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August 9, 2013

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

Via email and US mail

Dear Mitch,

We are writing to express our concerns about FDA's recent communications with Lorillard Tobacco Company regarding FDA's substantial equivalence determinations for Lorillard's Newport Non-Menthol Gold Box 100s (STN SE0003730) and Newport Non-Menthol Gold Box (STN SE0003731) new product applications. While the law gives explicit instructions about what health information related to new tobacco product submissions under section 905(j) must be made available upon request by any person, FDA failed to follow these dictates and instead offered Lorillard alternatives to fulfilling the provisions of the law. Following is a review of the problem and our suggestions for how FDA ought to proceed in future substantial equivalence submissions.

As a brief background, on June 25, 2013, the FDA announced its decision to authorize the marketing of Lorillard's new tobacco products, Newport Non-Menthol Gold Box 100s (STN SE0003730) and Newport Non-Menthol Gold Box (STN SE0003731) through the substantial equivalence pathway. In its Substantially Equivalent Order Letters for each of these products, 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," and that interested persons should request health information directly from Lorillard. On July 8, 2013, I wrote to Lorillard requesting that they provide me with specific documents and information related to its new product applications for each of these products. In response to these requests, 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." On August 2, 2013, we submitted FOIA requests to FDA to obtain this information.

This burdensome process could have been avoided had FDA's original SE letters to Lorillard more accurately tracked the plain language of the law. Moreover, FDA should not set a bad precedent that interferes with the clear intent of the law, which is to make the SE pathway transparent.

FDA's SE letters to Lorillard contained the following language:

> To fulfill the provisions of section 910(a)(4) of the FD&C Act, you opted not to provide an adequate summary of any health information related to the new tobacco product with your application, ***but agreed*** that such information will be available upon request by any person. Consistent with the

requirements of Section 910(a)(4) ***you may wish to consider providing the following*** when information is requested:

> A. A copy of your SE Report, ***redacted only to the extent necessary to exclude research subject identifiers***, and trade secret and confidential commercial information as defined in 21 CFR §20.61 and 20.63 and;
> B. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product ***or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."***

Alternatively, you may provide the following when information is requested:

> A. Description of the new tobacco product;
> B. Description of the predicate tobacco product;
> C. List of all differences in characteristics between the predicate and new tobacco products;
> D. ***Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health***; and
> E. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product ***or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]."***

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

This section of the FDA's letter to Lorillard correctly notes that Section 910(a)(4) of the Act governs the health information submitted; however, it does not appear to accurately reflect either the word or the intent of the law. Following is a description of some of our concerns.

As the highlighted sections above demonstrate, FDA suggests from its language that the industry has options in how "it may wish to consider" providing the information that is, in fact, required by law to be submitted and disclosed.

Section 910(a)(4)(A) says:

> **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 [i.e., the tobacco company wishing to introduce a new product, or Lorillard in this case] ***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***.

In contrast to the FDA's weak language, the law states that the company ***shall provide*** this information ***or state*** that it will be made available upon request. In addition, the FDA's letter says that Lorillard "agreed" to provide this information, suggesting that some sort of negotiating with the FDA was permitted or encouraged, and then says that Lorillard "may wish to consider providing" A or B, or alternatively, they "may provide" A, B, C, D, and E. When the word "shall" is used in a law or regulation, it expresses what is ***mandatory***, not what the subject of the law may "wish to consider" doing. However, FDA's soft suggestion that Lorillard "may wish to consider providing" information seems to disregard what the law dictates.

The explicit intention of Congress when it enacted the Family Smoking Prevention and Tobacco Control Act was to increase transparency even beyond the transparency demanded by other sections of the FD&C Act. Section 3(6) states that one of the purposes of this division is:

> In order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products.

And section 3(3) authorizes FDA:

> … to set national standards controlling the manufacture of tobacco products and the identity, ***public disclosure,*** and amount of ingredients used in such products.

The law very specifically states in section 910(a)(4)(B) what information is ***required*** as part of a submission (i.e., the company "***shall provide***"), and does not state that this information is recommended or suggested (in which case they would have used language like "should provide").

> Indeed, subsection (B) of Section 910(a)(4) is entitled, "**Required Information**" and states:
>
> **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.

The "summary of health information" that Lorillard made available on its website followed the exact format of the "alternative information" that FDA said Lorillard "may provide". They provided minimum information under each of the five subsections (A-E above). This information is not an "adequate summary" under the meaning of Section 910(a)(4)(B) because it does not contain the required "detailed information regarding data concerning adverse health effects." In fact, it contains no data at all. Rather, Lorillard's response contains descriptions, pre-digested analyses, and the conclusion that "the New Tobacco Product does not raise different questions of public health from the Predicate," with no supporting data or detailed documentation as plainly required by the language of the law.

For example, in section D of Lorillard's response on the "summary of the Evidence and Scientific Rational Concerning Why the Differences in Characteristics Do Not Rise Different Questions of Public Health," Lorillard states that it made comparisons of the characteristics (including "tar", nicotine and carbon monoxide smoke yields, design, materials, ingredients, eating source and composition) between the new product and the predicate, and that these comparisons yielded no different questions of public health. However, Lorillard does not provide the raw data on what those characteristics are, despite the fact that section 910(b)(1)(B) requires that an application ***shall contain***:

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

By failing to use the mandatory language required by the law, unless there is information that FDA did not make available, it would appear that FDA's SE letter gave Lorillard an opening to provide a general statement that there are no differences in adverse health effects, instead of requiring Lorillard to provide "detailed information regarding data" on adverse health effects as required by section 910(a)(4)(B) and section 910(b)(1)(B).

Further, there is no place in the law that suggests that the tobacco company can get away with not providing research data by making a statement that it "does not have or know of any research or data regarding any adverse health effects". Rather, Section 910(b)(1)(A) provides that an SE application ***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;

Based on the documents FDA made public, it appears that FDA not only allowed Lorillard to get away with a statement, but actually invited them to make a statement, saying that "Lorillard does not have or know of any research or data regarding adverse health effects…." Certainly Lorillard conducted or should have conducted their own studies into the health risks of their tobacco product, as this was a requirement for the SE application. And if they did not have or know of a report, they "reasonably should have known" of such reports, or the applications should have been denied. The statute clearly puts the burden on the applicant to proactively demonstrate that a change will not have "adverse health effects," and FDA should require each applicant to both provide that evidence and state to FDA that it believes it has conducted sufficient research to demonstrate that the change will have no adverse health effects.

Moreover, FDA did not appear to demand, and Lorillard's response did not address, the key purpose of the required submission regarding the protection of the public health which is described under the "Basis for Finding" substantial equivalence section. Section 910(c)(4) provides:

> **Basis for Finding.** For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –
>
> > **A.** the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
> > **B**. the increased or decreased likelihood that those who do not sue tobacco products will start using such products.

While Lorillard makes the brief statement that they know of no adverse health effects, they do not specifically address the increased or decreased likelihood that existing users will stop smoking these products, or the increased or decreased likelihood that non-users or former users will start using or return to using these products.

FDA should have demanded that Lorillard follow the dictates of Section 910(a)(4)(A) and provide an ***adequate*** summary as defined by Section 910(a)(4)(B) to include "detailed information regarding data concerning adverse health effects." As guidance for what is considered "adequate" and "detailed information," FDA should have looked at Section 910(B)(1) which lists in subsections A through G the required contents of an SE application. Since this information is what the statute required FDA to review to make its determination, this is the information that should be made available upon request by any person.

Section 910(a)(4)(B) ***requires FDA*** (not Lorillard) to make available to the public the "detailed information regarding data concerning adverse health effects" within 30 days of the issuance of its SE determination. Since FDA's SE letter was dated June 25, 2013, FDA should have made this detailed information available by July 25, 2013.

For the reasons outlined above, based on the information that has been provided to us, the way that the FDA handled its interaction with Lorillard in these substantial equivalence applications raises several questions about why the FDA took such a "soft" approach in dealing with these substantial equivalence applications which raise important issues of policy and precedent for future substantial equivalence applications:

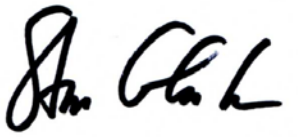
- In light of the strong disclosure requirements in Section 910(a)(4)(A), why do your letters say that Lorillard "agreed" to provide information to the public, suggesting that some sort of negotiating with the

FDA was permitted or encouraged, as well as saying that Lorillard "may wish to consider providing" A or B, or alternatively, they "may provide" A, B, C, D, and E?

- Why did FDA use optional, rather than mandatory, language in its letters to Lorillard?
- Why did FDA invite Lorillard to make a statement, saying that "Lorillard does not have or know of any research or data regarding adverse health effects…." when it is not delineated by the law?
- Did FDA require Lorillard to submit the information required by Section 910(B)(1), and did it rely on this information to make its SE determination? If not, why not, and what did FDA rely on?

So that we can better understand the FDA's decision-making process, we would be grateful if you would tell us whether or not you agree with our interpretation of the law, including the specific questions listed above.

Thank you for your consideration.



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