Lorillard, Inc.

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Laurie Lenkel, R.Ph., J.D., Director
FDA Ombudsman
Office of the Commissioner
10903 New Hampshire Avenue
White Oak Building 32, room 4260
Silver Spring, Maryland 20993

Re: Information Quality Appeal

Dear Ms. Lenkel:

Lorillard Tobacco Company submits this appeal and request for reconsideration requesting that FDA and the Center for Tobacco Products (CTP) correct certain data and information that was disseminated by FDA to the public and to the members of the Tobacco Products Scientific Advisory Committee (TPSAC) related to the scientific record on the use of menthol in cigarettes. This petition is submitted pursuant to the Data Quality Act (DQA) (also known as the Information Quality Act (IQA)), Pub. L. No. 106-554, tit. V, § 515, 114 Stat. 2763, 2763A-153, codified at 44 U.S.C. § 3516 note (2000), and implementing Office of Management and Budget (OMB), Health and Human Services (HHS), and FDA Guidelines.

On March 16, 2011, Lorillard submitted the enclosed request for correction to the Center for Tobacco Products. Specifically, Lorillard requested corrections to (1) FDA "White Papers" purporting to present the scientific literature on various issues related to menthol released before the October 7, 2010 TPSAC meeting, and (2) Table 1.1, summarizing conclusions from articles on menthol published in peer-reviewed journals, prior to the November 18, 2010 TPSAC meeting. Although FDA corrected some of the errors to Table 1.1 after receiving two emails from TPSAC industry representative Dr. Dan Heck, many problems remain. Neither the White Papers nor Table 1.1 meets the requirements for quality, utility, objectivity, and integrity demanded by the DQA.

Almost ten months later, FDA replied with the enclosed December 2, 2011 letter that Lorillard received on December 5, 2011. In its response, FDA fails to provide <u>any</u> substantive response to the concerns and issues raised by Lorillard's petition. Instead, FDA merely stated that "the White Papers and Table 1.1 are not subject to the [Data Quality

Act]."[1] FDA argued that its use of the disclaimer, "[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," transformed the documents so that they "did not represent official agency position" and "are not considered to be agency determinations subject to the [DQA Guidelines]."[2] The agency further argued that "[t]he nature of the White Papers and Table 1.1 as well as the context in which they were presented to FDA, confirms that they did not violate any IQA Guidelines."[3] For these reasons, FDA determined that the corrective actions sought by Lorillard were not necessary.[4]

Because these documents continue to be available and FDA's response fails to provide an adequate justification, Lorillard submits this request for reconsideration. As explained further below, it is clear that these documents are subject to, and must comply with, the DQA, despite FDA's claims to the contrary. FDA's limited use of its disclaimer does not cure the DQA defects, and the documents fail to meet the DQA's standards of "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency."[5] Lorillard requests that FDA correct the papers as proposed in the enclosed exhibits, prominently denote on its website that the original materials posted by FDA were inconsistent with the DQA and accordingly corrected, and announce the corrections to TPSAC members.

Discussion

1. The DQA does not distinguish between formal and informal disseminations.

Despite the agency's claims to the contrary, the DQA applies to the documents at issue. Although FDA attempts to limit the application of the Data Quality Act to the White Papers and Table 1.1 by its disclaimer stating that "the information in these materials is not a formal dissemination of information by FDA," the DQA does not distinguish between any type of "formal" or informal dissemination of information, nor does the DQA permit an agency to simply exempt certain documents from the statute by use of a disclaimer. OMB and HHS Guidelines define dissemination as "agency initiated or sponsored distribution of

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[1] Letter from David L. Ashley, Director, Office of Science, Center for Tobacco Products to Ronald Milstein, Senior Vice President, Legal and External Affairs, General Counsel and Secretary, Lorillard Tobacco Company (Dec. 2, 2011), at 6 (hereinafter FDA Response Letter).

[2] FDA Response Letter, at 2.

[3] *Id.* at 5.

[4] *Id.* at 2.

[5] 44 U.S.C. § 3516 note.

information to the public."[6] Thus all documents released or disseminated by the agency -- save for limited exceptions that do not apply here -- must comply with the DQA, regardless of their manner of dissemination. Thus, FDA-initiated distribution of information on its website will be considered a dissemination of information subject to the DQA, regardless of FDA's characterization of the information.

As FDA and other federal agencies have made clear, disclaimers are a disfavored or impermissible way to correct existing defects. In its guidance on presenting risk information in prescription drug and medical device promotion, FDA provides that it is important to consider the "net impression" of the piece rather than individual claims or sentences.[7] Similarly, FTC's Guide Concerning the Use of Endorsements and Testimonials in Advertising states that disclosures such as "results not typical" do not "adequately reduce[] the communication that the experiences depicted are generally representative" and that such disclaimers should not be used for otherwise improper claims.[8] Thus, it is improper for the agency to assert that its use of a disclaimer here makes up for its otherwise deficient documents.

Even if the disclaimer were appropriate, FDA overstates its use of the disclaimer. The disclaimer does not appear on the materials at issue. Although the disclaimer does appear on the webpage providing the briefing information, it does not appear on the actual White Papers or Table 1.1.[9] Anyone accessing these materials could easily overlook the agency's disclaimer and conclude that these materials represented FDA opinion. Further, printing the materials completely divorces them of any connection to the disclaimer.

2. The relevant materials undoubtedly were disseminated under the DQA.

The White Papers and Table 1.1 are both agency "initiated" distribution of information to the public that are, thus, dissemination of information pursuant to the DQA. Although section

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[6] 67 Fed. Reg. at 8460, incorporated into HHS Guidelines at Part I(D)(2)(h).

[7] FDA, Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009) at 4, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf.

[8] FTC, Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.2 n.1, http://www.ftc.gov/os/2009/10/091005revisedendorsementguides.pdf.

[9] The White Papers are marked only "[n]ot yet peer-reviewed – submitted for publication" on the first page. After industry representative Dan Heck repeatedly contacted FDA about problems with Table 1.1, FDA added the note "these statements are taken directly from articles and may not include all relevant results/conclusions. Please read the entire article."

907(e) of the Tobacco Control Act required FDA to refer to TPSAC for a report and recommendations on the issue of the impact of the use of menthol in cigarettes on the public health after the Committee's establishment, FDA was not required to generate materials to assist the advisory committee. Instead, FDA took it upon itself to "assist[] TPSAC by compiling available peer-reviewed studies on menthol and briefly summarizing them."[10] Accordingly, the resulting materials were agency initiated disseminations.

If FDA wished to assist TPSAC, it easily could have provided assistance in a way that did not interject its views and opinions. For example, as an alternative to the White Papers, FDA could have provided the relevant papers without summary or comment. In addition, as an alternative to Table 1.1, FDA could have compiled a list of the relevant papers that did not summarize the authors' results or conclusions. In its December 2, 2011 response, FDA states that "[n]either 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."[11] However, in selecting which articles to include—and which to exclude—the agency was making and communicating substantive judgments about the scientific literature. Similarly, when condensing articles with thousands of words into one to two sentence conclusions, the agency's views are inevitably transmitted. This was even more unavoidable when FDA synthesized dozens of reports into a single White Paper. Further, FDA cannot claim that its views were not transmitted because it excerpted sentences directly from the articles and included the disclaimer that the statements were taken directly from the articles. FDA exercised discretion in its decision to highlight select sentences and remove them from any surrounding context. The resulting materials unquestionably conveyed the agency's views and conclusions.

FDA characterizes the White Papers and Table 1.1 as being provided as "background information" as a part of the "briefing package" for TPSAC.[12] This, however, is inconsistent with how FDA used the materials. As FDA acknowledges in its response letter, the White Papers were published in a peer reviewed journal after they were presented to TSPAC.[13] The journal states that publication of the papers "has been supported by the Center for Tobacco Products,

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[10] FDA Response Letter, at 2.

[11] *Id.* at 3.

[12] *See id.* at 2 ("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."); *id.* at 3 ("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).").

[13] *See id.* at 3 n.6.

Food and Drug Administration."[14] Publishing these papers to communicate them to the scientific community and public at large does not fit with FDA's stated purpose of materials that were intended only as background material for TPSAC. This is particularly true, as the papers were published after FDA received the TPSAC report on menthol when the Committee presumably had no further need of the papers.

The fact that FDA has made corrections to Table 1.1 further demonstrates that the document reflects agency opinion. Although FDA characterized the changes it made as "minor wording changes, deletions, and additions to the documents" that "did not cause these documents to become representative of agency views or positions,"[15] this is not the case. In fact, FDA made substantive changes related to the authors' conclusions. These changes, made after the TPSAC meeting, show FDA's control over the materials and its effort to put forth credible information. FDA's concern about disseminating accurate materials further demonstrates that these materials were disseminated for use beyond the TPSAC, and are thus subject to the DQA.

3. The White Papers and Table 1.1 are subject to the DQA and must be corrected to meet its standard.

Accordingly, the information contained in the White Papers and Table 1.1 is subject to the DQA. As discussed in the enclosed March 16, 2011 letter, the information violates the DQA because it is not "objective" or "useful," and FDA has made no substantive argument to the contrary. FDA's response to Lorillard fails to make any attempt to defend its documents with respect to Lorillard's substantive concerns. The information presented in the White Papers and Table 1.1 is not objective because it is replete with errors and omissions and is not useful because it is inaccurate and incomplete.

In Exhibit A, which is a copy of the briefing materials submitted by Lorillard in advance of the March 2, 2011 TPSAC meeting, we address many of the inaccuracies and distortions present in the White Papers. In Exhibit B, we present examples of conspicuous errors and omissions in the updated Table 1.1 and propose recommendations for correcting these errors and omissions. These suggestions were included in Dr. Dan Heck's November 17. 2010 and December 4, 2010 emails to FDA, but FDA has not addressed all of these issues.

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[14] *Mentholated cigarettes and public health*, 9 TOBACCO INDUCED DISEASES Supp. 1 (May 2011), http://www.tobaccoinduceddiseases.com/content/pdf/1617-9625-9-S1-I1.pdf

[15] FDA Response Letter, at 5.

In short, far from providing objective, useful and unbiased information about menthol as described in the scientific literature, the White Papers and Table 1.1 are inaccurate, misleading, and incomplete. This information violates the Data Quality Act and implementing Guidelines. For all of the reasons presented above and stated in our previous March 16, 2011 letter, we request that FDA correct the White Papers as proposed in Exhibit A so that these papers will similarly comply with the Act. In addition, we request that FDA correct updated Table 1.1 as proposed in Exhibit B so that Table 1.1 will comply with the requirements of the Data Quality Act.

Because FDA documents are relied upon by the public, TPSAC, and others, it is critical that FDA fully and effectively correct these documents. FDA should ensure that its correction provides adequate notice to TPSAC and the public. FDA must prominently denote on its website that the original materials posted by FDA were inconsistent with the DQA and, as a result, have been corrected. FDA should also announce these same matters to TPSAC, either during the next TPSAC meeting or a more expedient public method. To the extent that the TPSAC report on menthol incorporates the inaccurate, misleading and incomplete research or conclusions described in the White Papers or Table 1.1, FDA should not consider or rely upon those portions of the report.

Lorillard views this denial of correction as the latest agency misstep concerning a pervasive problem with the information disseminated by FDA in connection with the proceedings of TPSAC. The obligation for FDA to provide complete and accurate reviews of the scientific literature is obvious and mandated by the DQA. We are hopeful that FDA will take this opportunity to make the necessary corrections so that the information disseminated by FDA fairly, completely and accurately represents the scientific evidence.

Lorillard wishes to assist the FDA in achieving its stated objective of conducting a sound, science-based, inclusive and objective evaluation of scientific matters relating to the regulation of tobacco products. We appreciate the agency's attention to this important matter.

Sincerely,

/S/

Ronald Milstein
Senior Vice President, Legal and External Affairs,
General Counsel and Secretary

Enclosures