



STANTON A. GLANTZ, PhD
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August 2, 2013

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

ATTN: Freedom of Information Act Officer

Re: Substantially Equivalent STN SE0003730

Dear FOIA Officer:

This is a request under the Freedom of Information Act.

I am affiliated with University of California San Francisco, an educational research institution, and this request is made to obtain information that will support a scholarly scientific purpose and not for a commercial use.

On June 25, 2013, the FDA announced its decision to authorize the marketing of Lorillard's new tobacco product, Newport Non-Menthol Gold Box 100s, through the substantial equivalence pathway. In its Substantially Equivalent Order Letter for Newport Non-Menthol Gold Box 100s (Submission Tracking Number (STN) SE0003730), FDA stated that to fulfill the provisions of section 910(a)(4) of the FD&C Act, Lorillard agreed that health information related to the new tobacco product "will be available upon request by any person."

Since FDA's letter instructed interested persons to request health information directly from Lorillard, on July 8, 2013, I wrote Lorillard Tobacco Company requesting that they provide me with specific documents and information related to its new product application for Newport Non-Menthol Gold Box 100s, STN SE0003730. (A copy of my letter is attached.)

In response to this request, Dr. Neil Wilcox, Lorillard's Senior Vice President and Chief Compliance Officer, replied by letter dated July 17, 2013 that summary health information was posted on Lorillard's web site, and that "for any other information, including a copy of the original SE reports submitted by Lorillard for these products, ***I recommend you contact FDA through a FOIA request*** [emphasis added]" (A copy of his letter is attached.)

Therefore, pursuant to 5 USC §552, 21 CFR §40, and sections 905, 907, and 910 of the FD&C Act, I request that copies of the following documents that Lorillard submitted to the FDA related to the STN SE0003730 application be provided to me:

1. The original Substantial Equivalence Reports submitted by Lorillard for STN SE0003730;
2. All information, research, investigations, or data reports submitted by 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. The 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 that Lorillard provided to the FDA. The 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;
4. The complete report submitted by Lorillard 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;
5. Any research or data submitted by Lorillard 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.
6. Any research or data submitted by Lorillard 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
7. All reports submitted by Lorillard that include full descriptions 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.

I request a waiver of all fees for this request. Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, is for a scientific scholarly purpose, and is not in my commercial interest. Specifically, disclosure of this information will contribute significantly to public understanding of how the FDA is evaluating substantial equivalence claims and how the tobacco industry is using the FDA’s substantial equivalence pathway to market new tobacco products. The disclosure of this information will be of significant value to the FDA and in the public interest by ensuring that the government’s process allows full understanding of the information that the tobacco companies provide to support claims of substantial equivalence. I have substantial knowledge and expertise in the field necessary to understand the information requested, and have significant capability and experience in disseminating such information to the public. If the FDA denies this request to waive the fees, I am willing to pay fees for this request up to a maximum of \$500. If you estimate that the fees will exceed this limit, please inform me first.

Disclosure of the requested information to me is in the public interest and will promote the objectives of the FDA and the Family Smoking Prevention and Tobacco Control Act.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Stanton A. Glantz". The signature is fluid and cursive, with the first name being the most prominent.

Stanton A. Glantz, PhD
Professor and Director

encl: Correspondence with Lorillard

cc: Mitch Zeller, JD, Director, Center for Tobacco Products
David Ashley MD, Director, Center for Tobacco Products Office of Science



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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

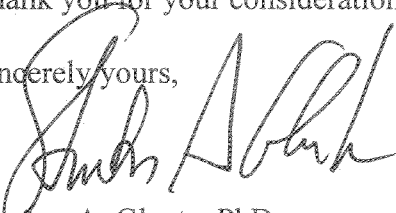
components, ingredients, additives, and properties), and of the principle or principles of operation of, the new Newport Non-Menthol Gold Box 100s tobacco product and of the predicate product;

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

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

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July 17, 2013

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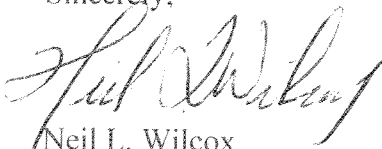
**Via Certified Mail
Return Receipt Requested**

Re: Submission Tracking Numbers (STNs) SE0003730 and SE0003731

Dear Dr. Glantz:

I have received your letters dated July 8, 2013 requesting, among other documents, a summary of any health information related to the tobacco products recently authorized by FDA for marketing (*viz.*, STN SE0003730 & STN 0003731). Please be advised that we have posted the health information documents on our web site (<http://www.lorillard.com/responsibility/new-products/>). For any other information, including a copy of the original SE reports submitted by Lorillard for these products, I recommend you contact FDA through a FOIA request.

Sincerely,


Neil L. Wilcox



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Office of the Executive Secretariat, OC
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Rockville, MD 20857

ATTN: Freedom of Information Act Officer

Re: Substantially Equivalent STN SE0003731

Dear FOIA Officer:

This is a request under the Freedom of Information Act.

I am affiliated with University of California San Francisco, an educational research institution, and this request is made to obtain information that will support a scholarly scientific purpose and not for a commercial use.

On June 25, 2013, the FDA announced its decision to authorize the marketing of Lorillard's new tobacco product, Newport Non-Menthol Gold Box through the substantial equivalence pathway. In its Substantially Equivalent Order Letter for Newport Non-Menthol Gold Box (Submission Tracking Number (STN) SE0003731), FDA stated that to fulfill the provisions of section 910(a)(4) of the FD&C Act, Lorillard agreed that health information related to the new tobacco product "will be available upon request by any person."

Since FDA's letter instructed interested persons to request health information directly from Lorillard, on July 8, 2013, I wrote Lorillard Tobacco Company requesting that they provide me with specific documents and information related to its new product application for Newport Non-Menthol Gold Box, STN SE0003731. (A copy of my letter is attached.)

In response to this request, Dr. Neil Wilcox, Lorillard's Senior Vice President and Chief Compliance Officer, replied by letter dated July 17, 2013 that summary health information was posted on Lorillard's web site, and that "for any other information, including a copy of the original SE reports submitted by Lorillard for these products, ***I recommend you contact FDA through a FOIA request*** [emphasis added]" (A copy of his letter is attached.)

Therefore, pursuant to 5 USC §552, 21 CFR §40, and sections 905, 907, and 910 of the FD&C Act, I request that copies of the following documents that Lorillard submitted to the FDA related to the STN SE0003731 application be provided to me:

1. The original Substantial Equivalence Reports submitted by Lorillard for STN SE0003731;
2. All information, research, investigations, or data reports submitted by 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. The 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 that Lorillard provided to the FDA. The 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;
4. The complete report submitted by Lorillard 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;
5. Any research or data submitted by Lorillard 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.
6. Any research or data submitted by Lorillard 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
7. All reports submitted by Lorillard that include full descriptions 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.

I request a waiver of all fees for this request. Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, is for a scientific scholarly purpose, and is not in my commercial interest. Specifically, disclosure of this information will contribute significantly to public understanding of how the FDA is evaluating substantial equivalence claims and how the tobacco industry is using the FDA’s substantial equivalence pathway to market new tobacco products. The disclosure of this information will be of significant value to the FDA and in the public interest by ensuring that the government’s process allows full understanding of the information that the tobacco companies provide to support claims of substantial equivalence. I have substantial knowledge and expertise in the field necessary to understand the information requested, and have significant capability and experience in disseminating such information to the public. If the FDA denies this request to waive the fees, I am willing to pay fees for this request up to a maximum of \$500. If you estimate that the fees will exceed this limit, please inform me first.

Disclosure of the requested information to me is in the public interest and will promote the objectives of the FDA and the Family Smoking Prevention and Tobacco Control Act.

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cc: Mitch Zeller, JD, Director, Center for Tobacco Products
David Ashley MD, Director, Center for Tobacco Products Office of Science



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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): 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

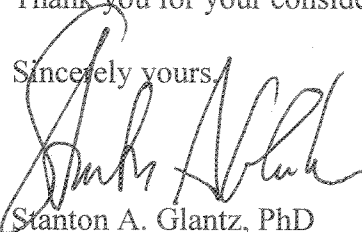
components, ingredients, additives, and properties), and of the principle or principles of operation of, the new Newport Non-Menthol Gold Box tobacco product and of the predicate product;

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,



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

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

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July 17, 2013

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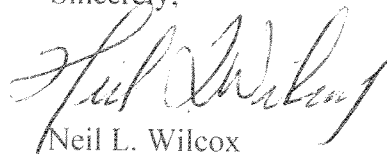
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Re: Submission Tracking Numbers (STNs) SE0003730 and SE0003731

Dear Dr. Glantz:

I have received your letters dated July 8, 2013 requesting, among other documents, a summary of any health information related to the tobacco products recently authorized by FDA for marketing (*viz.*, STN SE0003730 & STN 0003731). Please be advised that we have posted the health information documents on our web site (<http://www.lorillard.com/responsibility/new-products/>). For any other information, including a copy of the original SE reports submitted by Lorillard for these products, I recommend you contact FDA through a FOIA request.

Sincerely,



Neil L. Wilcox