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STANTON A. GLANTZ, PhD
Professor of Medicine (Cardiology)
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July 8, 2013

Lorillard Tobacco Company
Attn: Neil L. Wilcox, D.V.M., M.P.H.
Senior Vice President & Chief Compliance Officer
714 Green Valley Road
P.O. Box 10529
Greensboro, NC 27408

Via certified mail, return receipt requested

Re: Submission Tracking Number (STN): SE0003730

Dear Dr. Wilcox:

I am writing in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce for the new Lorillard product named, "Newport Non-Menthol Gold Box 100s". Based on its review of this Report, the Food and Drug Administration (FDA) determined that this new tobacco product is substantially equivalent to a tobacco product commercially marketed in interstate commerce as of February 15, 2007.

Section 910(a)(4) of the FD&C Act provides:

> A. **Summary.** As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.
>
> B. **Required Information.** Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

In his June 25, 2013 letter to you regarding your application, David L. Ashley, Director, Office of Science, FDA Center for Tobacco Products, stated that since you did not "provide an adequate summary of any health information related to the new tobacco product with your application," you "agreed that such information will be available upon request by any person."

Section 910(a)(3)(A) defines "substantially equivalent" to mean that the new tobacco product:

i. has the same characteristics as the predicate tobacco product; or

ii. Has different characteristics and the information submitted contains information, including clinical data… that demonstrates that … the product does not raise different questions of public health."

Section 910(a)(3)(B) defines "characteristics" to mean "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

Section 910(b)(1) provides that an application under this section shall contain:

A. full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

B. a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

C. a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

D. an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

E. such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

F. specimens of the labeling proposed to be used for such tobacco product; and

G. such other information relevant to the subject matter of the application as the Secretary may require.

Therefore, pursuant to the guidance provided by these statutory authorities and by Dr. Ashley's letter, I request that you provide the information described below:

1. A copy of your full Substantial Equivalence Report;

2. Full reports of all information, research, investigations, or data, published, in your possession, or otherwise known to, or which should reasonably be known to, Lorillard, concerning or showing the health risks or adverse health effects of the new Newport Non-Menthol Gold Box 100s tobacco product and whether this product presents less risk than other tobacco products and of the predicate product;

3. A complete list of all the characteristics (defined as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product", including the

components, ingredients, additives, and properties), and of the principle or principles of operation of, the new Newport Non-Menthol Gold Box 100s tobacco product and of the predicate product;

4. A complete list of all the differences in the characteristics (as defined in item 3) and principle(s) of operation between the new Newport Non-Menthol Gold Box 100s tobacco product and the predicate product;

5. A complete report on the evidence and scientific rationale concerning why the differences in the characteristics (as defined in item 3) and principle(s) of operation between the new Newport Non-Menthol Gold Box 100s tobacco product and of the predicate product do not raise different questions of public health;

6. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of each of the components, ingredients, additives, and properties contained in the new Newport Non-Menthol Gold Box 100s tobacco product and of the predicate product;

7. Any research or data you have in your possession or otherwise know of that demonstrates why any aspect of the new Newport Non-Menthol Gold Box 100s tobacco product and its construction, components, ingredients, additives, constituents, including smoke constituents, and properties fully meets each of the tobacco product standards set out in section 907 and is appropriate for the protection of the public health; and

8. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of, the new Newport Non-Menthol Gold Box 100s tobacco product.

Had you provided an adequate summary of health information containing detailed information regarding data concerning adverse health effects to FDA, this information would have been made available to the public by the Secretary within 30 days of the issuance of its substantial equivalence determination under the provisions of section 910(a)(4)(B). Therefore, I request that you provide this information to us within 30 days of receipt of this request.

Thank you for your consideration.

Sincerely yours,

Stanton A. Glantz, PhD
Professor of Medicine
Director, Center for Tobacco Control Research and Education

cc: David L. Ashley, Director, Office of Science, Center for Tobacco Products
Mitchell Zeller, Director, Center for Tobacco Products

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Senior Vice President & Chief Compliance Officer
714 Green Valley Road
P.O. Box 10529
Greensboro, NC 27408

Via certified mail, return receipt requested

Re: Submission Tracking Number (STN): SE0003731

Dear Dr. Wilcox:

I am writing in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce for the new Lorillard product named, "Newport Non-Menthol Gold Box". Based on its review of this Report, the Food and Drug Administration (FDA) determined that this new tobacco product is substantially equivalent to a tobacco product commercially marketed in interstate commerce as of February 15, 2007.

Section 910(a)(4) of the FD&C Act provides:

> A. **Summary.** As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.
>
> B. **Required Information.** Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

In his June 25, 2013 letter to you regarding your application, David L. Ashley, Director, Office of Science, FDA Center for Tobacco Products, stated that since you did not "provide an adequate summary of any health information related to the new tobacco product with your application," you "agreed that such information will be available upon request by any person."

Section 910(a)(3)(A) defines "substantially equivalent" to mean that the new tobacco product:

i. has the same characteristics as the predicate tobacco product; or

ii. Has different characteristics and the information submitted contains information, including clinical data… that demonstrates that … the product does not raise different questions of public health."

Section 910(a)(3)(B) defines "characteristics" to mean "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

Section 910(b)(1) provides that an application under this section shall contain:

A. full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

B. a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

C. a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

D. an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

E. such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

F. specimens of the labeling proposed to be used for such tobacco product; and

G. such other information relevant to the subject matter of the application as the Secretary may require.

Therefore, pursuant to the guidance provided by these statutory authorities and by Dr. Ashley's letter, I request that you provide the information described below:

1. A copy of your full Substantial Equivalence Report;

2. Full reports of all information, research, investigations, or data, published, in your possession, or otherwise known to, or which should reasonably be known to, Lorillard, concerning or showing the health risks or adverse health effects of the new Newport Non-Menthol Gold Box tobacco product and whether this product presents less risk than other tobacco products and of the predicate product;

3. A complete list of all the characteristics (defined as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product", including the

components, ingredients, additives, and properties), and of the principle or principles of operation of, the new Newport Non-Menthol Gold Box tobacco product and of the predicate product;

4. A complete list of all the differences in the characteristics (as defined in item 3) and principle(s) of operation between the new Newport Non-Menthol Gold Box tobacco product and the predicate product;

5. A complete report on the evidence and scientific rationale concerning why the differences in the characteristics (as defined in item 3) and principle(s) of operation between the new Newport Non-Menthol Gold Box tobacco product and of the predicate product do not raise different questions of public health;

6. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of each of the components, ingredients, additives, and properties contained in the new Newport Non-Menthol Gold Box tobacco product and of the predicate product;

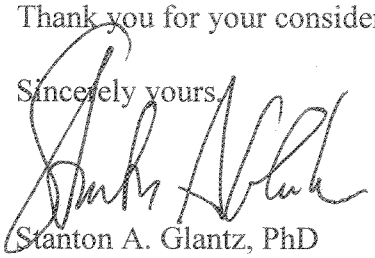
7. Any research or data you have in your possession or otherwise know of that demonstrates why any aspect of the new Newport Non-Menthol Gold Box tobacco product and its construction, components, ingredients, additives, constituents, including smoke constituents, and properties fully meets each of the tobacco product standards set out in section 907 and is appropriate for the protection of the public health; and

8. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of, the new Newport Non-Menthol Gold Box tobacco product.

Had you provided an adequate summary of health information containing detailed information regarding data concerning adverse health effects to FDA, this information would have been made available to the public by the Secretary within 30 days of the issuance of its substantial equivalence determination under the provisions of section 910(a)(4)(B). Therefore, I request that you provide this information to us within 30 days of receipt of this request.

Thank you for your consideration.

Sincerely yours,



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