DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

DEC 0 2 2011

Ronald S. Milstein
Senior Vice President,
Legal and External Affairs,
General Counsel and Secretary
Lorillard Tobacco Company
714 Green Valley Road
Greensboro, North Carolina 27408

Dear Mr. Milstein:

This letter responds to your request for correction under the Information Quality Act (IQA),[1] dated March 16, 2011 (Request for Correction). Your Request for Correction concerns Table 1.1 and several White Papers that were primarily prepared by staff from the Department of Health and Human Services (i.e., the Food and Drug Administration (FDA), the National Institutes of Health, and the Centers for Disease Control and Prevention) and were provided as background information to members of FDA's Tobacco Products Scientific Advisory Committee (TPSAC).

Your Request for Correction contains two primary contentions. First, that the "White Papers" (brief summaries of scientific, peer-reviewed literature), which had not been subject to peer-review prior to providing them to TPSAC, "suffer from a lack of objectivity, contain misleading analyses of pertinent data, and often fail to report on highly relevant findings contained in the articles discussed" and thus do not meet IQA standards. Second, that Table 1.1, although updated, does not "meet the requirements for quality, utility, objectivity, and integrity demanded by the IQA."

In your Request for Correction, you are seeking correction of the White Papers and an updated Table 1.1. In addition, you request that "these corrections and any other corrections made in the future be announced conspicuously and on the record." In particular, you state that "FDA must prominently denote on its website that the original materials posted by FDA were inconsistent with the IQA and, as a result, have been corrected," that this be "announced during the next TPSAC meeting," and that "FDA should not consider or rely upon those portions of the report."

Specifically you refer to Table 1.1 and the following White Papers:

- Marketing of menthol cigarettes and consumer perceptions
- Sensory properties of menthol and smoking topography
- Menthol and initiation of cigarette smoking
- Menthol cigarette smoking and nicotine dependence
- Menthol cigarettes and smoking cessation behavior

[1] Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554 (Appendix C), 114 Stat. 2763A-153.

- The health effects of menthol cigarettes as compared to non-menthol cigarettes
- Epidemiology of menthol cigarette use in the United States[2]

All these documents were provided to TPSAC as background information and are available on FDA's website.[3]

For the reasons described below, FDA does not agree that your requested corrections are necessary. The referenced materials as presented partway through a lengthy TPSAC process to examine the public health impact of menthol in cigarettes were marked on FDA's website with disclaimers stating that "[t]he findings and conclusions in these reports have not been formally disseminated by FDA and should not be construed to represent any agency determination or policy." As these documents did not represent official agency position, they are not considered to be agency disseminations subject to the guidelines that the Office of Management and Budget (OMB), HHS, and FDA issued to implement the IQA (collectively, the IQA Guidelines).[4]

I. Background

It is useful to provide some background about the presentations to TPSAC that are the basis for your Request for Correction. Section 907(e) of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), required FDA, immediately upon the establishment of TPSAC, to refer to TPSAC for a report and recommendations, the issue of the impact of the use of menthol in cigarettes on the public health.

TPSAC is an advisory committee established in accordance with the Federal Advisory Committee Act and the Tobacco Control Act.[5] As such, TPSAC provides independent advice and recommendations to FDA. Members of TPSAC do not participate in FDA decision-making and TPSAC is not responsible for any final agency actions. *See* 21 CFR 14.5(b) ("The Commissioner [of Food and Drugs] has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.")

FDA assisted TPSAC by compiling available peer-reviewed studies on menthol and briefly summarizing them. Some of these summaries were initially presented at the March 30-31, 2010, TPSAC meeting. These summaries were later written in the form of White Papers, which were provided to TPSAC as background information for the October 7, 2010, TPSAC Meeting. The White Paper authors did not endorse any of the underlying studies, or purport to offer a detailed assessment of the published studies or of potential error sources. The White Papers all noted that

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[2] None of the authors on this White Paper are FDA staff or on detail to the FDA.

[3] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180903.htm.

[4] For OMB guidelines, see 67 Fed. Reg. 8452 (2002). FDA-specific guidelines are available on the Internet at http://www.aspe.hhs.gov/infoquality/guidelines/fda.shtml and are part of the Department of Health and Human Services Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (HHS Guidelines), which are available on the Internet at http://www.aspe.hhs.gov/infoquality/Guidelines/part1.shtml.

[5] The Tobacco Control Act provides an exemption from compliance with Section 14 of the Federal Advisory Committee Act relating to renewal of an Advisory Committee (21 USC 387q(d)(3)).

they had not yet been peer-reviewed.[6] In addition, the summary of the briefing package for the October 7, 2010, meeting had a disclaimer regarding White Papers prepared by FDA staff. The disclaimer stated that "[t]he findings and conclusions in these reports have not been formally disseminated by FDA and should not be construed to represent any agency determination or policy." At the October 7, 2010, TPSAC meeting itself, there was a brief presentation on the main differences between the March 30-31, 2010, presentations and the White Papers provided in the background package. The differences were due to the addition of multiple source documents that were suggested by the public, TPSAC, and/or industry, and which resulted in some minor wording changes.

Two tables were made available as part of the background package for the November 18, 2010, TPSAC meeting: a table of evidence from peer-reviewed journals that was also included in the White Papers (Table 1.1) and a table containing additional, potentially relevant references for the TPSAC writing groups' review, but that were not included in the White Papers (Table 1.2). In addition, FDA staff prepared two documents. One document contained a bibliography of menthol references received from the public prior to September 1, 2010, that were not included in the White Papers, and an explanation as to why each reference was not considered relevant for a White Paper. The other document listed the menthol publications received from the public from September 1 through October 31, 2010, with notations indicating which publications were not included in either Tables 1.1 or 1.2. Both Tables 1.1 and 1.2 contained similar information, including author name(s), article title, year published, funding sources, type of study, subject description (including special population(s)), sample size (N), and author's conclusion(s) related to menthol. FDA made it clear that Table 1.1 was a working table that should be used as a tool for TPSAC to develop their own tables, as stated during the November 18, 2010, TPSAC meeting:

- "There was a working table of articles in the white papers as a tool for the writing work groups as they developed their data tables. This was designed to be a working document that the writing groups could use as they were preparing their data tables, and they could fill in, edit, add, delete, change, however they wanted." (11/18/2010 transcript, page 23, lines 9-20)
- "The committee members will be reviewing the articles themselves and creating their own data tables for the report. And again, they can either edit these or make their own as they see fit." (11/18/2010 transcript, page 24, lines 4-8)

Neither the White Papers nor Table 1.1 purported to provide the agency's views or conclusions with respect to the science of menthol or attempted to guide TPSAC to a particular conclusion. Instead, they provided brief summaries of some findings reported in peer-reviewed studies, in order to aid TPSAC in commencing its work. The table included a column headed "Selected Authors' Results/Conclusion(s) related to menthol", and the following footnote was included on every page of the updated version of Table 1.1, "Note: these statements are taken directly from articles and may not include all relevant results/conclusions. Please read the entire article." Full copies of articles referenced in the White Papers and Table 1.1 were provided to the TPSAC writing group members, with non-writing group members receiving them upon request.

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[6] Since the time they were presented to TPSAC, the White Papers have been published in a peer reviewed journal. Mentholated cigarettes and public health, *Tobacco Induced Diseases* 9 (suppl. 1): I1, S1-S7. http://www.tobaccoinduceddiseases.com/supplements/9/S1.

As part of the process used for developing TPSAC's Menthol Report, members of the committee as well as members of the public were asked to critically evaluate the scientific articles described in the White Papers and Table 1.1 and suggest additional studies for TPSAC's consideration. In the announcement for each TPSAC meeting, information was provided on how any member of the public could submit written materials to TPSAC or make an oral presentation at the open public hearing portion of the TPSAC meeting. As you note in your Request for Correction, your company submitted materials to TPSAC providing additional information and explaining why you thought the White Papers and Table 1.1 were inadequate. These documents were provided to TPSAC members and made available on FDA's website. Comments and suggestions for edits and/or recommendations were considered. Regarding the White Papers, FDA provided a separate document explaining why several hundred submitted/suggested articles were not included and that document was part of the background information for the November 18, 2010, TPSAC meeting (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM233424.pdf). After consent of the TPSAC chair, studies that were suggested were shared in full with the TPSAC members. Additionally, following comments and feedback, Table 1.1 was updated and included as background information for the January 10-11, 2011, TPSAC meeting. The web page for the background information displays the following disclaimer: "The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee."

The Menthol Report, like all advisory committee outcomes, is advice to FDA, prepared independently by TPSAC. *See* 21 C.F.R. § 14.5(a) (stating that the purpose of an advisory committee is to provide advice and recommendations to the Commissioner). FDA will consider the Menthol Report and other information available to the agency.

II. Applicability of IQA and Related Guidelines

a. FDA's use of a disclaimer was appropriate

In your Request for Correction, you assert that FDA "attempts to limit the definition of 'dissemination'" by using a disclaimer (Request for Correction at 11), and that "FDA-initiated distribution of information on its website will be considered a dissemination of information subject to the Data Quality Act, regardless of FDA's characterization of the information" (Id. at 12).

We disagree with your characterization of the disclaimer and your conclusion with respect to the applicability of the IQA. As discussed above, the purpose of the disclaimer was to make clear to TPSAC and the public the summary nature of the White Papers and Table 1.1 and the fact that these documents had been created only to describe the peer-reviewed literature that they briefly discussed and not to state an official agency position. In other words, these documents were designed to be tools for TPSAC, rather than scientific conclusions of the agency. They did not state or purport to state the agency's views regarding the studies to which they referred, or to use those studies in support of any agency position. The documents were summaries and as such, could not include all of the information in the peer-reviewed articles being summarized. The documents were provided to TPSAC partway through a year-long process, during which TPSAC was to independently review all of the available data and during which TPSAC members, industry representatives, and the public

were invited to comment and criticize, and suggest additional studies and information. The documents were also provided publicly on FDA's web site because they were provided to TPSAC members as part of a background package. Consistent with FACA and our transparency goals, FDA's practice is to post background packages for all advisory committee meetings. It was clear from statements made by FDA staff at the meeting and from the nature of the documents themselves that these were not agency views or endorsements.

The purpose of the disclaimer was to prevent members of TPSAC or the public from assuming that the findings and conclusions in the White Papers and Table 1.1 represented agency conclusions. In other words, the agency's goal in including a disclaimer was to ensure that the public understood that these were working documents which did not represent the official position of the agency with respect to the scientific articles that they summarized. Thus, we conclude that the disclaimer was appropriate and that your requested corrective actions are not necessary.

b. The nature of the White Papers and Table 1.1 as well as the context in which they were presented by FDA, confirms that they did not violate any IQA guidelines

In your Request for Correction, you claim that the documents that are the subject of your request violate the IQA and the IQA Guidelines because the information presented in those documents is not "objective" or "useful" (Request for Correction at 11).

We disagree that the White Papers and Table 1.1 violate the IQA and related guidelines. As discussed above, the nature and purpose of the documents were made clear and FDA's use of a disclaimer was appropriate. As you note, information must be presented within context. The context of these documents was such that their primary intended audience was an advisory committee subject to the Federal Advisory Committee Act (FACA). Because the committee was asked to consider a large amount of data and information in a relatively short amount of time, summaries of the existing literature were a useful starting point for TPSAC. Because TPSAC is subject to FACA, the agency also made these documents available to the public, even though they were not primarily meant to be used by the general public.

The disclaimer was not the only means by which FDA ensured that these documents were not taken as representing agency views or position. Throughout the process, FDA encouraged TPSAC members to review the articles in their entirety rather than rely solely on FDA's summaries. In addition, FDA included in its compilations both positive and negative findings of publicly-available peer-reviewed studies. FDA did not interpret the data but rather presented the findings from these studies. While FDA did make minor wording changes, deletions, and additions to the documents based on comments from the public and industry, this did not cause these documents to become representative of agency views or position.

III. Conclusion

Your Request for Correction asks for two separate corrective actions. First, you request FDA "prominently denote on its website that the original materials posted by FDA were inconsistent with the IQA and, as a result, have been corrected." Second, you request that "FDA should also announce these same matters during the next TPSAC meeting."

When placed in appropriate context, as discussed above, the White Papers and Table 1.1 are not subject to the IQA. Further, FDA has shown that it has been thoughtful and inclusive in evaluating recommendations for edits or additions to the White Papers and Table 1.1 that it received from the public, industry, and TPSAC members. Therefore, we do not believe that any additional action is needed.

Going forward, if you have additional concerns about the quality of data being considered by TPSAC, we encourage you to again use FDA's existing procedures to raise these concerns so TPSAC will have an opportunity to consider them in a timely manner. These procedures include submitting comments to the public docket or speaking at an open public hearing portion of an advisory committee meeting.

We assure you that as the agency continues to implement the Tobacco Control Act, we will apply, at the appropriate juncture, any applicable provision of the IQA Guidelines.

Thank you again for your letter. If you do not agree with this decision on your request, you may send a Request for Reconsideration within 30 days of receipt of this decision. Your Request for Reconsideration should be designated as "Information Quality Appeal" and should include a copy of your original request as well as this decision. Your appeal should state the reasons why you believe this response to your Request for Correction is inadequate. The request may be sent electronically to Ombuds@OC.FDA.gov or by mail to:

FDA Ombudsman
Office of the Commissioner
10903 New Hampshire Avenue
White Oak Building 32, room 4260
Silver Spring, Maryland 20993

Sincerely,

/S/

David L. Ashley, Ph.D.
Director, Office of Science
Center for Tobacco Products