DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

NOV 30 2011

Jim J. Tozzi, PhD
Center for Regulatory Effectiveness
1601 Connecticut Ave., NW, Suite 500
Washington, DC 20009

Dear Dr. Tozzi:

This is in response to your letter dated August 8, 2011, addressed to Lawrence R. Deyton, MSPH, MD, Director, Center for Tobacco Products, asserting that the peer review plan for FDA's "Assessment of the Impact of Mentholated Cigarettes on Tobacco Toxicology and Chemistry, Marketing and Consumer Perceptions, Epidemiology of Cigarette Use, Smoking Initiation, Tobacco Dependence, Smoking Cessation, Biomarkers of Exposure, and Disease Risk" (referred to below as "Mentholated Cigarettes Assessment") does not comply with the OMB's "DQA Peer Review Rules." By this we understand you to mean the "Final Bulletin: Final Information Quality Bulletin for Peer Review," 70 Federal Register 2664 (January 14, 2005) ("the OMB Bulletin").

Our peer review agenda is posted at http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm. For each planned peer review of influential scientific information or highly influential scientific assessments, we fill out and publish a peer review form that identifies the title, subject, and purpose of a planned report; identifies an agency contact; designates whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; identifies the timing of a planned review; states how the review will be conducted, such as through individual letter reviews; describes if there is an opportunity for public comment and the timing and form of that public comment; identifies the anticipated number and expertise of the peer reviewers; indicates whether the agency plans to use an outside organization to select the peer reviewers; indicates whether the public will be asked to nominate peer reviewers; and, indicates whether the peer reviewers will be provided with public comments. See section V.2 of the OMB Bulletin, 70 FR 2664 at 2676-77. This form is used for all of FDA planned peer reviews and provides all of the information required for peer review planning under the OMB Bulletin. The agency's web page itself is the mechanism for the public to learn about the Information Quality Act generally and to review and comment on the current peer review agenda and on specific peer review plans.

As the OMB Bulletin notes, even for highly influential scientific assessments, "the Bulletin leaves significant discretion to the agency formulating the peer review plan." 70 FR at 2665. There is no one right way to conduct a peer review. As you note, for example, draft assessments would be made available for public review at the same time as peer review only where "feasible and appropriate" (in the discretion of the agency). However, in the Bulletin OMB recognizes that "[i]n some cases, an assessment may be so sensitive that it is critical that the agency's assessment achieve a high level of quality before it is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the assessment." 70 FR 2672.

The specific peer review plan for the Mentholated Cigarettes Assessment has been posted to FDA's website. All of the information listed above has been identified in the peer review plan for mentholated cigarettes. Our plan is to release the Mentholated Cigarettes Assessment for public comment after it has been peer reviewed, to ensure that it is the strongest possible scientific work product. This may not have been as clear as it could have been in the description of the opportunities for public comment. To ensure that it is clear, we will add a specific reference to the release for comment of the peer-reviewed assessment in addition to the peer review report.

We encourage you to review the completed peer review reports posted in full on FDA's website. In addition to describing the nature and scope of the review and of the findings and conclusions of the peer reviewers, the reports include a great deal of other information, such as identifying the reviewers and their affiliations, setting forth in full the individual reviewers' comments (sometimes, the identity of the reviewer is masked), and indicating what actions the agency has taken in response to the comment. As noted, the completed report on the peer review of the Mentholated Cigarettes Assessment likewise will be posted in full when it is available. We will publish in the *Federal Register* a notice of availability for comment on the report and the peer-reviewed Mentholated Cigarettes Assessment (a link to the assessment also will be posted on the website). We have not yet made any decisions about public or advisory committee meetings concerning the Mentholated Cigarettes Assessment.

We do not see a need to address your argument that the OMB Bulletin is legally binding on the agency in this response; FDA and HHS have affirmed their support for the use of peer review in policies developed in accordance with the OMB Bulletin. As stated at the HHS Information Quality Peer Review Web Site:

> HHS shares the goal of assuring that the best available scientific and technical information is used to support regulatory and programmatic decision making. HHS makes use of different types of peer review throughout the agency to inform decisions ranging from selecting meritorious scientific research proposals and assessing the quality and productivity of intramural research programs to reviewing scientific information in the development of policies for research, clinical practice, and public health. HHS peer review policies and processes have been designed to meet the highest standards of integrity, objectivity, fairness, and rigor.

Thank you for your interest in our work.

Sincerely,

Leslie Kux, J.D.
Acting Assistant Commissioner
For Policy