DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

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Stanton Glantz, Ph.D.
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Director, Center for Tobacco Control Research and Education
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San Francisco, CA 94143-1390

Re: Submission Tracking Number (STN): TC0000783

Dear Dr. Glantz:

We received your August 9 letter regarding the Food and Drug Administration's (FDA) communication with Lorillard Tobacco Company concerning the Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 910(a)(4)'s health information requirement. We appreciate the concerns you have expressed and have addressed them below.

We take seriously the statutory requirement that manufacturers provide health information in the context of a substantial equivalence (SE) report. As you note, Section 910(a)(4)(A) of the FD&C Act requires a person submitting a 905(j) report to provide an adequate summary of health information related to the tobacco product or state that such information will be made available upon request. Section 910(a)(4)(B) requires that any summary shall contain detailed information regarding data concerning adverse health effects and be made available to the public by the Secretary within 30 days of a determination that the product is substantially equivalent to another tobacco product. Section 910(a)(4) does not define with specificity what must be included as health information. Accordingly, CTP identified potential information that Lorillard could provide to requestors to fulfill the provisions of Section 910(a)(4). As noted in FDA's letter to Lorillard, there may be other ways to satisfy the requirements of Section 910(a)(4).

Under the statute, a manufacturer has the option to comply with its obligation to provide health information either by 1) providing an adequate summary as part of its 905(j) submission, or 2) stating in its application that it will make such health information available upon request by any person. If a manufacturer chooses to provide an adequate summary, FDA will make the summary publicly available within 30 days of the issuance of a substantial equivalence order per Section 910(a)(4)(B). However, if the manufacturer chooses to state that such health information is available upon request, the manufacturer becomes responsible for making the information available when requested by any person. The decision whether to provide the summary as part of the 905(j) submission or include a statement that the manufacturer will provide such information upon request is a manufacturer's to make. In this case, Lorillard chose to include such a statement in its submission.

We would also like to take the opportunity to address your concerns regarding Lorillard's response in relation to Sections 910(b) and (c)(4). These sections relate directly to a premarket tobacco application (PMTA) submission, not to a SE submission. A PMTA is required when a new tobacco product is neither SE nor exempt from the requirement to obtain a SE determination pursuant to a regulation issued under Section 905(j)(3). In such cases, a manufacturer must submit a PMTA under Section 910(b) of the FD&C Act and receive a marketing authorization order under Section 910(c)(1)(A)(i) prior to marketing the product.

Section 910(b)(1) sets forth the required contents of a PMTA application. Where a manufacturer has submitted a PMTA, Section 910(c)(4) details the basis for FDA to make a finding as to whether or not the marketing of a new tobacco product is "appropriate for the protection of the public health." Because Lorillard did not submit a PMTA, Sections 910(b)(1) and 910(c)(4) do not govern this submission.

Finally, we want you to know that we take the commitment to transparency very seriously. Please visit http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm#2 for the information FDA has made publicly available regarding substantial equivalence and SE decisions. Please note that FDA cannot publicly disclose any information that is trade secret or commercial confidential information. FDA has been working to provide as much information to the public as it can within applicable legal constraints. We note, regarding instances where we find that a product is not substantially equivalent, that we have gone to great lengths to release information about our reasoning. We will continue this commitment to transparency in all of our decision-making.

Thank you, again, for contacting us concerning this matter. If you have additional questions regarding this matter please call 1-800 CTP-1373 or email your questions to ASKCTP@fda.hhs.gov.

Sincerely,

Mitchell Zeller

Mitchell Zeller
Director, Center for Tobacco Products