Technical Project Lead Memorandum:

SE Report SE0003731

New Product	
Product Name	Newport Non-Menthol Gold Box
Package Size	20 cigarettes per pack, 10 packs per carton
Package Type	Box
Product ID	2003905
Applicant	Lorillard Tobacco Company
Status	Regular
Product Category	Cigarette
Product Sub-Category	Conventional Filtered
Recommendation	
Issue a Substantial Equivalence (SE) order	

Technical Project Lead (TPL):

Signature: (b) (6) **Date:** 6/25/13

Matthew R. Holman, Ph.D.
Director
Division of Product Science

Signatory Decision:

☑ Concur with TPL Recommendation and Basis of Recommendation

☐ Concur with TPL Recommendation with additional comments (see separate memo)

☐ Do Not Concur with TPL Recommendation (see separate memo)

Signature: (b) (6) **Date:** 6/25/13

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

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1. BACKGROUND

1.1. PREDICATE INFORMATION

The applicant submitted the following predicate product:

Table 1. Predicate Product

Manufacturer	Lorillard Tobacco Company
Name	2007 Newport Lights Menthol 80 Hard Box
Package Size	20 cigarettes per pack, 10 packs per carton
Product ID	2000314
Product Category	Cigarette
Product Sub-Category	Conventional Filtered
Claimed Status	Grandfathered Product

The applicant stated that the predicate product is no longer on the market.

1.2. OVERVIEW OF SUBSTANTIAL EQUIVALENCE CLAIM AND REVIEW

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

To utilize the substantial equivalence pathway, a product must either have the same characteristics as a valid predicate product or have different characteristics but the new product is not appropriate to regulate under the premarket tobacco application pathway because the product does not raise different questions of public health.

FDA finds that the new product has different characteristics than the predicate tobacco product, but that these differences are such that the new product does not raise different questions of public health.

1.3. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original SE Report SE0003731 in October 2011. FDA sent the applicant an administrative advice and information (A/I) request letter for this SE Report. In response, the applicant submitted amendment SE0004148 to the original SE Report in February 2012. Following our review of the original and amended SE Reports, we sent a scientific A/I letter to the applicant in October 2012 citing specific deficiencies to be addressed. The applicant responded to the scientific A/I letter by amending their SE Report (SE0005305) in December 2012. On February 1, 2013, additional clarifications were requested through a teleconference with the applicant. The applicant responded on February 8, 2013, with an additional amendment (SE0007186).

1.4. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0003731.

2. DIFFERENCES BETWEEN NEW AND PREDICATE PRODUCTS

The new product has the following key differences compared to the predicate product:

- Absence of menthol
- Presence of fire standard compliant (FSC) cigarette paper (as opposed to conventional cigarette paper)
- Changes to design features to maintain consistency of smoke delivery

3. COMPLIANCE REVIEWS

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States, not in test markets, as of February 15, 2007). The OCE review dated June 22, 2012 and amended May 14, 2013, concludes that 2007 Newport Lights Menthol 80 Hard Box is an eligible predicate tobacco product, as the applicant established that the predicate tobacco product is grandfathered.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether Newport Non-Menthol Gold Box is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 910(a)(2)(A)(i)(II) of the FD&C Act. The OCE review dated February 4, 2013, amended May 14, 2013, and amended June 19, 2013, concludes that Newport Non-Menthol Gold Box is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEWS

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

4.1. CHEMISTRY

Chemistry reviews were completed by Matthew Walters, Ph.D. on September 24, 2012, and by Zhong Li, Ph.D. on March 1, 2013.

The final chemistry review concludes that the new product does not raise different questions of public health and, therefore, recommends that an SE order be issued based on product composition information submitted in the SE Report and amendments. The composition of the new and predicate products is nearly identical with the exception that menthol was omitted from, and fire standard

compliant (FSC) paper was added to, the new product. The new and predicate products contain essentially identical tobacco blends consisting of (b) (4) (b) (4) The other ingredients and additives, including the flavors and casings, are essentially identical except for the absence of menthol and the addition of FSC banded cigarette paper and burn modifiers in FSC cigarette paper. Overall, the chemistry review concludes that the differences in the identity or quantities of ingredients and additives between the predicate and new products are such that the new product does not raise different questions of public health.

The chemistry review also evaluates tar, nicotine, and carbon monoxide data in this report. The review found this data was similar for the new and predicate products under both intense and non-intense smoking regimens. Therefore, the review concludes that the differences in tar, nicotine, or carbon monoxide data are such that the new product does not raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Christopher Brown on October 2, 2012, and March 13, 2013.

The final engineering review concludes that the new product does not raise different questions of public health and, therefore, recommends that an SE order be issued based on product design information submitted in the SE Report. The primary difference in product design between the new and predicate product is use of fire standard compliant (FSC) paper in the new product. With this design difference, other design parameters were modified in the new product to provide comparable flow rate and dilution of the mainstream smoke in the new and predicate products. Overall, the engineering review concludes that the differences in the product design between the predicate and new products are such that the new product does not raise different questions of public health.

4.3. TOXICOLOGY

Toxicology reviews were completed by Phil Yeager, Ph.D. on October 11, 2012, and June 3, 2013.

The final toxicology review concludes that the new product does not raise different questions of public health and, therefore, recommends that an SE order be issued based on toxicology information submitted in the SE Report. It is noted that the toxicology review deferred evaluation of the tar, nicotine, and carbon monoxide data to the chemistry review.

4.4. SOCIAL SCIENCE

A social science review was completed by David Portnoy, Ph.D. on June 12, 2013.

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. But studies do not suggest that the absence of menthol (i.e., lack of menthol as a characterizing flavor) would increase the likelihood of youth appeal of the new product. The social science review concludes that the new product does not raise different questions of public health from a social science perspective. It should be noted that, because the new product lacks menthol, the social science review did not evaluate the full extent of the literature concerning the addition of menthol and initiation.

The applicant did not provide a health information summary. To fulfill the provisions of Section 910(a)(4) of the FD&C Act, Lorillard Tobacco Company has stated that it will make such information available upon request by any person.

4.5. ADDICTION

An addiction review was completed by Megan Schroeder, Ph.D. on June 12, 2013.

The addiction review concludes that the new product does not raise different questions of public health from an addiction perspective. The available information regarding menthol in cigarettes does not indicate that absence of menthol (i.e., lack of menthol as a characterizing flavor) would increase the likelihood of initiation and the level/severity of dependence, and/or decrease the likelihood of cessation success. It should be noted that, because the new product lacks menthol, the addiction review did not evaluate the full extent of the literature concerning the addition of menthol and initiation, dependence, and cessation. The review concludes that, because nicotine content appears to be lower in the new product compared to the predicate product, the nicotine content of the new product does not raise different questions of public health.

5. ENVIRONMENTAL DECISION

On June 4, 2013, Hoshing Chang, Ph.D., prepared a finding of no significant impact (FONSI) that was supported by an Environmental Assessment. The FONSI was signed by RADM David L. Ashley on June 4, 2013.

6. CONCLUSIONS AND RECOMMENDATIONS

The key differences in characteristics between the new product and the predicate product consisted primarily of exclusion of menthol, change from conventional to fire standard compliant paper, and changes to design features to maintain consistency of delivery of emissions.

Evaluation of available scientific studies and other information shows that menthol added as a characterizing flavor to cigarettes compared to equivalent cigarettes without menthol as a characterizing flavor supports the premise of an increased likelihood of initiation, level/severity of dependence, and/or decreased likelihood of cessation success. This finding coupled with other available scientific evidence supports the conclusion that exclusion of use of menthol in the new product compared to the predicate product would not adversely impact initiation, dependence or cessation and, therefore, the new product does not raise different questions of public health.

The design features of the new product were altered to achieve the same smoke delivery characteristics as the predicate product. Thus, the evidence points that the depth of inhalation for users of the two products would be equivalent such that the new product does not raise different questions of public health.

Use of fire standard compliant paper in place of conventional cigarette paper and alteration of ventilation and paper porosity design features could alter the delivery of HPHCs to the users of the product. TNCO measured using both the ISO and Health Canada smoking regimens submitted for both the new and predicate products indicated that the constituents in smoke delivered from the comparison products maintains an equivalent risk to the user, and thus, the new product does not raise different questions of public health. Furthermore, FDA review of data on additional HPHCs measured by Lorillard to support a demonstration of substantial equivalence for a similar product with the same key differences from a predicate product found that, related to these HPHCs, the new product did not raise different questions of public health.

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new product does not raise different questions of public health. I concur with these reviews and recommend that an SE order be issued.

In addition, an order letter can be issued because FDA examined the environmental effects of finding this new product substantially equivalent and made a finding of no significant impact.

An SE order should be issued for the new tobacco product in SE0003731, as identified on the cover page of this memo.