 Newport Lt M 100 Hard Box) data:

The Newport Non-Menthol Gold Box 100s and 2007 Newport Lt M 100 Hard Box TNCO yields were measured using the (b) (4), respectively. Since the Newport Non-Menthol Gold Box 100s TNCO data was collected using a different smoking regime than the 2007 Newport Lt M 100 Hard Box TNCO data, it was necessary to (b) (4) TNCO values for the Newport Non-Menthol Gold Box 100s product in order to make meaningful comparisons to the (b) (4) TNCO yields of the 2007 Newport Lt M 100 Hard Box product. The (b) (4) Newport Non-Menthol Gold Box 100s CAM TNCO values were calculated using (b) (4) of the testing methodologies. Furthermore, the total variability requires the implementation of an (b) (4) to determine substantial equivalence. The (b) (4) were calculated based on the (b) (4) are used for the purpose of comparing the smoke constituents of the subject and predicate products, and are defined in this submission as the (b) (4). This approach is illustrated as a flow chart in Appendix A, Figure 2.

If the (b) (4) Newport Non-Menthol Gold Box 100s (b) (4) TNCO values are within the (b) (4) of the 2007 Newport Lt M 100 Hard Box (b) (4) TNCO yields, the two products would be substantially equivalent. Figure 1, shown below, is a graphical example of this approach using (b) (4) data; the corresponding nicotine and carbon monoxide comparisons were completed using the same methodology. The data supports the claim that the Newport Non-Menthol Gold Box 100s TNCO yields are substantially equivalent to the 2007 Newport Lt M 100 Hard Box yields. (b) (4) are shown in Appendix A, Table 3.

Figure 1: Graphical representation of the comparison of Newport Non-Menthol Gold Box 100s subject (b) values to 2007 Newport Lt M 100 Hard Box predicate (b) values.

(b) (4)



The (b) (4) for tar, nicotine and carbon monoxide are summarized in the table below along with smoke yield data for the subject and predicate products.

	Subject [†]		Predicate [*]		SUBSTANTIALLY EQUIVALENT
	NEWPORT NON-MENTHOL GOLD BOX 100S	WITHIN (b)	2007 NPT LT M 100 HARD BOX	(b) (4)	
Tar (mg/cig)	(b) (4)	YES	(b) (4)	(b) (4)	YES
Nicotine (mg/cig)	(b) (4)	YES	(b) (4)	(b) (4)	YES
CO (mg/cig)		YES			YES

* Data generated using (b) (4)

† Data generated using (b) (4)

Because the smoke constituents shown above for the Newport Non-Menthol Gold Box 100s are within the (b) of the 2007 Newport Lt M 100 Hard Box predicate product, the two products are substantially equivalent. (b) (4)

3. Design Features

A comparison of design attributes of the Newport Non-Menthol Gold Box 100s cigarette and the corresponding design attributes for the 2007 Newport Lt M 100 Hard Box predicate product is attached as Appendix B. As discussed above, the Newport Non-Menthol Gold Box 100s product is required to comply with FSC regulations (1). To meet the FSC regulations, LTC developed a starch banded cigarette paper for the tobacco column called LIP paper (10). The use of LIP paper required a slight increase in air dilution in order to maintain consistent TNCO yields with the 2007 predicate product. Air dilution targets for the subject and predicate products are listed in Appendix B. All design modifications associated with the use of LIP paper are marked in Appendix B.

In addition to the use of LIP paper, tipping paper basis weight was reduced slightly. Tipping paper of the predicate products was pre-perforated; the subject tipping paper was non-porous. The subject product is (b) (4) to the target air dilution level during cigarette production. The color of the tipping paper for the predicate was cork-on-white whereas the tipping paper for the subject is white. (b) (4)

(b) (4) Both subject and predicate products utilize the same filter, although the plug wrap used for the 2007 Newport LT M 100 predicate product is porous whereas the Newport Non-Menthol Gold Box 100s is non-porous. The porous plug wrap used on the 2007 Newport Lt M 100 Hard Box was a structural material used with pre-perforated tipping paper prior to the introduction of (b) (4) capabilities. (b) (4)

(b) (4) As a result, the design of the Newport Non-Menthol Gold Box 100s cigarette is substantially equivalent to the 2007 Newport Lt M 100 Hard Box predicate product. Moreover, as discussed above, the two products are substantially equivalent in terms of their TNCO yields.

4. Listing of Ingredients and Materials

A comparison of ingredients and materials in the Newport Non-Menthol Gold Box 100s cigarette and the 2007 Newport Lt M 100 Hard Box predicate product is attached as Appendix C. As mentioned in the Design section above, the use of LIP paper required certain design modifications in order to maintain smoke yields and taste characteristics consistent with the 2007 Newport Lt M 100 Hard Box predicate product. The use of LIP paper also had several minor ingredients and materials modifications between the subject and predicate products. These modifications are identified in Appendix C. First, the use of LIP paper introduced small amounts of modified starch as a new material that was not present in the non-LIP predicate product. However, (b) (4) and does not impact smoke analyte yields at the levels employed in LIP paper. The remaining components of the LIP paper band formula are already used as ingredients in the cigarette paper wrapper. (b) (4)

In addition to the ingredients and materials modifications for Newport Non-Menthol Gold Box 100s related to the LIP paper use, other modifications in ingredients and materials are noted in Appendix C. The subject product does not include menthol and, as a result, utilizes a lower level of ethyl alcohol. The plug wrap used for Newport Non-Menthol Gold Box 100s was changed from the plug wrap used on the 2007 Newport Lt M 100 Hard Box predicate product.

(b) (4) The tipping paper basis weight was reduced slightly compared with the 2007 Newport Lt M 100 Hard Box predicate which in turn reduced the (b) (4) relative to the predicate product. (b) (4)

No other material and ingredient modifications were implemented for this product. Furthermore, the removal of menthol leads to a concurrent decrease in ethyl alcohol, since menthol is added into the predicate as a solution in ethyl alcohol. As a result, the ingredients and materials of the Newport Non-Menthol Gold Box 100s cigarette are substantially equivalent to the 2007 Newport

Lt M 100 Hard Box predicate product. Moreover, as discussed above, the two products are substantially equivalent in terms of their TNCO yields.

5. Description of Heating Source

The Newport Non-Menthol Gold Box 100s cigarette employs a smoldering fire cone as its heating source, as does the 2007 Newport Lt M 100 Hard Box predicate product. Comparing heating sources, the subject of this submission and the predicate product are substantially equivalent.

6. Description of Composition

The combination of the various elements (*i.e.* materials, ingredients, design) which make up the characteristics of the Newport Non-Menthol Gold Box 100s cigarette have not changed and are substantially equivalent to the 2007 Newport Lt M 100 Hard Box predicate product.

7. Other

(b) (4)



Appendix A

Appendix A: TNCO comparisons for Newport Non-Menthol Gold Box 100s with the 2007
Newport Lt M 100 Hard Box Predicate Product

Appendix A; TNCO Summary

The smoking regime used by the Lorillard Smoke Science Laboratory (b) (4)

Under the (b) (4) the tar, nicotine and carbon monoxide (TNCO) yields were slightly lower than the results generated using the (b) (4). However, the parameters of the two regimes (Table 1) are relatively similar and are therefore reasonable to compare data collected from the two regimes.

Table 1: A comparison of the (b) (4) smoking regime parameters.

Parameter	Standard Smoking Regimes	
	(b) (4)	(b)
Puff Volume (ml)	(b) (4)	
Puff Duration (s)	(b) (4)	
Puff Frequency (s)	(b) (4)	
Ventilation Holes	(b) (4)	
Conditioning Atmosphere	(b) (4)	
Smoking Environment	(b) (4)	
Air Velocity <i>Linear Individual Port</i> <i>Linear Average & Rotary</i>	(b) (4)	
Butt Length <i>(choose highest value)</i>	(b) (4)	

Note: RH – Relative Humidity; ml/min – milliliters per minute; mm – millimeters.

The major differences in the two smoking regimes are the (b) (4)

Depending on the construction parameters of the particular sample, this difference could result in lower mainstream yields for the (b) (4) due to a fewer number of puffs. The most apparent difference between the two regimes,

however, is the (b) (4) . The (b) (4) is set at a level sufficient to exhaust sidestream smoke, whereas the (b) (4) s explicitly stated. Variation in the set smoking machine (b) (4) can generate differences in mainstream smoke yields due to the effect of (b) (4) Table 2 contains (b) (4) data collected using the two aforementioned smoking regimes which was (b) (4) between the mainstream smoke yields.

Table 2: (b) (4)

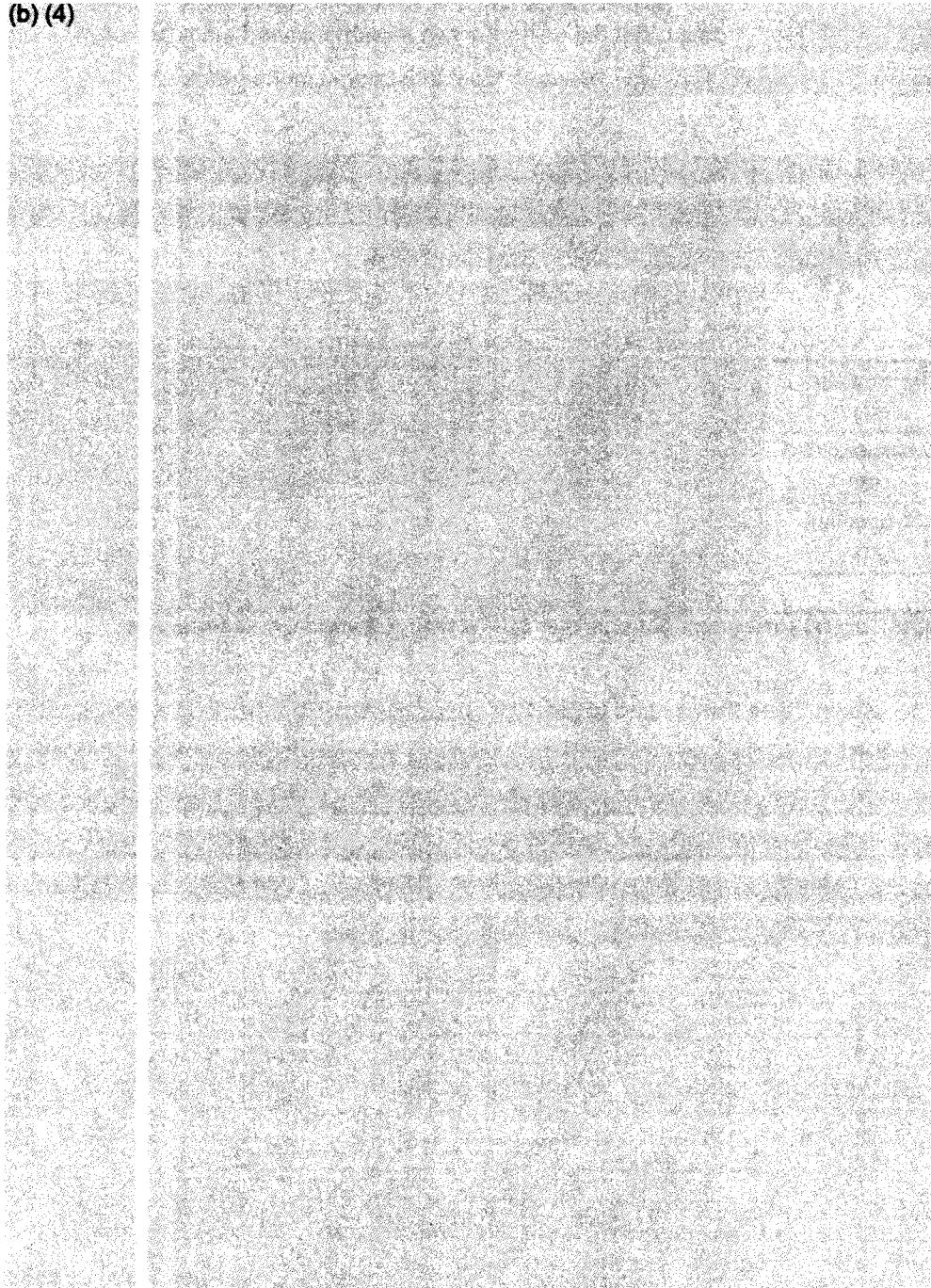
(b) (4)

Tar (mg/cig) SD	(b) (4)
Nicotine (mg/cig) SD	(b) (4)
CO (mg/cig) SD	(b) (4)
n	(b) (4)

Note: mg/cig – milligrams per cigarette; SD – standard deviation; n – sample size.

The data in Table 2 was used to (b) (4)

Figure 1: (b) (4) for (a) tar, (b) nicotine, and (c) carbon monoxide for the (b) (4)



(b) (4)



(b) (4)

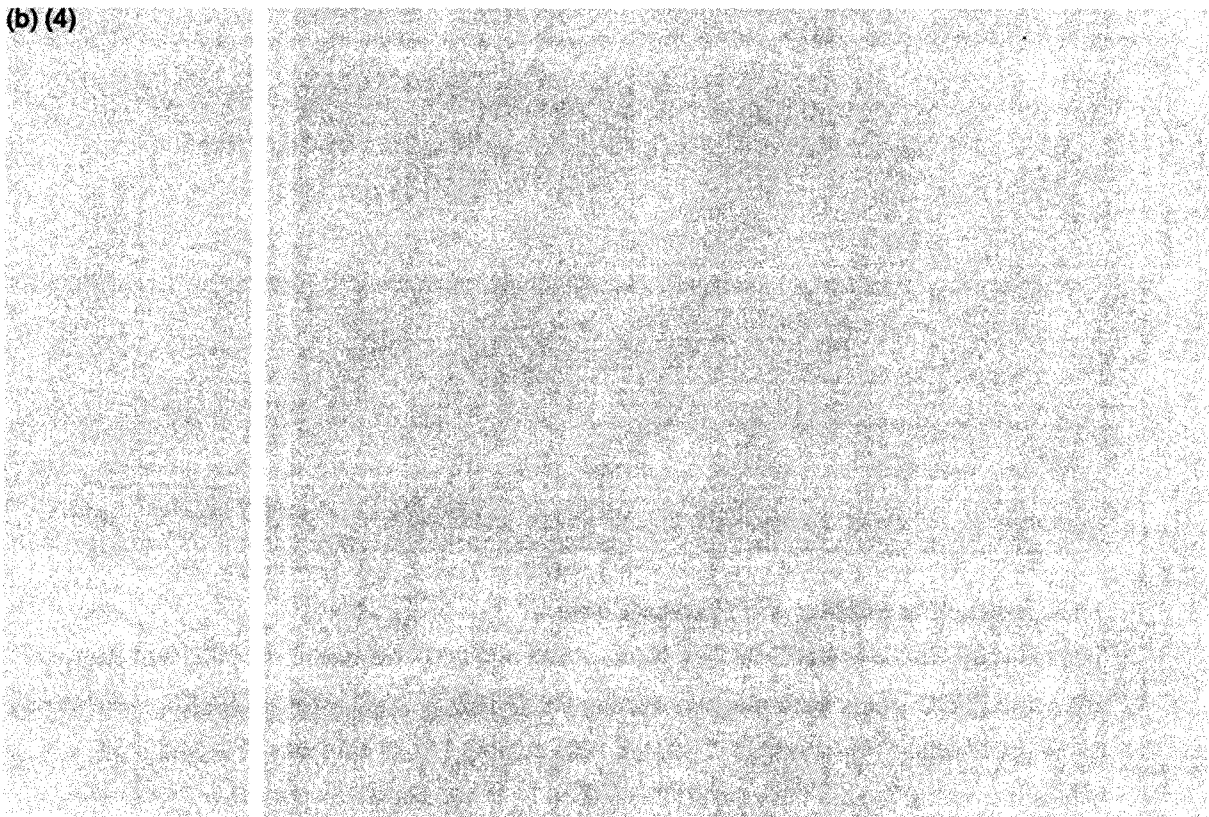


Treatment of the Subject and Predicate data:

The Newport Non-Menthol Gold Box 100s subject and 2007 Newport Lt M 100 Hard Box predicate TNCO yields were measured using the (b) (4) [redacted], respectively. Since the Newport Non-Menthol Gold Box 100s subject TNCO data was collected using a different smoking regime than the 2007 Newport Lt M 100 Hard Box predicate TNCO data, it was necessary to (b) (4) [redacted] TNCO values for the Newport Non-

Menthol Gold Box 100s subject product in order to (b) (4)
TNCO yields of the 2007 Newport Lt M 100 Hard Box predicate product. (b) (4)
illustrated in Figure 1.

The total variability requires the implementation of (b) (4)
(b) (4) to demonstrate that two products are substantially equivalent. The
(b) (4) utilized within the context of this report were calculated based on the
(b) (4)
are used for the purpose of comparing the smoke constituents of the subject
and predicate products, and are defined in this submission as the (b) (4)
The approach implemented for the comparison of projected subject tar,
nicotine, and carbon monoxide values to the predicate product yields is illustrated in Figure 2.



The TNCO yields of the subject Newport Non-Menthol Gold Box 100s are deemed substantially equivalent to the predicate 2007 Newport Lt M 100 Hard Box if the (b) (4) values are within the (b) (4) of the 2007 Newport Lt M 100 Hard Box (b) (4) TNCO yields. Figure 3 is an example of this approach using tar data, and the corresponding nicotine and carbon monoxide comparisons were completed using the same methodology. The data supports the claim that the subject Newport Non-Menthol Gold Box 100s TNCO yields are substantially equivalent to the predicate 2007 Newport Lt M 100 Hard Box yields. (b) (4)

(b) (4)

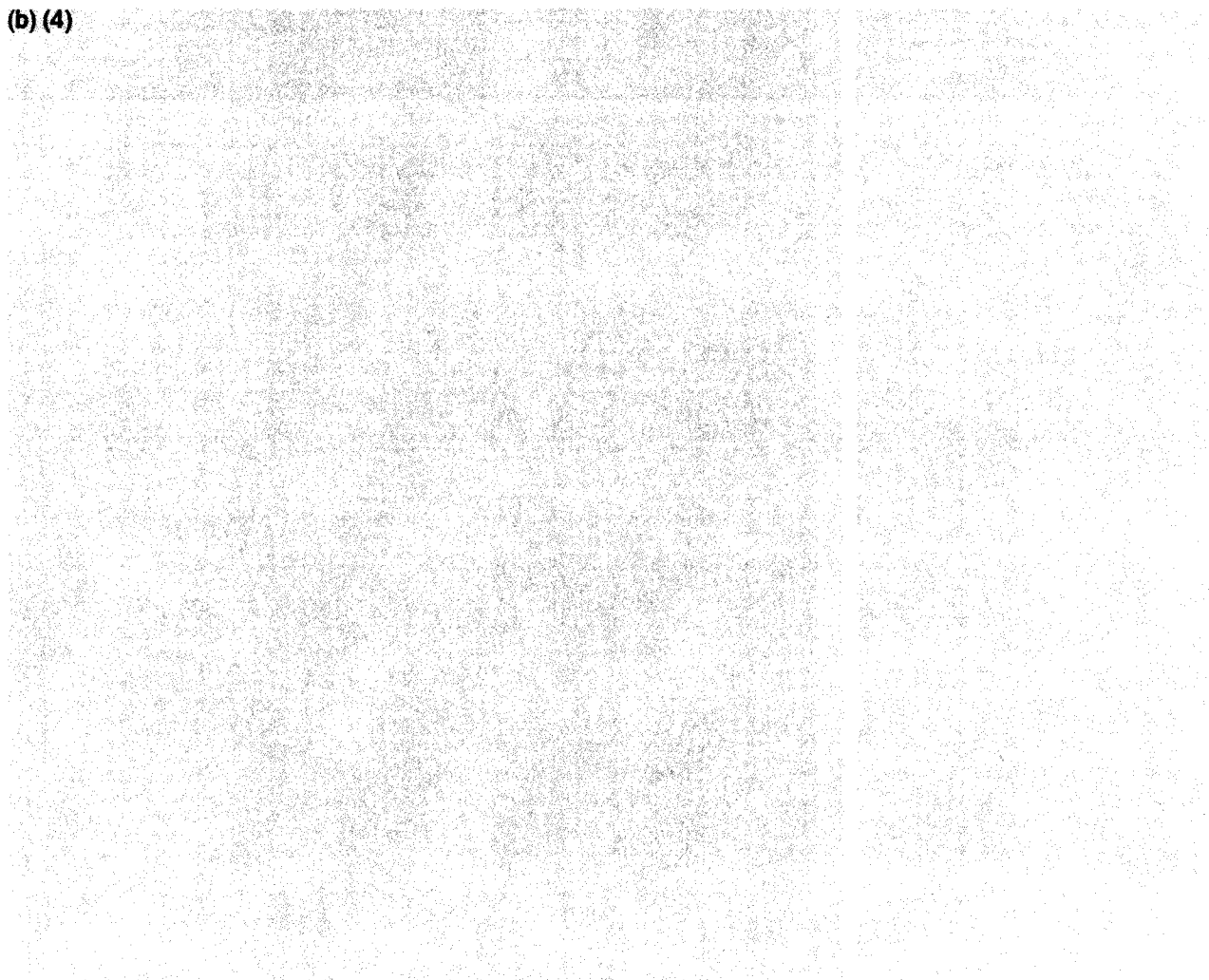


Table 3: Newport Non-Menthol Gold Box 100s subject I(b) TNCO, (b) (4) TNCO, and 2007 Newport Lt M 100 Hard Box predicate (b) TNCO means, and the corresponding (b) (4)

	Subject			Predicate		SUBSTANTIALLY EQUIVALENT
	NEWPORT NON-MENTHOL GOLD BOX 100S			2007 NPT LT M 100 HARD BOX		
	(b) (4)		WITHIN (b)	(b)	(b) (4)	
	Mean	Mean		Mean	(b) (4)	
Tar (mg/cig)	(b) (4)		YES	(b) (4)		YES
Nicotine (mg/cig)			YES			YES
CO (mg/cig)			YES			YES

Appendix B

**Appendix B: Comparison of Design Attributes for Newport Non-Menthol Gold Box 100s with the
2007 Newport Lt M 100 Hard Box Predicate Product**

Design			Subject	Predicate	Notes
Component		unit of measure	2012 Newport Non-Menthol Gold Box 100s	2007 Newport Light 100 Hard Box	
Cigarette	Cigarette ID	<i>cigarette length</i>	mm	(b) (4)	
		<i>cigarette paper weight</i>	mg		
		<i>cigarette rod weight</i>	mg		
		<i>cigarette weight</i>	mg		
		<i>circumference</i>	mm		
		<i>air dilution</i>	%		
		<i>pack moisture</i>	%		
		<i>pack menthol</i>	%		
		<i>rod length (tobacco section)</i>	mm		
		<i>finished tobacco blend weight</i>	mg		
Tobacco Blend	Final Tobacco Blend ID (b) (4)		%		
			%		
			%		
			%		
			%		
Filter	Filter rod ID	<i>tip length</i>	mm		
		<i>tip pressure drop</i>	mm-H ₂ O		
	plug wrap ID	<i>basis weight</i>	g/m ²		
		<i>porosity</i> <i>plasticizer (type)</i>	Coresta		
Tipping Paper	Tipping Paper ID	<i>roll size width</i>	mm		
		<i>basis weight</i>	g/m ²		
		<i>opacity</i>	%		
		<i>porosity</i>			
Cigarette Paper	Cigarette paper ID	<i>bobbin width</i>	mm		
		<i>tensile strength (dry)</i>	g/width		
		<i>basis weight (base paper)</i>	g/m ²		
		<i>basis weight (printed)</i>	g/m ²		
		<i>inherent porosity</i>	Coresta		
		<i>citrates</i>	WT %		
	LIP banding material ID				
<i>LIP band width</i>	mm				
<i>LIP band spacing</i>	mm				

(b) (4)

Appendix C

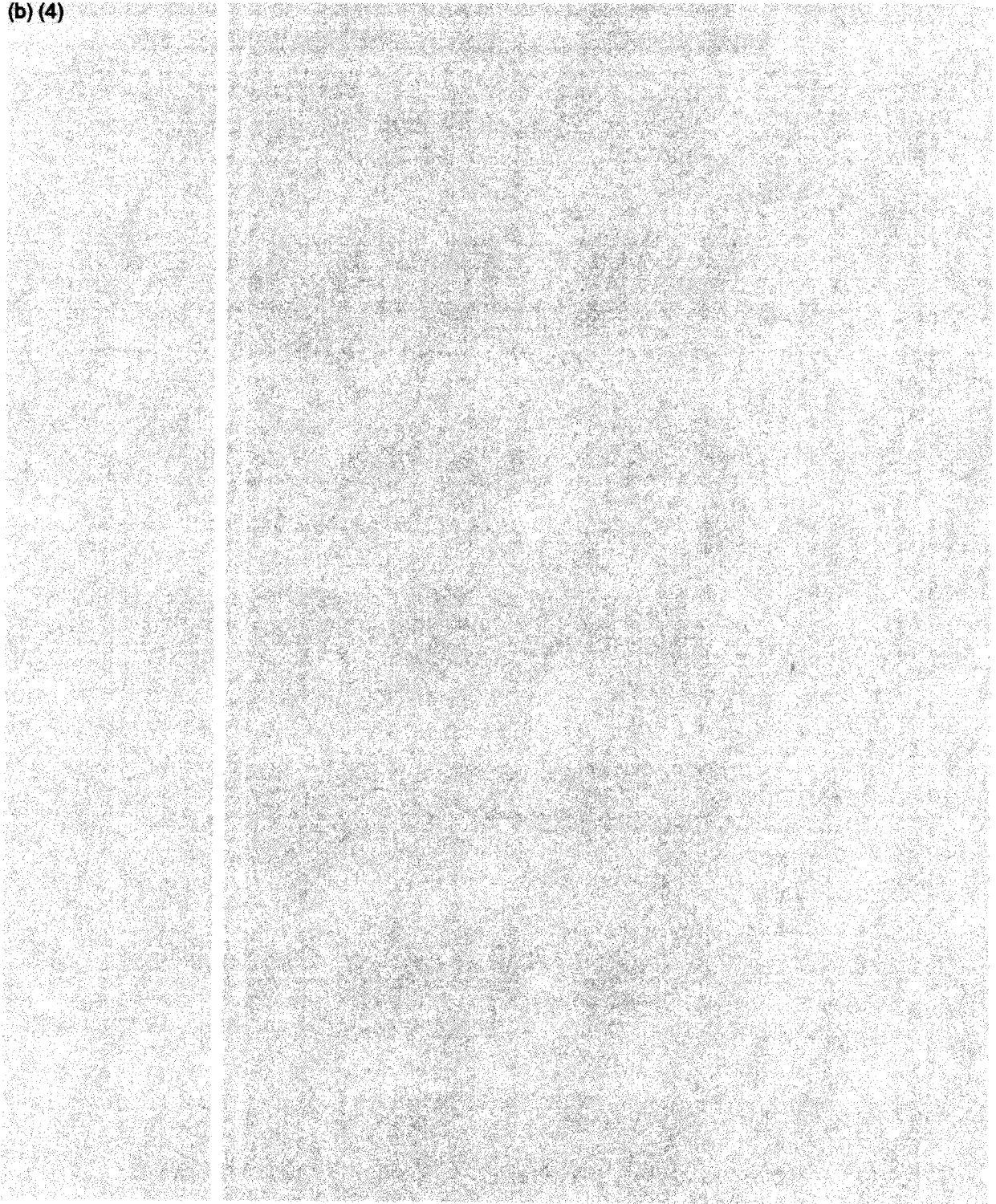
Appendix C: Ingredients and material comparisons for Newport Non-Menthol Gold Box 100s
with the 2007 Newport Lt M 100 Hard Box Predicate Product

Appendix D

Appendix D: (b) (4) [REDACTED]
(b) (4) [REDACTED]

Appendix D: Additional TNCO Comparisons

(b) (4)



(b) (4)



(b) (4)

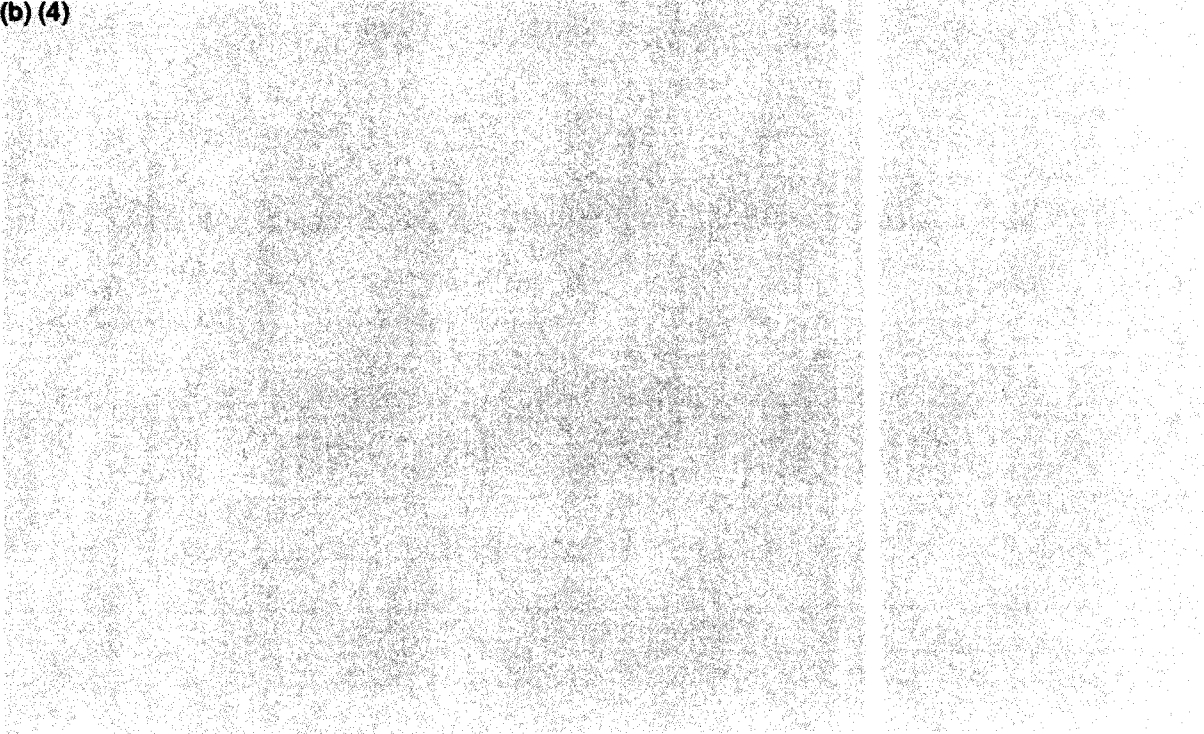


Appendix E

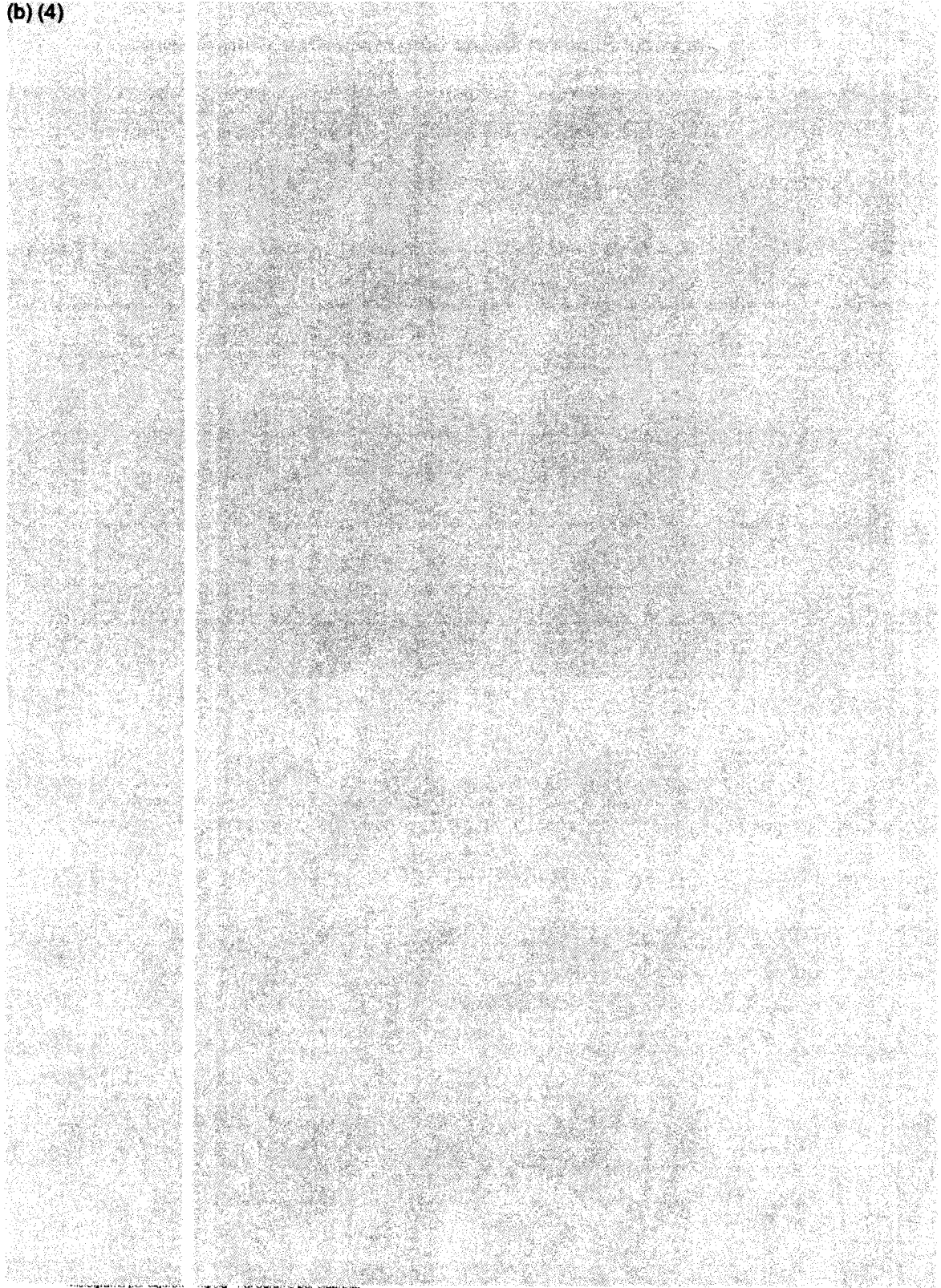
Appendix E: (b) (4) [Redacted]
[Redacted]

Appendix E: Select Smoke Constituent Data Comparisons

(b) (4)



(b) (4)



(b) (4)



Appendix F

Appendix F: Environmental Assessment for the Newport Non-Menthol Gold Box 100s subject product.

**Appendix F: Environmental Assessment
Newport Non-Menthol Gold Box 100s Cigarette**

This environmental assessment has been prepared in accordance with 21 C.F.R. § 25.40 as part of a submission under section 905(j) of the Federal Food, Drug, and Cosmetic Act.

- 1) **Date:** October 12, 2011
- 2) **Name of Notifier:** Lorillard Tobacco Company
- 3) **Address:** 714 Green Valley RD; Greensboro, NC, 27408
- 4) **Description of the proposed action:**

Requested action:

Production and sales of a substantially equivalent cigarette to a product in commerce be allowed.

Need for action:

Lorillard wishes to introduce a new tobacco product that is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or to a tobacco product that FDA has previously determined is substantially equivalent.

Location of use:

The tobacco product will be manufactured at Lorillard Tobacco Company's Greensboro, NC facility.

The mailing address of the facility is: 714 Green Valley Rd.; Greensboro, NC, 27408

The tobacco product will be distributed and sold nationally to consumers for use as a cigarette.

The product uses conventional design, construction, ingredients and delivers TNCO and other smoke constituents at substantially equivalent levels to products already in commerce (e.g., 2007 Newport Lt M 80 Hard Box).

Location of disposal:

The used cigarettes will be disposed of as typical of other used cigarettes through deposit in municipal solid waste landfills.

- 5) **Identification of the proposed substance/cigarette subject to the proposed action:**
Menthol will not be added to this cigarette compared to cigarettes of similar construction and deliveries already in commerce. Except for menthol, there are no measurable physical or chemical differences between a similar cigarette containing menthol and this cigarette without menthol.

Trade name: Newport Non-Menthol Gold Box 100s

Reference Identification Number (internal): 2003906

Product Identification Number: 0-26100-00661-2

- 6) **Introduction of cigarette to the environment:**
 - a) **Introduction of substances into the environment as a result of manufacture:**

No extraordinary circumstances apply to the manufacture of this tobacco product compared to other commercially available tobacco products. The tobacco product manufactured without menthol would not introduce any new substances into the environment versus a tobacco product with menthol.
 - b) **Introduction of cigarettes into the environment as a result of use:**

The product will not introduce materials into the environment beyond the waste produced when using the cigarette as designed.
 - c) **Introduction of cigarettes into the environment as a result of disposal:**

The product will not introduce materials into the environment beyond the waste produced when using the cigarette as designed.

- 7) **Fate of cigarettes released into the environment:**

We do not anticipate the fate of any materials from this cigarette to be any different from other cigarette commercially available. Except for menthol, there are no measurable physical or chemical differences with a similar cigarette containing menthol and therefore no different environmental fate is anticipated.

- 8) **Environmental effects of the released cigarette:**

We do not anticipate the environmental effects of any materials from this cigarette to be any different from other cigarette commercially available. Except for menthol, there are no measurable physical or chemical differences between a similar cigarette containing menthol and therefore no different environmental effects are anticipated.

- 9) **Use of resources and energy:**

The use of resources and energy are not expected to be greater than those already used for the manufacture, distribution and sales of existing, commercially available cigarettes. Therefore, no additional resources or energy will be required.

- 10) **Mitigation measures:**

We identify no adverse environmental effects, based upon our review of the available data and information for Newport Non-Menthol Gold Box 100s cigarette and its proposed use as a cigarette. Therefore, mitigation measures are not required and are not proposed.

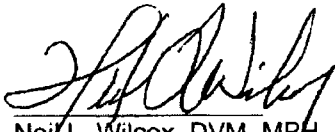
- 11) **Alternatives to the proposed action:**

We identify no adverse environmental effects, based upon our review of adequate and complete data and information. Therefore alternatives are not proposed.

- 12) **List of preparer:**
 - (b) (4)
 - Kevin H Reinert, PhD
Director, Scientific Affairs

13) **Certification:**

The undersigned certifies that the information presented is true, accurate and complete to the best of their knowledge as of October 12, 2011



Neil L. Wilcox, DVM, MPH
Sr. Vice President & Chief Compliance Officer

Appendix G
References

1. Smoking and Tobacco Control, Monograph 7, The FTC Cigarette Test for Determining Tar, Nicotine and Carbon Monoxide Yields of U. S. Cigarettes, U. S. Department of Health and Human Services, NIH Publication Number 96-4028, August 1996.
2. Federal Trade Commission, Report of "Tar," Nicotine, and Carbon Monoxide of the Smoke of 1249 Varieties of Domestic Cigarettes for the Year 1995.
3. Federal Register, Volume 45, Number 134, Page 46,483, July 10, 1980.
4. Federal Trade Commission in Federal Register, Volume 32, Number 147, Page 11,178, August 1, 1967.
5. Determination of Total and Nicotine-Free Dry Particulate Matter Using a Routine Analytical Smoking Machine, ISO 4387.
6. Determination of Nicotine in Smoke Condensates: Gas Chromatograph Method, ISO 10315.
7. Determination of Carbon Monoxide in Vapor Phase of Cigarette Smoke Condensates: NDIR Method, ISO 8454.
8. Determination of Water in Smoke Condensates – Part 1: Gas Chromatograph Method, ISO 10362.1.
9. (b) (4)
10. US Patent 7836898, Nov 23, 2010.
11. R.R. Baker, E.C. Massey, G. Smith, Food Chem. Toxicol. 42 (Suppl.), 2004, 53–83.
12. R.R. Baker, L.J. Bishop, in: Proceedings of the 16th Int. Symp. Anal. Appl. Pyrolysis, 2004, vol. 74, 2005, pp 145–170.
13. R.R. Baker, S. Coburn, C. Liu, J. Tetteh, J. Anal. Appl. Pyrolysis 74, 2005, 171–180.
14. Presented to FDA-CTP on February 4, 2011.
15. R. Baker, Beiträge zur Tabakforschung International, Contributions to Tobacco Research, Vol. 20, No. 1, February 2002.
16. (b) (4)
17. (b) (4)



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FEB 13 2012

BY: CTP / DCC

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

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Fax (336) 335-7752
E-Mail: nwilcox@lortobco.com

February 10, 2012

SE0004149

U.S. Food and Drug Administration
Center for Tobacco Products
Attn: Ms. Florence Moore
Lead Regulatory Health Project Manager
c/o Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850-3229

CONFIDENTIAL
CONTAINS TRADE SECRETS

RE: RESPONSE TO ADVICE/INFORMATION REQUEST FOR SE0003730

Dear Ms. Moore,

This letter responds to FDA's Advice/Information Request dated February 6, 2012, in connection with submission SE0003730. FDA's Request included three questions regarding Lorillard's October 12, 2011 Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce ("905(j) Report") for Newport Non-Menthol Gold Box 100s.

Below please find Lorillard's responses to your requests. For your convenience, we have reprinted each request, followed by our response.

Request 1

Full identification of your new tobacco product (i.e., how the new product is uniquely identified for a consumer such as brand, subbrand, size, quantity, packaging)

Lorillard's Response:

The identification of the new tobacco product was provided on page 3 section 2.4 of the 905(j) Report. Please find below additional information as requested:

Brand name: Newport
Subbrand (brand variant): Non-Menthol Gold 100s
Size: 100s – 100mm cigarette length (rod + filter).
Format: Hard box pack
Quantity: 20 cigarettes in each pack, 10 packs per carton
UPC Number: 0 26100 00661 2

Corporate Office:
714 Green Valley Road
Greensboro, NC 27408

Page 1 of 5

Mail to:
P.O. Box 10529
Greensboro, NC 27404-0529

Packaging: Please find attached as Appendix A an example of the pack and carton design for the new tobacco product in print form and on disk.

Request 2

Full identification of your predicate tobacco product (i.e., how the predicate product is uniquely identified for a consumer such as brand, subbrand, size, quantity, packaging)

Lorillard's Response:

The identification of the predicate tobacco product was provided on page 3 section 2.5 of the 905(j) Report. Please find below additional information as requested:

Brand name: Newport
Subbrand (brand variant): Lights Menthol Gold Box 100's
Size: 100s - 100 mm cigarette length (rod+filter)
Format: Hard box pack
Quantity: 20 cigarettes per pack, 10 packs per carton
UPC Number: 0-26100-00572-1
FDA-assigned TP number: TP-0004208

Packaging: Please find attached as Appendix B an example of the pack and carton design of the predicate tobacco product, as it was available at retail on February 15, 2007. Please note that the predicate tobacco product is no longer on the market.

Request 3

A statement of your action to comply with the requirements of Section 907 (see section 905(j)(1)(B) of the FD&C Act), including those standards under Section 907(a) of the FD&C Act and any promulgated through regulation. If any of the standards are not applicable to your product, provide a statement to that effect.

Lorillard's Response:

We hereby confirm that the subject product is in compliance with Section 907. Specifically, the subject product does not contain any characterizing flavors and, therefore, the "Special Rule for Cigarettes" in Section 907(a)(1)(A) is not applicable. As the agency recently acknowledged, there are no currently applicable tolerance limits for pesticide chemical residues that apply to domestically grown tobacco and, accordingly, the "Additional Special Rule" set forth in section 907(a)(1)(B) is not applicable¹. Lorillard is not aware of any other tobacco standard applicable

¹ See, e.g., Letter from Lawrence R. Deyton, M.S.P.H., M.D., Director, FDA Center for Tobacco Products, to James E. Swauger, Ph.D., DABT, R.J. Reynolds Tobacco Company (December 6, 2011), available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM282742.pdf>.

U.S. Food and Drug Administration
Center for Tobacco Products
February 10, 2012

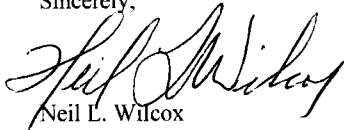
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to cigarettes promulgated under Section 907. Lorillard fully intends to comply with such final standards once lawfully promulgated.

Please note that Lorillard considers the information contained in this letter to constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter and its appendices are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

We hope that this additional information will support your expeditious review and favorable decision on our 905(j) Report. Please do not hesitate to contact me should you need any clarifications.

Sincerely,



Neil L. Wilcox

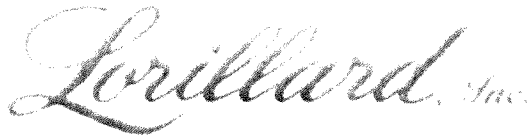
Enclosures

Appendix A

(See Attachment)

Appendix B

(See Attachment)



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DEC 06 2012
CTP/DCG

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

(336) 335-7656
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E-Mail: nwilcox@lortobco.com

This letter, the enclosed answers, appendices, and all data and information contained in this response constitute confidential commercial information and trade secrets.

December 3, 2012

Center for Tobacco Products
Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
DEC 06 2012
BY: CTP/DCG
SE 0005958

Re: Response to Advice/Information Request for SE0003730

Dear Sir/Madam:

Reference is made to the Advice and Information Request (dated October 26, 2012) issued by the FDA Center for Tobacco Products (CTP) regarding the report submitted under Section 905(j) of the Food, Drug, and Cosmetic Act (FDCA) by Lorillard Tobacco Company (Lorillard) for Newport Non-Menthol Gold Box 100s ("SE Report"). This letter and accompanying attachments constitute a complete response to CTP's Advice and Information Request.

In the attached response, Lorillard sets forth each request issued by CTP, followed by Lorillard's response. In some cases, we have also provided detailed Appendices with the requested information, as well as additional, supporting information.

While Lorillard has provided complete responses to CTP's information requests, respectfully, many of CTP's requests go well beyond what is required for the agency to make a determination of substantial equivalence. The substantial equivalence pathway under Section 905(j) was intended as a streamlined pathway for the review of new tobacco products. However, the agency has adopted an approach that requires the submission of burdensome and unnecessary data. Much of the information requested by CTP in its Advice and Information Request is not necessary to conclude that the predicate and subject products are substantially equivalent. For example, CTP is demanding that Lorillard submit an extensive amount of information about the components used in product packaging at carton and shipping container level. Lorillard is not aware of any scientific data suggesting that differences in product packaging cardboard bear any

Center for Tobacco Products
Food and Drug Administration
December 3, 2012

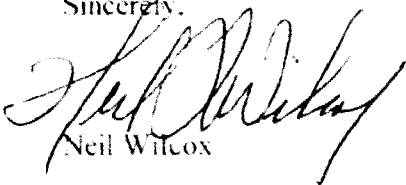
relationship to the relative safety of cigarettes, and such detailed packaging information is clearly not necessary to conclude that the products are substantially equivalent. In this regard, CTP seems to be persisting in an interpretation that "same" characteristics (as required by one part of the standard for a substantially equivalent product) must be read as "identical," even though nothing in the statute compels this conclusion and even though the agency has not adopted such an interpretation for other statutory requirements that use similar language (e.g. generic drugs, 510(k)s).

The statute indicates that applications submitted pursuant to Section 905(j) of the FDCA are subject to a 90-day review period, but CTP's letter was not issued until more than a year after Lorillard submitted its 905(j) report. Moreover, many of the categories of data and information requested in the Advice and Information Request were never set forth in any regulation, guidance document, or any other formal source of information. Instead, these requirements appear to have been implemented on a case-by-case basis or announced for the first time in the August 21, 2012 webinar organized for small businesses. Had this information been necessary to CTP's determination of substantial equivalence, the agency should have made a formal announcement so that Lorillard could have provided the necessary information before now.

Despite our significant concerns, in an effort to expedite the review and approval of these 905(j) reports, Lorillard is providing the requested information, which should permit FDA to promptly issue a substantial equivalence order.

This letter, the attached answers, appendices, and all data and information contained in this response constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter, the attached answers, appendices, and all data and information contained in this response are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(e) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

Sincerely,



Neil Wilcox

Enclosures

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FEB 11 2013
BY: CTP/MAILROOM

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

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February 8, 2013

SE 000 7185 - 7186

Ms. Rosanna Beltre
Regulatory Project Manager
Center for Tobacco Products
U.S. Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

Via Federal Express

Re: SE0003730 and SE0003731: Answers to February 1, 2013 Clarifying Questions for Response to Scientific AI Letter for SE0003730 and SE0003731

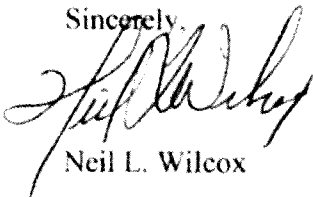
Dear Ms. Beltre:

Please find enclosed Lorillard Tobacco Company's answers to your February 1, 2013 Clarifying Questions for Response to Scientific AI Letter for SE0003730 and SE0003731.

This cover letter, the enclosed answers and all data and information contained herein constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this cover letter, the enclosed answers and all data and information contained herein are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

Please do not hesitate to contact us promptly should any further clarification be necessary.

Sincerely,



Neil L. Wilcox

Enclosure



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FEB 13 2013
BY: CTP/MAILROOM

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Senior Vice President &
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February 12, 2013

SE 000 7199

Ms. Rosanna Beltre
Regulatory Project Manager
Center for Tobacco Products
U.S. Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

Via Federal Express

FEB 13 2013

Re: SE0003730 and SE0003731: Answers to February 8, 2013 Clarifying Questions for Environmental Assessment for SE0003730 and SE0003731

Dear Ms. Beltre:

Please find enclosed Lorillard Tobacco Company's answers to your February 8, 2013 Clarifying Questions for Environmental Assessment ("EA") for SE0003730 and SE0003731.

This document and all data and information contained herein constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this document and all data and information contained herein are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

For SE0003730:

- 1) Please explain whether "Newport Non-Menthol Gold Box 100s" is intended to (A) compete with or replace other non-menthol cigarettes currently on the market, or (B) is intended to cause initiation of new users.**

Answer: (A) "Newport Non-Menthol Gold Box 100s" is intended to compete with other non-menthol cigarettes currently on the market.

- 2) Please explain whether "Newport Non-Menthol Gold Box 100s" is reasonably expected to increase the total market volume for non-menthol cigarettes.**

Answer: "Newport Non-Menthol Gold Box 100s" is not reasonably expected to increase the total market volume for non-menthol cigarettes.

Ms. Rosanna Beltre
Regulatory Project Manager
Center for Tobacco Products
February 12, 2013

- 3) **Please provide a projection of the market volume of “Newport Non-Menthol Gold Box 100s” you expect to introduce into the market in the first year of your marketing and the fifth year of your marketing of that product. This information assists the agency in assessing environmental effects, such as the amount of waste we expect will be generated. Any such information may be identified as a confidential appendix to the public EA document.**

Answer: “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.

For SE0003731:

- 4) **Please explain whether “Newport Non-Menthol Gold Box” is intended to (A) compete with or replace other non-menthol cigarettes currently on the market, or (B) is intended to cause initiation of new users.**

Answer: (A) “Newport Non-Menthol Gold Box” is intended to compete with other non-menthol cigarettes currently on the market.

- 5) **Please explain whether “Newport Non-Menthol Gold Box” is reasonably expected to increase the total market volume for non-menthol cigarettes.**

Answer: “Newport Non-Menthol Gold Box” is not reasonably expected to increase the total market volume for non-menthol cigarettes.

- 6) **Please provide a projection of the market volume of “Newport Non-Menthol Gold Box” you expect to introduce into the market in the first year of your marketing and the fifth year of your marketing of that product. This information assists the agency in assessing environmental effects, such as the amount of waste we expect will be generated. Any such information may be identified as a confidential appendix to the public EA document.**

Answer: “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) units (cigarettes) in the fifth year. Please note that brand volume projections are usually revised annually based on actual sales and market dynamics.

We also wish to bring to FDA’s attention the following information, which we believe will further assist FDA in assessing environmental effects:

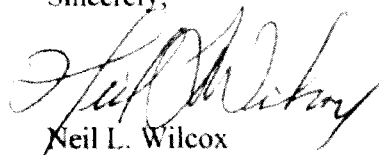
Ms. Rosanna Beltre
Regulatory Project Manager
Center for Tobacco Products
February 12, 2013

According to Management Science Associates, Inc., an independent third-party database management organization which collects wholesale shipment data from various cigarette manufacturers, during the past twenty years, the total industry volume has decreased by more than 220 billion units (cigarettes), while over 3600 new brands were introduced in the U.S. market in that same period of time.

According to the Federal Trade Commission Cigarette Report for 2009 and 2010, the total number of cigarette units sold or given away by the major manufacturers declined from 402.2 billion in 2001 to 281.7 in 2010¹. Therefore, it can be reasonably anticipated that the total industry volume will continue to shrink in the future.

Please do not hesitate to contact us promptly should any further clarification be necessary.

Sincerely,



Neil L. Wilcox

¹ Federal Trade Commission Cigarette Report for 2009 and 2010, at <http://www.ftc.gov/os/2012/09/120921cigarettereport.pdf>



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OCT 13 2011

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

BY: **CTP/DCC**
336) 251-2556
Fax 336) 385-7592
E-Mail: nlwilcox@lorillard.com
SL 020 3731

October 12, 2011

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

**BY CERTIFIED MAIL/
RETURN RECEIPT REQUESTED**

**Re: Lorillard Tobacco Company Section 905(j)
Report for Newport Non-Menthol Gold Box**

Dear Dr. Dayton:

As required by section 905(j) of the Federal Food, Drug and Cosmetic Act (FDCA), Lorillard Tobacco Company (Lorillard) submits this report and supporting information (the "905(j) Report") to demonstrate that Newport Non-Menthol Gold Box is substantially equivalent to the 2007 Newport Lt M 80 Hard Box.

The 2007 Newport Lt M 80 Hard Box was commercially marketed in the United States as of February 15, 2007. Comparisons of the characteristics (including materials, ingredients, design, composition, heating source, etc.) between the subject of this submission, the Newport Non-Menthol Gold Box cigarette, and the predicate product, the 2007 Newport Lt M 80 Hard Box, demonstrate that the subject product has the same characteristics as the predicate product or does not raise different questions of public health. The products are, therefore, substantially equivalent as defined in Section 910 of the FDCA. 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.

As stated in Section 905(j)(1) of the FDCA, Lorillard is required to file this 905(j) Report at least 90 days prior to introducing the subject product into interstate commerce for commercial distribution. Moreover, Lorillard understands that this product may not be commercially distributed in the United States until FDA has issued an order authorizing such distribution. To this end, and understanding that there is no mandatory time-frame under which FDA must issue an order in response to this 905(j) Report, Lorillard respectfully requests that FDA give this non-provisional product 905(j) Report high priority. Lorillard reasonably expects that FDA will act in the spirit of the FDCA, within the 90 days recommended, and further believes that the FDA is bound to issue an order within a predictable and reasonable time-frame. Lorillard has expended extensive resources to prepare for the manufacturing and distribution of this product; delaying the market launch of this product would have a substantial impact on Lorillard's business. To expedite this process, Lorillard remains ready to provide any additional information as may be requested by FDA.

Corporate Office:
714 Green Valley Road
Greensboro, NC 27408

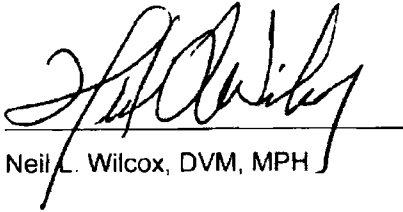
Mail to:
P.O. Box 10529
Greensboro, NC 27404-0529

Substantial Equivalence Submission
Newport Non-Menthol Gold Box
Lorillard Tobacco Company
Page 2

Please note that Lorillard considers the information contained in this letter to constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter and its contents are exempt from public disclosure under 5 U.S.C. § 552(b) (4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j). Please let us know if you require additional information or clarification of these matters.

Should you have any questions regarding this submission, please do not hesitate to contact me at 336-335-7656 or nwilcox@lortobco.com.

Sincerely,



Neil L. Wilcox, DVM, MPH

Enclosure



Substantial Equivalence Product Submission

Lorillard Tobacco Company

Newport Non-Menthol Gold Box

Submitted: October 12, 2011

1. Substantial Equivalence Product Submission Index

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2. Summary Section

2.1 Submitter Name & Address

Lorillard Tobacco Company
714 Green Valley RD.
Greensboro, NC 27408

2.2 Submitter Contact Information

Neil L. Wilcox, DVM, MPH
Senior Vice President & Chief Compliance Officer
Lorillard Tobacco Company
Phone: 336-335-7656
Fax: 336-335-7752
Email: nwilcox@lortcbo.com

2.3 Submission Date

October 12, 2011

2.4 Subject Product Information

Trade Name: Newport Non-Menthol Gold Box
Reference Identification Number (internal): 2003905
Product Identification Number: 0-26100-00660-5
Owner / Registrant: Lorillard Tobacco Company (LTC)

2.5 Predicate Product Information

Trade Name: 2007 Newport Lt M 80 Hard Box
Reference Identification Number (internal): 2000314
Owner / Registrant: Lorillard Tobacco Company (LTC)

2.6 Summary Section Narrative

Comparisons of the characteristics (including tar, nicotine and carbon monoxide smoke yields, design, materials, ingredients, heating source and composition) between the subject of this submission, the Newport Non-Menthol Gold Box cigarette, and the predicate product, the 2007 Newport Lt M 80 Hard Box, demonstrate that the subject product has the same characteristics

as the predicate product or does not raise different questions of public health. The products are, therefore, substantially equivalent as defined in Section 910 of the Federal Food, Drug and Cosmetic Act, (FDCA).

The subject product contains two categories of modifications as compared to the predicate product. First, the subject product contains no menthol and a lower level of ethyl alcohol, whereas the predicate product contained menthol as a flavoring. Second, Lorillard implemented several minor changes to the subject product as compared to the predicate in order to comply with the Fire Standard Compliant (FSC) requirements imposed by most states. Compliance with the FSC Regulations necessitates use of a special paper for the tobacco column called Low Ignition Propensity (LIP) paper. As a result of the use of the LIP paper, the Newport Non-Menthol Gold Box product required a slight modification of certain ingredients and commonly used design elements to maintain equivalence with the 2007 Newport Lt M 80 Hard Box predicate product, which was non-FSC. The modifications related to LIP paper use and other modifications are discussed in the sections to follow.

Based on the information set forth in the following sections, the Newport Non-Menthol Gold Box cigarette is substantially equivalent to the 2007 Newport Lt M 80 Hard Box predicate tobacco product that was commercially available in the U.S. marketplace on or before February 15, 2007 and does not raise different questions of public health.

2.7 Supporting Data for Substantial Equivalence Determination

Substantial equivalence for the Newport Non-Menthol Gold Box cigarette relative to the 2007 Newport Lt M 80 Hard Box predicate product is based upon comparisons of their tar, nicotine and carbon monoxide smoke yields, design, materials, ingredients, heating source and compositions. Detailed comparisons of smoke yields, and product attributes are provided in the sections to follow.

2.8 Tar, Nicotine and Carbon Monoxide (TNCO) Comparisons

For more than 50 years, measurements of tar and nicotine smoke deliveries have been used as representative constituents of particulate phase yields from cigarettes (1, 2). Similarly, for almost 30 years, carbon monoxide has been used as a representative component of the vapor phase constituents of cigarette smoke (3). Standardized smoking regimens are typically used in the laboratory to measure smoke constituent yields including tar, nicotine, and carbon

monoxide. (b) (4) [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted] resulted in TNCO yields, which were slightly lower than the results generated using the (b) (4) [redacted]. However, the parameters of the two regimes are relatively similar, and it is therefore reasonable to compare data collected from the two regimes (Table 1 in Appendix A describes the differences in parameters between the (b) (4) [redacted] smoking methods).

The major differences in the two smoking regimes are the butt length (or smoking endpoint) and the smoking machine air velocity. These changes result in different mainstream yields for the (b) (4) [redacted] relative to the (b) (4) [redacted]. However, (b) (4) [redacted]

[redacted]
[redacted]
[redacted]
[redacted]

are standard test items used for laboratory research as a basis for comparing data collected in different laboratories or different analytical test methodologies. They were chosen because their TNCO yields span a range typical of commercial cigarettes.

Over 2300 data points for the (b) (4) [redacted] and details are shown in Table 2 in Appendix A. (b) (4) [redacted]

(b) (4) [redacted]
[redacted]
[redacted]
[redacted] (Figure 1

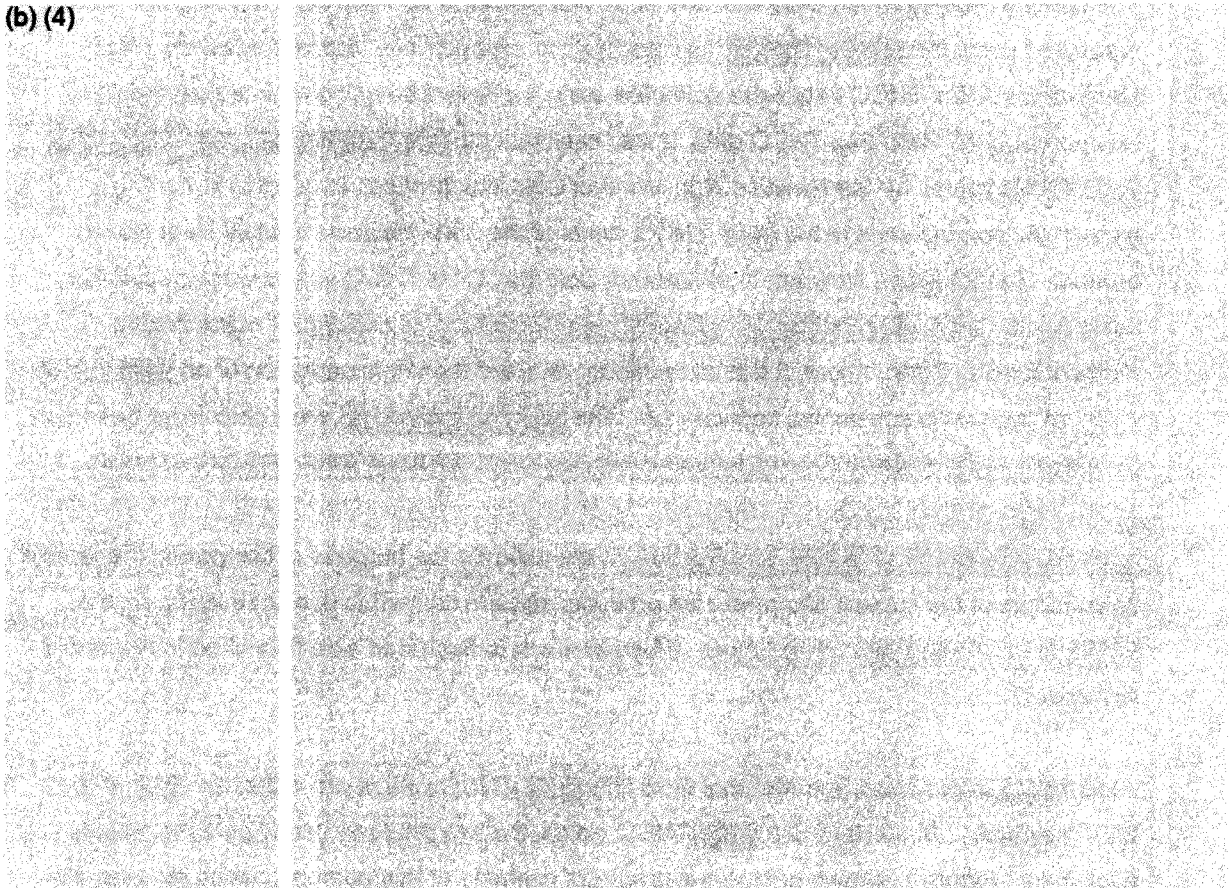
in Appendix A). Therefore, utilizing this (b) (4) [redacted] for the comparison of the subject yields, generated using the (b) (4) [redacted], and the predicate yields, generated using the (b) (4) [redacted], is a valid approach to demonstrate that two products are substantially equivalent.

2.9 Comparison of the Subject (Newport Non-Menthol Gold Box) and Predicate (2007 Newport Lt M 80 Hard Box) Data

The Newport Non-Menthol Gold Box and 2007 Newport Lt M 80 Hard Box TNCO yields were measured using the (b) (4), respectively. Since the Newport Non-Menthol Gold Box TNCO data were collected using a different smoking regime than the 2007 Newport Lt M 80 Hard Box TNCO data, it was necessary to (b) (4) TNCO values for the Newport Non-Menthol Gold Box product, in order to make meaningful comparisons to the (b) TNCO yields of the 2007 Newport Lt M 80 Hard Box product. The (b) (4) Newport Non-Menthol Gold Box CAM TNCO values were calculated using (b) (4) of the testing methodologies. Furthermore, the total variability requires the implementation of an (b) (4) to determine substantial equivalence. The (b) (4) were calculated based on the (b) (4) are used for the purpose of comparing the smoke constituents of the subject and predicate products and are defined in this submission as the (b) (4). This approach is illustrated as a flow chart in Appendix A, Figure 2.

If the (b) (4) Newport Non-Menthol Gold Box (b) TNCO values are within the (b) of the 2007 Newport Lt M 80 Hard Box (b) TNCO yields, the two products would be substantially equivalent. Figure 1, shown below, is a graphical example of this approach using (b) data; the corresponding nicotine and carbon monoxide comparisons were completed using the same methodology. The data support the claim that the Newport Non-Menthol Gold Box TNCO yields are substantially equivalent to the 2007 Newport Lt M 80 Hard Box yields (b) (4) are shown in Appendix A, Table 3.

Figure 1: Graphical representation of the comparison of Newport Non-Menthol Gold Box subject (b) values to 2007 Newport Lt M 80 Hard Box predicate (b) values.



The (b) (4) ranges for tar, nicotine and carbon monoxide are summarized in the table below along with smoke yield data for the subject and predicate products.

	Subject [†]		Predicate [*]		SUBSTANTIALLY EQUIVALENT
	NEWPORT NON-MENTHOL GOLD BOX	WITHIN (b)	2007 NPT LT M 80 HARD BOX	(b) (4)	
Tar (mg/cig)	(b) (4)	YES	(b) (4)	(b) (4)	YES
Nicotine (mg/cig)		YES			YES
CO (mg/cig)		YES			YES

^{*} Data generated using (b)
[†] Data generated using (b)

Because the smoke constituents shown above for the Newport Non-Menthol Gold Box are within the (b) of the 2007 Newport Lt M 80 Hard Box predicate product, the two products are substantially equivalent.

3. Design Features

A comparison of design attributes of the Newport Non-Menthol Gold Box subject cigarette and the corresponding design attributes for the 2007 Newport Lt M 80 Hard Box predicate product is attached as Appendix B. As discussed above, the Newport Non-Menthol Gold Box product is required to comply with FSC regulations (1). To meet the FSC regulations, LTC developed a starch banded cigarette paper for the tobacco column called LIP paper (10). The use of LIP paper required a slight increase in air dilution in order to maintain consistent TNCO yields with the 2007 predicate product. Air dilution targets for the subject and predicate products are listed in Appendix B. All design modifications associated with the use of LIP paper are marked in Appendix B.

In addition to the use of LIP paper, tipping paper basis weight was reduced slightly. Tipping paper of the predicate products was pre-perforated; the subject tipping paper was nonporous. The subject product is (b) (4) to the target air dilution level during cigarette production. The color of the tipping paper for the predicate was cork-on-white whereas the tipping paper for the subject is white. (b) (4). Both subject and predicate products utilize the same filter, although the plug wrap used for the 2007 Newport Lt M 80 Hard Box predicate product is (b) (4) whereas the Newport Non-Menthol Gold Box is nonporous. The porous plug wrap used on 2007 Newport Lt M 80 Hard Box was a structural material used with pre-perforated tipping paper prior to the introduction of (b) (4) capabilities. (b) (4). As a result, the design of the Newport Non-Menthol Gold Box cigarette is substantially equivalent to the 2007 Newport Lt M 80 Hard Box predicate product. Moreover, as discussed above, the two products are substantially equivalent in terms of their TNCO yields.

4. Listing of Ingredients and Materials

A comparison of ingredients and materials in the Newport Non-Menthol Gold Box cigarette and the 2007 Newport Lt M 80 Hard Box predicate product is attached as Appendix C. As mentioned in the Design section above, the use of LIP paper required certain design modifications in order to maintain smoke yields and taste characteristics consistent with the 2007 Newport Lt M 80 Hard Box predicate product. The use of LIP paper also had several minor ingredient and material modifications between the subject and predicate products. These modifications are identified in Appendix C. First, the use of LIP paper introduced small amounts of modified starch as a new material that was not present in the non-LIP predicate product. However, the (b) (4) [REDACTED] and does not impact smoke analyte yields at the levels employed in LIP paper. The remaining components of the LIP paper band formula are already used as ingredients in the cigarette paper wrapper. (b) (4) [REDACTED]

In addition to the ingredients and materials modifications for Newport Non-Menthol Gold Box related to the LIP paper use, other modifications in materials and ingredients are noted in Appendix C. The subject product does not include menthol and, as a result, utilizes a lower level of ethyl alcohol. The plug wrap used for Newport Non-Menthol Gold Box was changed from the plug wrap used on the 2007 Newport Lt M 80 Hard Box predicate product. (b) (4) [REDACTED]

[REDACTED] The tipping paper basis weight was reduced slightly compared with the 2007 Newport Lt M 80 Hard Box predicate which in turn reduced the (b) (4) [REDACTED] relative to the predicate product. (b) (4) [REDACTED]

[REDACTED] No other ingredient and material modifications were implemented for this product. Furthermore, the removal of menthol leads to a concurrent decrease in ethyl alcohol, since menthol is added into the predicate as a solution in ethyl alcohol. As a result, the materials and ingredients of the Newport Non-Menthol Gold Box cigarette are substantially equivalent to the 2007 Newport Lt M 80 Hard Box predicate product. Moreover, as discussed above, the two products are substantially equivalent in terms of their TNCO yields

5. Description of Heating Source

The Newport Non-Menthol Gold Box subject cigarette employs a smoldering fire cone as its heating source, as does the 2007 Newport Lt M 80 Hard Box predicate product. Comparing heating sources, the subject of this submission and the predicate product are substantially equivalent.

6. Description of Composition

The combination of the various elements (*i.e.*, materials, ingredients, design) which make up the characteristics of the Newport Non-Menthol Gold Box cigarette have not changed and are substantially equivalent to the 2007 Newport Lt M 80 Hard Box predicate product

7. Other

(b) (4)



Appendix A

**Appendix A: TNCO comparisons for Newport Non-Menthol Gold Box with the 2007 Newport Lt
M 80 Hard Box Predicate Product**

Appendix A: TNCO Summary

The smoking regime used by the Lorillard Smoke Science Laboratory was (b) (4)

Under the (b) (4) the tar, nicotine and carbon monoxide (TNCO) yields were slightly lower than the results generated using the (b) (4). However, the parameters of the two regimes (Table 1) are relatively similar and are therefore reasonable to compare data collected from the two regimes.

Table 1: A comparison of the (b) (4) parameters.

Parameter	Standard Smoking Regimes	
	(b) (4)	(b) (4)
Puff Volume (ml)	(b) (4)	(b) (4)
Puff Duration (s)	(b) (4)	(b) (4)
Puff Frequency (s)	(b) (4)	(b) (4)
Ventilation Holes	(b) (4)	(b) (4)
Conditioning Atmosphere	(b) (4)	(b) (4)
Smoking Environment	(b) (4)	(b) (4)
Air Velocity <i>Linear Individual Port</i> <i>Linear Average & Rotary</i>	(b) (4)	(b) (4)
Butt Length <i>(choose highest value)</i>	(b) (4)	(b) (4)

Note: RH – Relative Humidity; ml/min – milliliters per minute; mm – millimeters.

The major differences in the two smoking regimes are the (b) (4)

Depending on the construction parameters of the particular sample, this difference could result in lower mainstream yields for the (b) (4) due to a fewer number of puffs. The most apparent difference between the two regimes,

however, is the (b) (4). The (b) (4) is set at a level sufficient to exhaust sidestream smoke, whereas the (b) (4) is explicitly stated. Variation in the set's smoking machine (b) (4) can generate differences in mainstream smoke yields due to the effect of (b) (4). Table 2 contains (b) (4) data collected using the two aforementioned smoking regimes which was (b) (4) between the mainstream smoke yields.

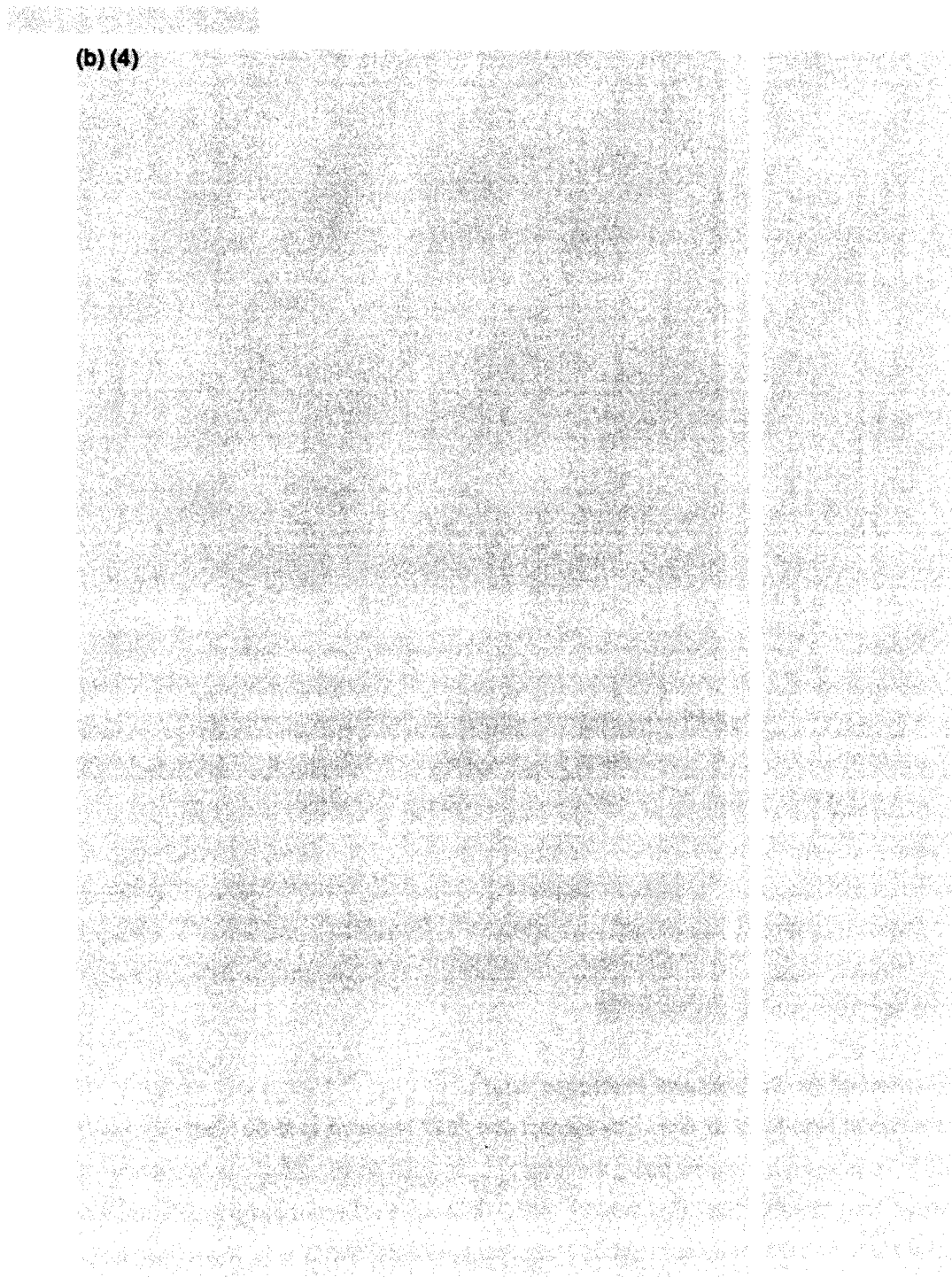
Table 2: (b) (4)
 (b) (4)
 (b) (4)

(b) (4)	
Tar (mg/cig) SD	
Nicotine (mg/cig) SD	
CO (mg/cig) SD	
<i>n</i>	

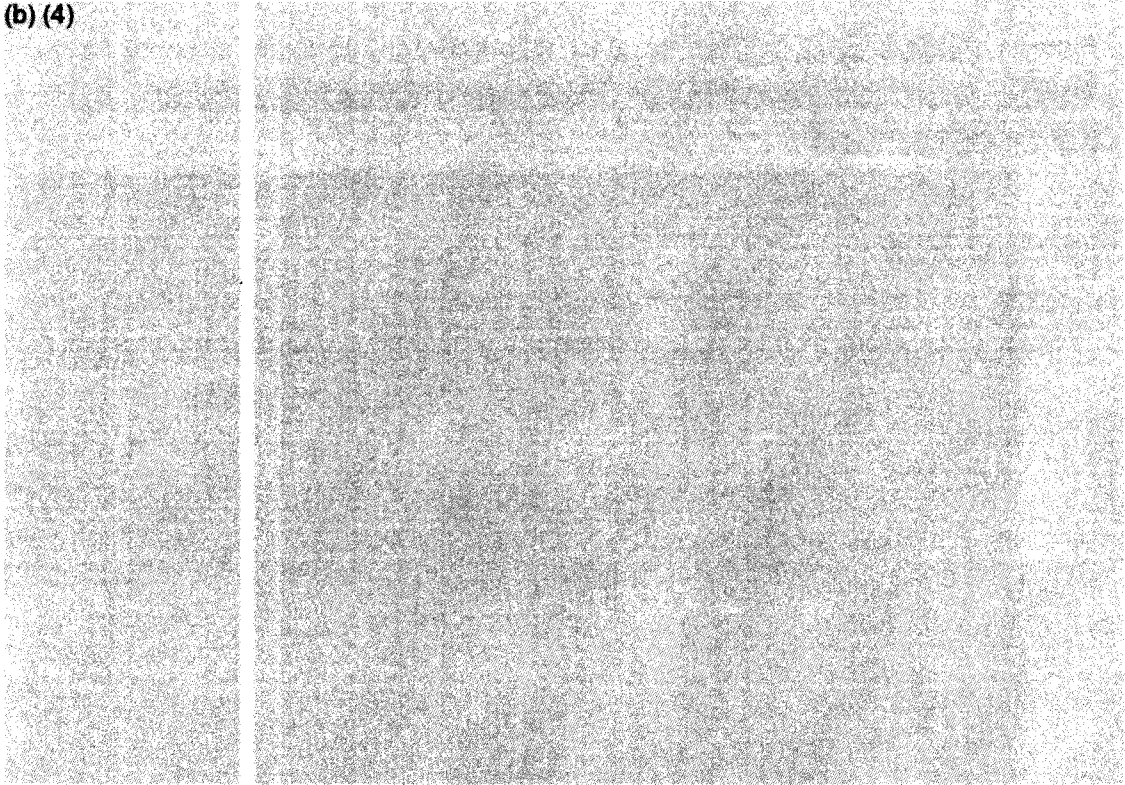
Note: mg/cig – milligrams per cigarette; SD – standard deviation; *n* – sample size.

The data in Table 2 was used to (b) (4)
 (b) (4)
 (b) (4)
 (b) (4)
 (b) (4)

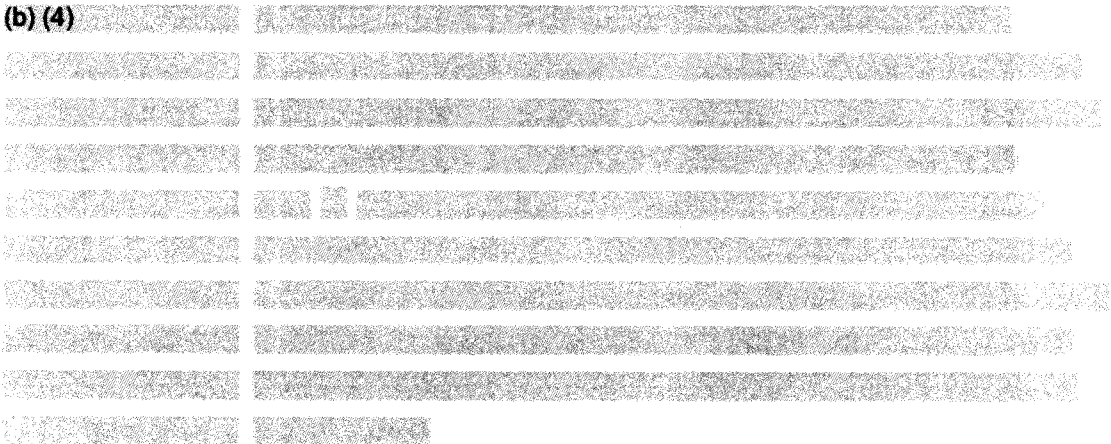
Figure 1: (b) (4) for (a) tar, (b) nicotine, and (c) carbon monoxide for the (b) (4)



(b) (4)



(b) (4)



Treatment of the Subject and Predicate data:

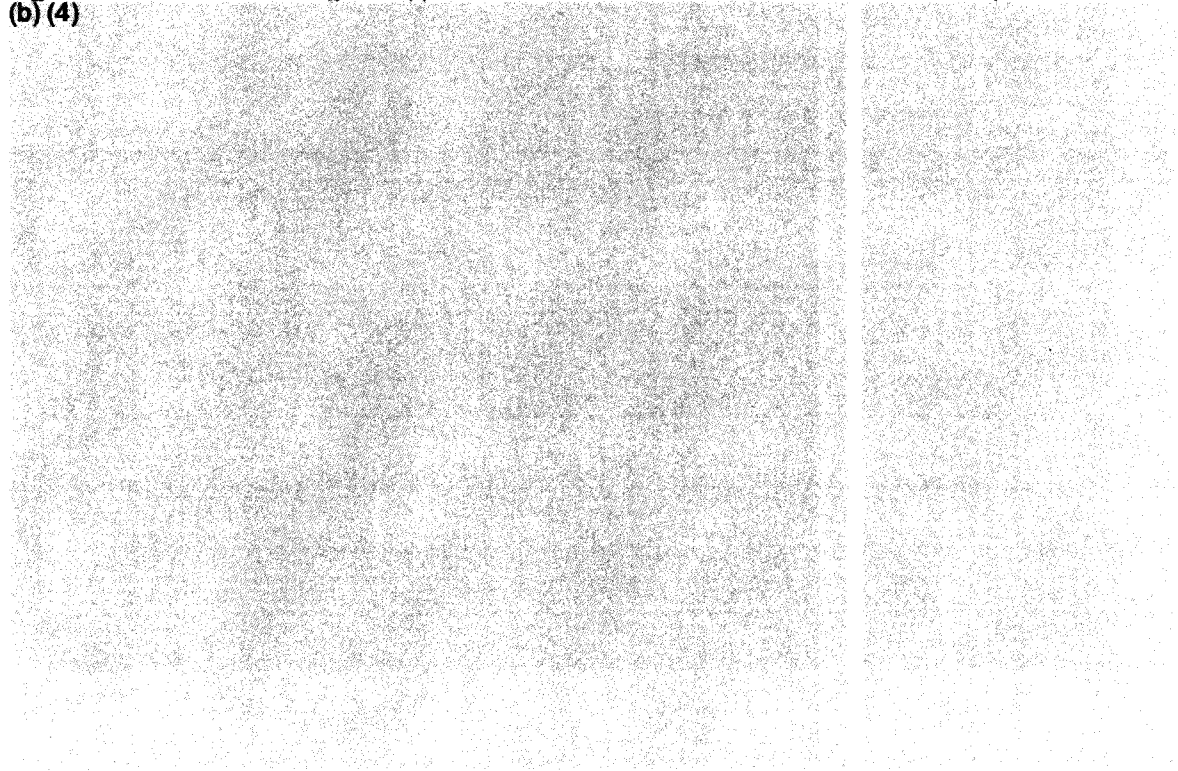
The Newport Non-Menthol Gold Box subject and 2007 Newport Lt M 80 Hard Box predicate TNCO yields were measured using the (b) (4) _____, respectively. Since the Newport Non-Menthol Gold Box subject TNCO data were collected using a different smoking regime than the 2007 Newport Lt M 80 Hard Box predicate TNCO data, it was necessary to

(b) (4) _____ TNCO values for the Newport Non-Menthol Gold Box

subject product in order to (b) (4) TNCO yields of the 2007 Newport Lt M 80 Hard Box predicate product. (b) (4) illustrated in Figure 1.

The total variability requires the implementation of (b) (4) to demonstrate that two products are substantially equivalent. The (b) (4) utilized within the context of this report were calculated based on the (b) (4) are used for the purpose of comparing the smoke constituents of the subject and predicate products, and are defined in this submission as the (b) (4). The approach implemented for the comparison of projected subject tar, nicotine, and carbon monoxide values to the predicate product yields is illustrated in Figure 2.

Figure 2: Flowchart outlining the approach used to demonstrate TNCO's substantial equivalence. (b) (4)



The TNCO yields of the subject Newport Non-Menthol Gold Box are deemed substantially equivalent to the predicate 2007 Newport Lt M 80 Hard Box if the (b) (4) values are within the (b) of the 2007 Newport Lt M 80 Hard Box (b) TNCO yields. Figure 3 is an example of this approach using tar data, and the corresponding nicotine and carbon monoxide comparisons were completed using the same methodology. The data supports the claim that the subject Newport Non-Menthol Gold Box TNCO yields are substantially equivalent to the predicate 2007 Newport Lt M 80 Hard Box yields. (b) (4)

(b) (4)

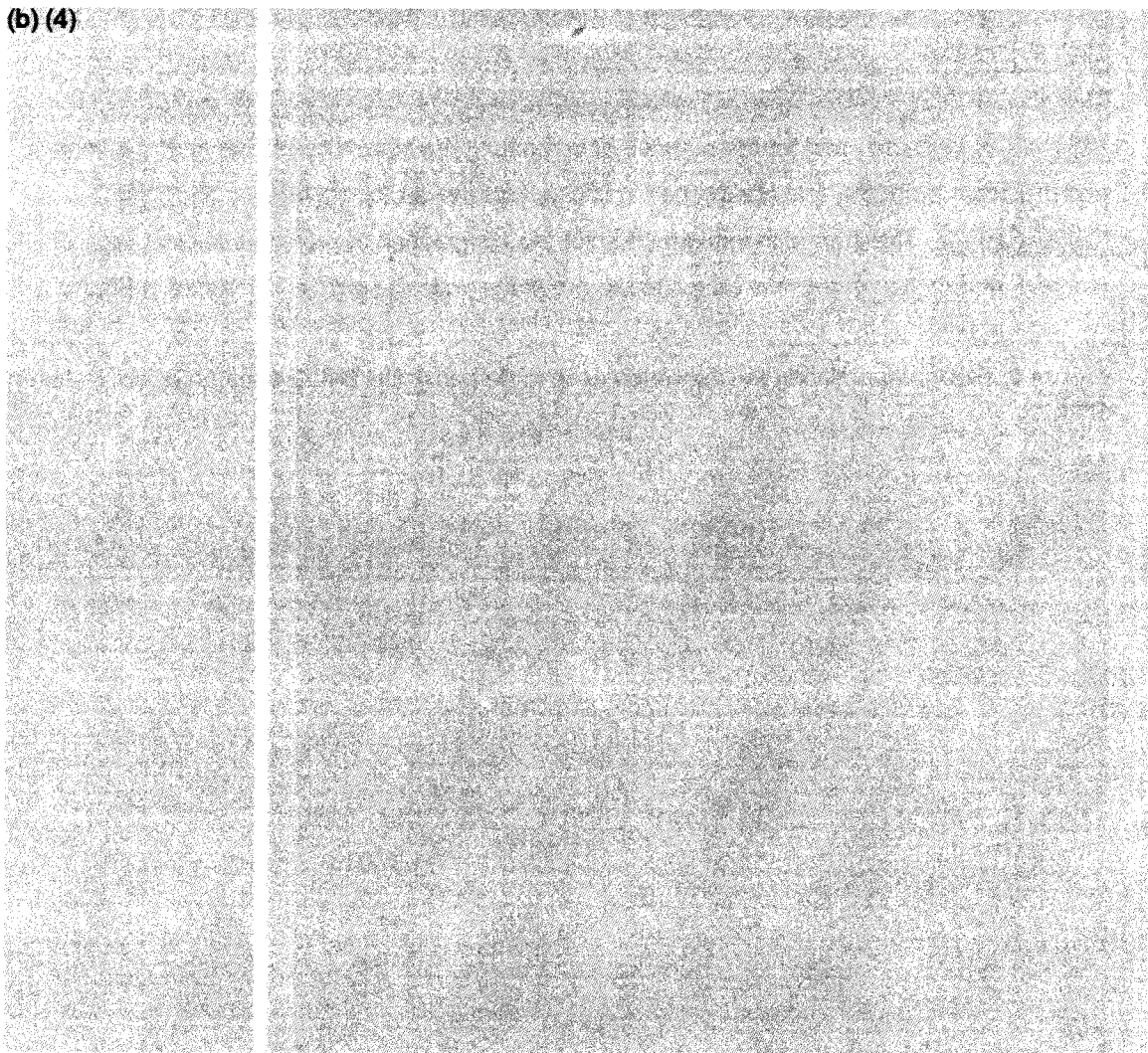


Table 3. Newport Non-Menthol Gold Box subject (b) (4) TNCO, (b) (4) TNCO, 2007 Newport Lt M 80 Hard Box predicate (b) (4) TNCO means, and the corresponding (b) (4)

	Subject		Predicate		SUBSTANTIALLY EQUIVALENT
	NEWPORT NON-MENTHOL GOLD BOX		2007 NPT LT M 80 HARD BOX		
	(b) (4)	(b) (4)	(b) (4)	(b) (4)	
	Mean	Mean	WITHIN (b) (4)	Mean (b) (4)	
Tar (mg/cig)	(b) (4)	(b) (4)	YES	(b) (4)	YES
Nicotine (mg/cig)	(b) (4)	(b) (4)	YES	(b) (4)	YES
CO (mg/cig)	(b) (4)	(b) (4)	YES	(b) (4)	YES

Appendix B

**Appendix B: Comparison of Design Features for Newport Non-Menthol Gold Box with the 2007
Newport Lt M 80 Hard Box Predicate Product**

Design			Subject	Predicate	Notes	
Component		unit of measure	2012 Newport Non-Menthol Gold Box	2007 Newport Light 80 Hard Box		
Cigarette	Cigarette ID		(b) (4)			
		<i>cigarette length</i>				mm
		<i>cigarette paper weight</i>				mg
		<i>cigarette rod weight</i>				mg
		<i>cigarette weight</i>				mg
		<i>circumference</i>				mm
		<i>air dilution</i>				%
		<i>pack moisture</i>				%
		<i>pack menthol</i>				%
		<i>rod length (tobacco section)</i>				mm
	<i>finished tobacco blend weight</i>	mg				
Tobacco Blend	Final Tobacco Blend ID		(b) (4)			
						%
						%
						%
						%
Filter	Filter rod ID		(b) (4)			
		<i>tip length</i>				mm
		<i>tip pressure drop</i>				mm-H ₂ O
	plug wrap ID					
		<i>basis weight</i>	g/m ²			
		<i>porosity</i>	Coresta			
		<i>plasticizer (type)</i>				
Tipping Paper	Tipping Paper ID		(b) (4)			
		<i>roll size width</i>				mm
		<i>basis weight</i>				g/m ²
		<i>opacity</i>				%
		<i>porosity</i>				
Cigarette Paper	Cigarette paper ID		(b) (4)			
		<i>bobbin width</i>				mm
		<i>tensile strength (dry)</i>				g/width
		<i>basis weight (base paper)</i>				g/m ²
		<i>basis weight (printed)</i>				g/m ²
		<i>inherent porosity</i>				Coresta
		<i>citral</i>				WT %
		LIP banding material ID				
		<i>LIP band width</i>				mm
		<i>LIP band spacing</i>				mm

(b) (4)

Appendix C

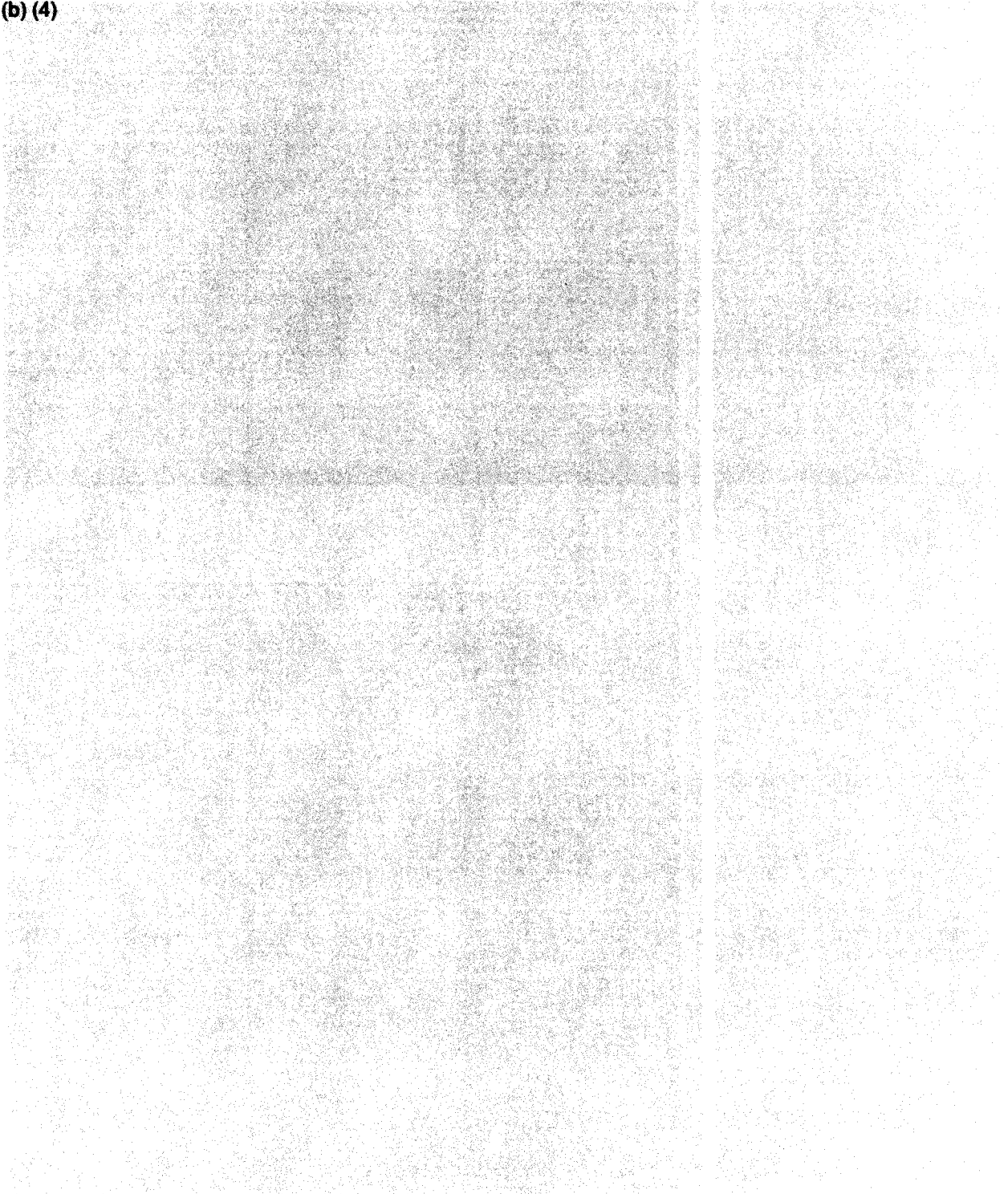
Appendix C: Ingredients and materials comparisons for Newport Non-Menthol Gold Box with the 2007 Newport Lt M 80 Hard Box Predicate Product

Appendix D

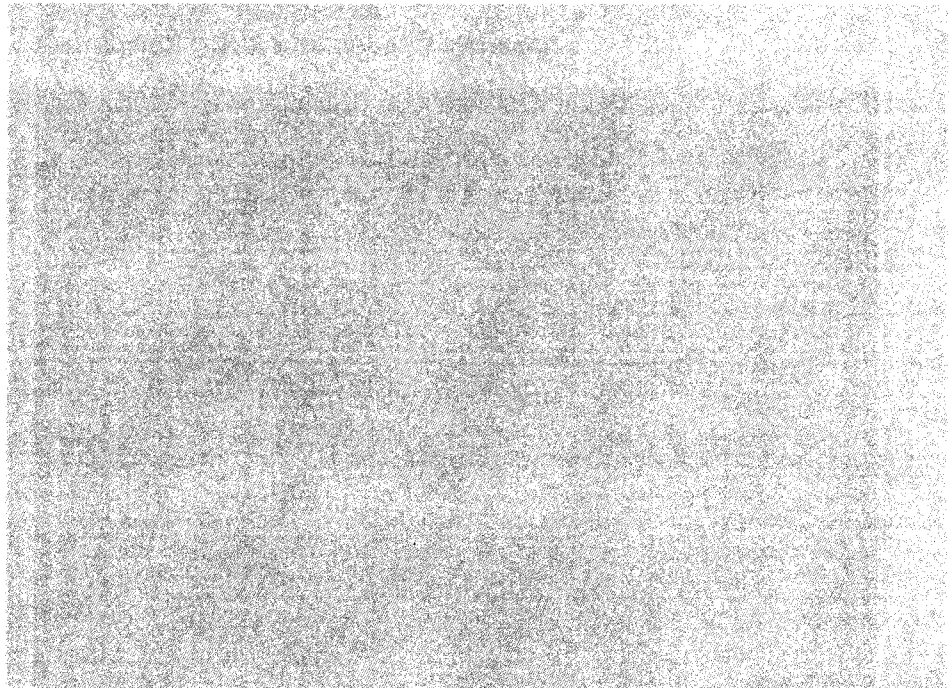
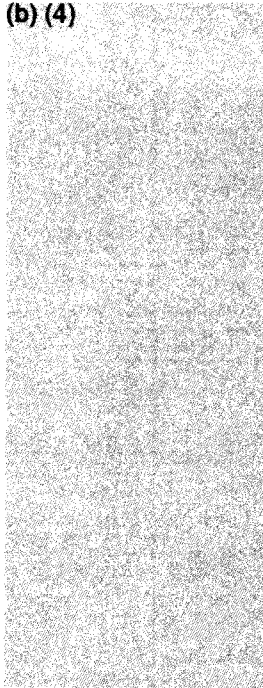
Appendix D: (b) (4) [REDACTED]
[REDACTED]

Appendix D: Additional TNCO Comparisons

(b) (4)



(b) (4)



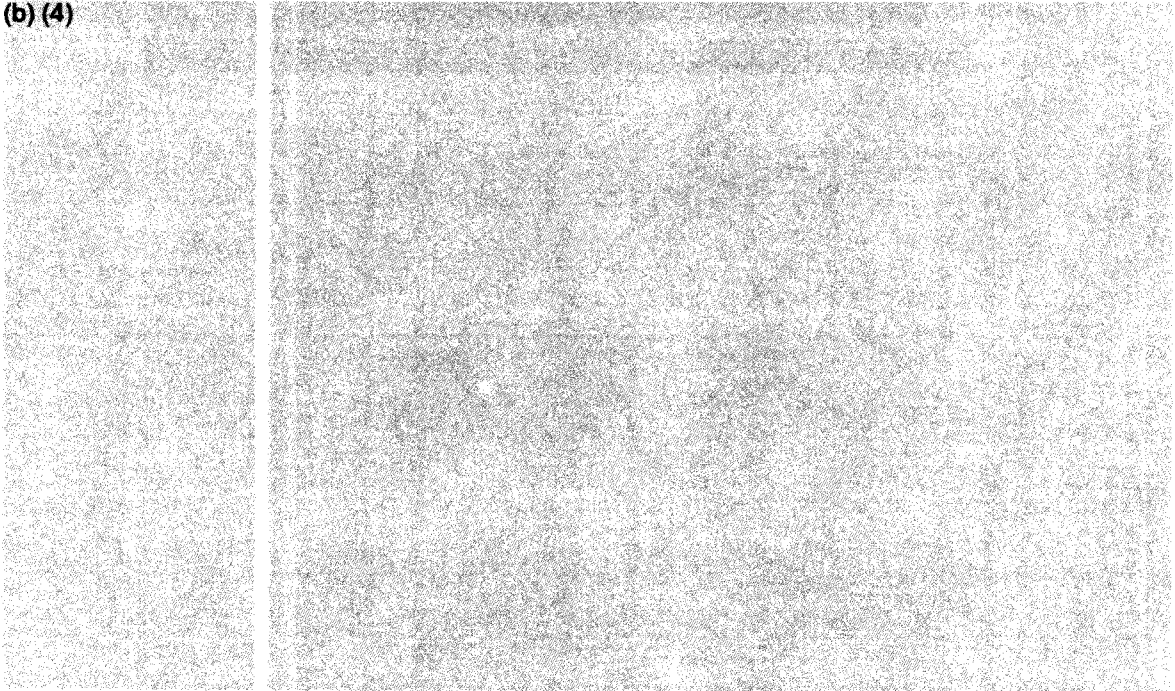
Appendix E

Appendix E: (b) (4)

[Redacted content]

Appendix E: Select Smoke Constituent Data Comparisons

(b) (4)



(b) (4)



(b) (4)



Appendix F

Appendix F: Environmental Assessment for the Newport Non-Menthol Box subject product.

**Appendix F: Environmental Assessment
Newport Non-Menthol Gold Box Cigarette**

This environmental assessment has been prepared in accordance with 21 C.F.R. § 25.40 as part of a submission under section 905(j) of the Federal Food, Drug, and Cosmetic Act.

- 1) **Date:** October 12, 2011
- 2) **Name of Notifier:** Lorillard Tobacco Company
- 3) **Address:** 714 Green Valley RD; Greensboro, NC, 27408
- 4) **Description of the proposed action:**

Requested action:

Production and sales of a substantially equivalent cigarette to a product in commerce be allowed.

Need for action:

Lorillard wishes to introduce a new tobacco product that is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or to a tobacco product that FDA has previously determined is substantially equivalent.

Location of use:

The tobacco product will be manufactured at Lorillard Tobacco Company's Greensboro, NC facility.

The mailing address of the facility is: 714 Green Valley Rd.; Greensboro, NC, 27408

The tobacco product will be distributed and sold nationally to consumers for use as a cigarette.

The product uses conventional design, construction, ingredients and delivers TNCO and other smoke constituents at substantially equivalent levels to products already in commerce (e.g., 2007 Newport Lt M 80 Hard Box).

Location of disposal:

The used cigarettes will be disposed of as typical of other used cigarettes through deposit in municipal solid waste landfills.

- 5) **Identification of the proposed substance/cigarette subject to the proposed action:** Menthol will not be added to this cigarette compared to cigarettes of similar construction and deliveries already in commerce. Except for menthol, there are no measurable physical or chemical differences between a similar cigarette containing menthol and this cigarette without menthol.

Trade name: Newport Non-Menthol Gold Box

Reference Identification Number (internal): 2003905

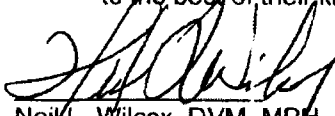
Product Identification Number: 0-26100-00660-5

- 6) **Introduction of cigarette to the environment:**
- a) **Introduction of substances into the environment as a result of manufacture:**
No extraordinary circumstances apply to the manufacture of this tobacco product compared to other commercially available tobacco products. The tobacco product manufactured without menthol would not introduce any new substances into the environment versus a tobacco product with menthol.
- b) **Introduction of cigarettes into the environment as a result of use:**
The product will not introduce materials into the environment beyond the waste produced when using the cigarette as designed.
- c) **Introduction of cigarettes into the environment as a result of disposal:**
The product will not introduce materials into the environment beyond the waste produced when using the cigarette as designed.
- 7) **Fate of cigarettes released into the environment:**
We do not anticipate the fate of any materials from this cigarette to be any different from other cigarette commercially available. Except for menthol, there are no measurable physical or chemical differences with a similar cigarette containing menthol and therefore no different environmental fate is anticipated.
- 8) **Environmental effects of the released cigarette:**
We do not anticipate the environmental effects of any materials from this cigarette to be any different from other cigarette commercially available. Except for menthol, there are no measurable physical or chemical differences between a similar cigarette containing menthol and therefore no different environmental effects are anticipated.
- 9) **Use of resources and energy:**
The use of resources and energy are not expected to be greater than those already used for the manufacture, distribution and sales of existing, commercially available cigarettes. Therefore, no additional resources or energy will be required.
- 10) **Mitigation measures:**
We identify no adverse environmental effects, based upon our review of the available data and information for Newport Non-Menthol Gold cigarette and its proposed use as a cigarette. Therefore, mitigation measures are not required and are not proposed.
- 11) **Alternatives to the proposed action:**
We identify no adverse environmental effects, based upon our review of adequate and complete data and information. Therefore alternatives are not proposed.
- 12) **List of preparer:**
(b) (4)

Kevin H Reinert, PhD
Director, Scientific Affairs

13) **Certification:**

The undersigned certifies that the information presented is true, accurate and complete to the best of their knowledge as of October 12, 2011

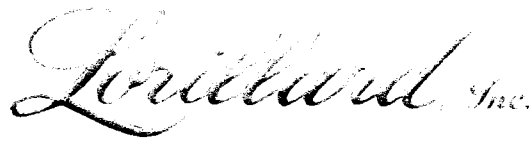


Neil L. Wilcox, DVM, MPH
Sr. Vice President & Chief Compliance Officer

Appendix G

References

1. Smoking and Tobacco Control, Monograph 7, The FTC Cigarette Test for Determining Tar, Nicotine and Carbon Monoxide Yields of U. S. Cigarettes, U. S. Department of Health and Human Services, NIH Publication Number 96-4028, August 1996.
2. Federal Trade Commission, Report of "Tar," Nicotine, and Carbon Monoxide of the Smoke of 1249 Varieties of Domestic Cigarettes for the Year 1995.
3. Federal Register, Volume 45, Number 134, Page 46,483, July 10, 1930.
4. Federal Trade Commission in Federal Register, Volume 32, Number 147, Page 11,178, August 1, 1967.
5. Determination of Total and Nicotine-Free Dry Particulate Matter Using a Routine Analytical Smoking Machine, ISO 4387.
6. Determination of Nicotine in Smoke Condensates: Gas Chromatograph Method, ISO 10315.
7. Determination of Carbon Monoxide in Vapor Phase of Cigarette Smoke Condensates: NDIR Method, ISO 8454.
8. Determination of Water in Smoke Condensates – Part 1: Gas Chromatograph Method, ISO 10362.1.
9. (b) (4)
10. US Patent 7836898, Nov 23, 2010.
11. R.R. Baker, E.D. Massey, G. Smith, Food Chem. Toxicol. 42 (Suppl.) (2004) 53–83.
12. R.R. Baker, L.J. Bishop, in: Proceedings of the 16th Int. Symp. Anal. Appl. Pyrolysis, 2004, vol. 74, 2005, pp 145–170.
13. R.R. Baker, S. Coburn, C. Liu, J. Tetteh, J. Anal. Appl. Pyrolysis 74 (2005) 171–180.
14. Presented to FDA-CTP on February 4, 2011.
15. R. Baker. Beiträge zur Tabakforschung International, Contributions to Tobacco Research. Vol. 20, No. 1. February 2002.
16. (b) (4)
17. (b) (4)



RECEIVED

FEB 13 2012

BY: CTP / DCC

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

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February 10, 2012

U.S. Food and Drug Administration
Center for Tobacco Products
Attn: Ms. Florence Moore
Lead Regulatory Health Project Manager
c/o Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850-3229

**CONFIDENTIAL
CONTAINS TRADE SECRETS**

RE: RESPONSE TO ADVICE/INFORMATION REQUEST FOR SE0003731

Dear Ms. Moore,

This letter responds to FDA's Advice/Information Request dated February 6, 2012, in connection with submission SE0003730. FDA's Request included three questions regarding Lorillard's October 12, 2011 Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce ("905(j) Report") for Newport Non-Menthol Gold Box.

Below please find Lorillard's responses to your requests. For your convenience, we have reprinted each request, followed by our response.

Request 1

Full identification of your new tobacco product (i.e., how the new product is uniquely identified for a consumer such as brand, subbrand, size, quantity, packaging)

Lorillard's Response:

The identification of the new tobacco product was provided on page 3 section 2.4 of the 905(j) Report. Please find below additional information as requested:

Brand name: Newport
Subbrand (brand variant): Non-Menthol Gold Box
Size: 80mm cigarette length (rod + filter).
Format: Hard box pack
Quantity: 20 cigarettes in each pack, 10 packs per carton
UPC Number: 0 26100 00660 5

Packaging: Please find attached as Appendix A an example of the pack and carton design for the new tobacco product in print form and on disk.

Request 2

Full identification of your predicate tobacco product (i.e., how the predicate product is uniquely identified for a consumer such as brand, subbrand, size, quantity, packaging)

Lorillard's Response:

The identification of the predicate tobacco product was provided on page 3 section 2.5 of the 905(j) Report. Please find below additional information as requested:

Brand name: Newport
Subbrand (brand variant): Lights Menthol Gold Box
Size: 80 mm cigarette length (rod+filter)
Format: Hard box pack
Quantity: 20 cigarettes per pack, 10 packs per carton
UPC Number: 0-26100-00576-9
FDA-assigned TP number: TP-0004209

Packaging: Please find attached as Appendix B an example of the pack and carton design of the predicate tobacco product, as it was available at retail on February 15, 2007. Please note that the predicate tobacco product is no longer on the market.

Request 3

A statement of your action to comply with the requirements of Section 907 (see section 905(j)(1)(B) of the FD&C Act), including those standards under Section 907(a) of the FD&C Act and any promulgated through regulation. If any of the standards are not applicable to your product, provide a statement to that effect.

Lorillard's Response:

We hereby confirm that the subject product is in compliance with Section 907. Specifically, the subject product does not contain any characterizing flavors and, therefore, the "Special Rule for Cigarettes" in Section 907(a)(1)(A) is not applicable. As the agency recently acknowledged, there are no currently applicable tolerance limits for pesticide chemical residues that apply to domestically grown tobacco and, accordingly, the "Additional Special Rule" set forth in section 907(a)(1)(B) is not applicable.¹ Lorillard is not aware of any other tobacco standard applicable

¹ See, e.g., Letter from Lawrence R. Deyton, M.S.P.H., M.D., Director, FDA Center for Tobacco Products, to James E. Swauger, Ph.D., DABT, R.J. Reynolds Tobacco Company (December 6, 2011), available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM282742.pdf>.

U.S. Food and Drug Administration
Center for Tobacco Products
February 10, 2012

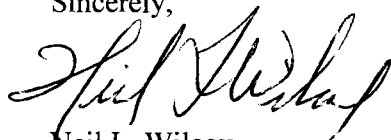
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to cigarettes promulgated under Section 907. Lorillard fully intends to comply with such final standards once lawfully promulgated.

Please note that Lorillard considers the information contained in this letter to constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter and its appendices are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

We hope that this additional information will support your expeditious review and favorable decision on our 905(j) Report. Please do not hesitate to contact me should you need any clarifications.

Sincerely,



Neil L. Wilcox

Enclosures

U.S. Food and Drug Administration
Center for Tobacco Products
February 10, 2012

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Appendix A

(See Attachment)

U.S. Food and Drug Administration
Center for Tobacco Products
February 10, 2012

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Appendix B

(See Attachment)

Lorillard, Inc

RECEIVED
DEC 10 2012
BY: CTP MAIL ROOM

Neil L. Wilcox, DVM, MPH
Senior Vice President &
Chief Compliance Officer

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E-Mail: nwilcox@lortobco.com

This letter, the enclosed answers, appendices, and all data and information contained in this response constitute confidential commercial information and trade secrets.

December 3, 2012

Center for Tobacco Products
Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED

BY: CTP / DCC

Re: Response to Advice/Information Request for SE0003731

RECEIVED

BY: CTP / DCC

Dear Sir/Madam:

Reference is made to the Advice and Information Request (dated October 26, 2012) issued by the FDA Center for Tobacco Products (CTP) regarding the report submitted under Section 905(j) of the Food, Drug, and Cosmetic Act (FDCA) by Lorillard Tobacco Company (Lorillard) for Newport Non-Menthol Gold Box ("SE Report"). This letter and accompanying attachments constitute a complete response to CTP's Advice and Information Request.

In the attached response, Lorillard sets forth each request issued by CTP followed by Lorillard's response. In some cases, we have also provided detailed Appendices with the requested information, as well as additional, supporting information.

While Lorillard has provided complete responses to CTP's information requests, respectfully, many of CTP's requests go well beyond what is required for the agency to make a determination of substantial equivalence. The substantial equivalence pathway under Section 905(j) was intended as a streamlined pathway for the review of new tobacco products. However, the agency has adopted an approach that requires the submission of burdensome and unnecessary data. Much of the information requested by CTP in its Advice and Information Request is not necessary to conclude that the predicate and subject products are substantially equivalent. For example, CTP is demanding that Lorillard submit an extensive amount of information about the components used in product packaging at carton and shipping container level. Lorillard is not aware of any scientific data suggesting that differences in product packaging cardboard bear any

Center for Tobacco Products
Food and Drug Administration
December 3, 2012

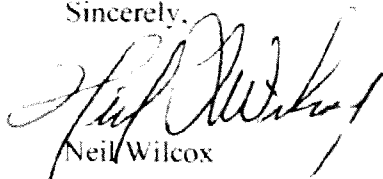
relationship to the relative safety of cigarettes, and such detailed packaging information is clearly not necessary to conclude that the products are substantially equivalent. In this regard, CTP seems to be persisting in an interpretation that "same" characteristics (as required by one part of the standard for a substantially equivalent product) must be read as "identical," even though nothing in the statute compels this conclusion and even though the agency has not adopted such an interpretation for other statutory requirements that use similar language (e.g. generic drugs, 510(k)s).

The statute indicates that applications submitted pursuant to Section 905(j) of the FDCA are subject to a 90-day review period, but CTP's letter was not issued until more than a year after Lorillard submitted its 905(j) report. Moreover, many of the categories of data and information requested in the Advice and Information Request were never set forth in any regulation, guidance document, or any other formal source of information. Instead, these requirements appear to have been implemented on a case-by-case basis or announced for the first time in the August 21, 2012 webinar organized for small businesses. Had this information been necessary to CTP's determination of substantial equivalence, the agency should have made a formal announcement so that Lorillard could have provided the necessary information before now.

Despite our significant concerns, in an effort to expedite the review and approval of these 905(j) reports, Lorillard is providing the requested information, which should permit FDA to promptly issue a substantial equivalence order.

This letter, the attached answers, appendices, and all data and information contained in this response constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this letter, the attached answers, appendices, and all data and information contained in this response are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

Sincerely,



Neil Wilcox

Enclosures

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February 8, 2013

St 000 7185 - 7186

Ms. Rosanna Beltre
Regulatory Project Manager
Center for Tobacco Products
U.S. Food and Drug Administration
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

Via Federal Express

Re: SE0003730 and SE0003731: Answers to February 1, 2013 Clarifying Questions for Response to Scientific AI Letter for SE0003730 and SE0003731

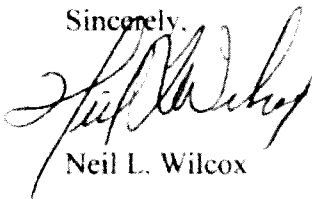
Dear Ms. Beltre:

Please find enclosed Lorillard Tobacco Company's answers to your February 1, 2013 Clarifying Questions for Response to Scientific AI Letter for SE0003730 and SE0003731.

This cover letter, the enclosed answers and all data and information contained herein constitute confidential commercial information and trade secrets pursuant to 21 C.F.R. § 20.61. As such, this cover letter, the enclosed answers and all data and information contained herein are exempt from public disclosure under 5 U.S.C. § 552(b)(4) and FDCA § 906(c) and protected as trade secrets under 18 U.S.C. § 1905 and FDCA § 301(j).

Please do not hesitate to contact us promptly should any further clarification be necessary.

Sincerely,



Neil L. Wilcox

Enclosure

