

MAY 11 2011

Jim J. Tozzi
Center for Regulatory Effectiveness
1601 Connecticut Avenue, N.W., Suite 500
Washington, D.C. 20009

Dear Mr. Tozzi:

This letter responds to your request for correction under the Information Quality Act (IQA),¹ dated September 20, 2010 (Request for Correction). Your Request for Correction concerns certain slides prepared by FDA staff and statements made by FDA staff during presentations to the Tobacco Products Scientific Advisory Committee (TPSAC) on March 30, 2010, regarding menthol in cigarettes.

Your Request for Correction contends that these slides and statements, and the published, peer-reviewed studies to which they referred, do not meet IQA standards. Your Request for Correction states that the presentations were offered as the "unqualified opinion" of FDA, and that the presentations endorsed the underlying studies by failing to present complete information regarding possible sources of error or limitations of the studies. Your Request for Correction also contends that the presentations were "made as part of a peer review proceeding within the meaning of the IQA peer review guidelines," and therefore were required to carry "the disclaimer required by the peer review guidelines."

In your Request for Correction, you state that you are not seeking correction of specific statements on the slides or in the transcript because they are part of the record of the TPSAC proceedings. Instead, you state that you seek clear FDA acknowledgements, both to TPSAC at its next meeting and to the public in connection with the website materials, that the presentations and the studies on which they are based do not meet IQA standards and were presented to TPSAC for peer review purposes only.

The slides and statements to which you refer relate to three slide presentations that were made at the March 30, 2010 TPSAC meeting:

- Menthol Cigarettes and Smoking Initiation
- Menthol Cigarettes and Nicotine Dependence
- Menthol Cigarettes and Smoking Cessation

All of these presentations, as well as the transcript for the meeting, are available on FDA's website.²

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-I 53.

² <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/fobaccoProductsScientificAdvisoryCommittee/ucm180903.htm>.

For the reasons described below, FDA does not agree that your requested corrections are necessary but we have concluded that a general disclaimer is appropriate under the guidelines that the Office of Management and Budget (OMB), HHS, and FDA issued to implement the IQA (collectively, the IQA Guidelines)?

We also determined that it could be helpful to provide a copy of your Request for Correction to members of TPSAC so that they had an opportunity to consider your concerns about the slides and statements, and the studies to which they refer, as TPSAC developed its report to FDA on the public health effects of menthol (Menthol Report). These materials were provided to TPSAC members on December 9, 2010, and we included a copy in the publicly available background materials for the January 10-11, 2011, meeting of TPSAC.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 was required to submit its Menthol Report to FDA not later than 1 year after its establishment (i.e., March 23, 2011).

As you know, 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.")

Due to the tight statutory timeframe established for the TPSAC Menthol Report, FDA staff decided to assist TPSAC by compiling available peer-reviewed studies on menthol and briefly summarizing some of the scientific publications and the studies' main findings in the slides that are the subject of the Request for Correction. Copies of the scientific publications were provided to TPSAC, which was expected to independently review and evaluate each study. The purpose of this first TPSAC meeting on menthol was to help TPSAC members understand the range of information that had so far been identified, so the TPSAC members could focus requests to the agency for additional information. The process for identifying relevant published literature was described at the first TPSAC meeting on March 30, 2010.⁶ FDA staff began with a publicly-available bibliography of scientific publications on menthol and tobacco, previously prepared by the National Cancer Institute

³ 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/partl.shtml>.

⁴ Available on the Internet at [http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237534.htm#Request for Correction](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237534.htm#Request%20for%20Correction).

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)).

⁶ Transcript of March 30, 2010 TPSAC Meeting, at 88-89.

(NCI) by searching several databases frequently used by scientific researchers. FDA staff updated this bibliography using the same search terms and databases. In addition, the literature reviewed in this process identified additional scientific publications and studies that may have been missed in the initial searches.

The staff presentations to TPSAC did not endorse any of the underlying studies, or purport to offer a detailed assessment of the published studies or of potential error sources. Nor did the presentations provide the agency's point of view with respect to the science of menthol or guide TPSAC to a particular conclusion. Instead, they provided a brief summary of some findings reported in peer-reviewed studies, to help TPSAC begin its work. As FDA staff explained during the meeting:

[W]hat we did is we looked at the published research that we could find on some specific topics related to menthol that could be presented to the Committee and would get a start on what's out there in terms of the published literature so the Committee could start thinking about what other information they need to complete this report.

...

But the primary purpose of this first meeting is really for the Committee to start thinking about and telling us what you will need and what approach you want to take to completing the report within the statutorily required deadline of one year.⁷

As noted above, all of the scientific articles cited by CTP staff in their initial presentations to TPSAC were provided to TPSAC so that its members could themselves critically evaluate the studies described. TPSAC members were also asked to identify any additional relevant articles that FDA staff might have missed.⁸ The TPSAC process was also designed so that the public and industry would have opportunities to comment on these publicly available studies and on the science of menthol, and to suggest additional studies for TPSAC's consideration. TPSAC and the subcommittee tasked with drafting TPSAC's Menthol Report had 10 meetings regarding menthol. TPSAC was never formally or informally charged with conducting a peer review of the materials and scientific studies provided. The public notices, published in the Federal Register, for TPSAC meetings and subcommittee meetings described the opportunity for industry and the public to submit written comments to TPSAC and also described the process for making a public presentation to TPSAC during the open public hearing portion of the meeting. Several persons took advantage of these opportunities. For example, you made presentations on March 31, 2010, July 16, 2010, September 27, 2010, January 10, 2011, February 10, 2011, March 2, 2011, and March 17, 2011.

The Menthol Report, like all advisory committee outcomes, is advice to FDA. See 21C.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

In your Request for Correction you claim that the presentations that are the subject of your request are disseminations of agency information within the meaning of the IQA (Request for Correction at 2). You also claim that the presentations were made as part of a peer review proceeding within the

⁷ Transcript of March 30, 2010 TPSAC Meeting, at 53-54.

^a Transcript of March 30, 2010 TPSAC Meeting, at 59.

meaning of the IQA peer review guidelines, and that they are required to carry a disclaimer described in OMB's Final Information Quality Bulletin for Peer Review (Peer Review Bulletin).⁹

We think the summary nature of the slides, and the purpose of describing the peer reviewed literature they briefly discussed, was made clear during the meeting. As explained in Section I, the presentations to TPSAC on March 30, 2010, 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. FDA staff presented a bibliography of scientific publications with brief summaries of some of the studies' findings. These presentations were given at the start of a year-long process, during which TPSAC was to independently review all of the available data and during which industry and the public were invited to comment and criticize, and suggest additional studies and information. It was clear from statements made by FDA staff at the meeting and from the nature of the presentations themselves that these were not final agency views or endorsements. We have concluded that a general disclaimer on the slides presented would have been appropriate and clarified the position of the agency with respect to the information presented to TPSAC. This general disclaimer would have stated: "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." As you recognize in your Request for Correction, the slides and transcript from the March 30, 2010, TPSAC meeting are part of the record of the proceedings and cannot be altered. We have posted this disclaimer on the website where the public can obtain copies of the slide presentations for the March 30, 2010, TPSAC meeting (available on the Internet at

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm207149.htm>). Beginning with the November 18, 2010, TPSAC meeting, we have posted this disclaimer on the FDA website where the public can obtain copies of the background information for each TPSAC meeting, and this disclaimer has also been included on slide presentations to TPSAC by FDA staff. In the future, we will provide disclaimers as considered appropriate.

We disagree that the presentations were required to bear a disclaimer as described in OMB's Peer Review Bulletin.¹⁰ OMB's Peer Review Bulletin explains that it applies to scientific information disseminations that contain findings or conclusions "that represent the official position of one or more agencies of the Federal government" (70 Fed. Reg. at 2666). The disclaimers described by the Peer Review Bulletin may be used when an agency wishes to disseminate influential scientific information to the public prior to completion of peer review. As explained in Section I, the presentations to TPSAC did not and were never intended to represent the official position of FDA, nor were these materials presented to TPSAC for purposes of peer review. As noted, however, we have provided a general disclaimer and, as appropriate, will do so in the future.

III. FDA's Actions in Response to Request for Correction

Your Request for Correction asks for two separate corrective actions. First, you request FDA to inform TPSAC at its next public meeting that the FDA slide and verbal presentations, and the studies on which they are based, do not meet IQA standards (Request for Correction at 23).

⁹ 70 Fed. Reg. 2664 (2005), available on the Internet at <http://www.whitehouse.gov/sites/default/finalreview041404.pdf>.

¹⁰ Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (2005).

Second, you request that FDA place a prominent note on its website where the March 30 TPSAC meeting materials can be found, stating that the information on the scientific literature contained therein and the studies on which that information is based do not meet FDA quality standards and place a similar note on the pdf files of slides, transcript, and website recording.

As noted, we concluded that a general disclaimer statement was appropriate and the statement was added to the website where the slides for the relevant TPSAC meeting can be obtained. We also informed the drafting subcommittee and the full TPSAC of your concerns about the quality of scientific studies and literature upon which they may rely in their report on the public health implications of menthol. We provided copies of your Request for Correction directly to members of TPSAC on December 9, 2010, and in the publicly available background package for the January 10-11, 2011, TPSAC meeting so that TPSAC members and the drafting subcommittee could consider your concerns as they completed their independent review of the scientific publications and prepared their report on the effects of menthol in cigarettes on the public health.

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 OMB Guidelines, HHS and FDA IQA Guidelines, and the Peer Review Bulletin.

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
White Oak Building 32, room 4260
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Sincerely,

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