May xx, 2010

[Address block]

Dear XX:

Under Section 907(e) of the Federal Food, Drug, and Cosmetic Act (the act), the FDA Tobacco Products Scientific Advisory Committee (TPSAC) is required to study "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities," and to provide the FDA Center for Tobacco Products (CTP) with a report and recommendations. To ensure a comprehensive review of this issue, CTP is requesting tobacco industry data and information to support the work of TPSAC.

For the purposes of this information request, the phrase "menthol cigarettes" refers to cigarettes that are marketed by reference to their menthol characteristics or flavoring or which are recognized by consumers as containing menthol favoring. The term "nonmenthol cigarettes" refers to cigarettes that are not marketed by reference to the menthol flavoring, even if such products contain menthol, so long as menthol is present at levels not recognized by consumers. Also for purposes of this document request, the term "menthol" includes menthol derived from both natural and synthetic sources, as well as menthol analogs and functional equivalents.

I. Submission Content

A. Submission of Documents Pursuant to a Section 904(b) Request

In accordance with section 904(b) of the act, FDA requests and therefore you are to submit all documents and underlying scientific information relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on a specified set of topics. "Research activities" may include, but are not limited to, focus groups, surveys, experimental clinical studies, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices.

For the purposes of this section 904(b) request, you are to submit documents and underlying scientific information relating to the following topics:

1. Dose-response relationships for the physiologic effects of mentholated tobacco smoke.
2. Chemosensory effects of menthol compounds in tobacco smoke, including effects at thermal and trigeminal receptors.
3. Impact of menthol on the neurobiology of tobacco dependence.
4. Dose-related interactions between menthol and nicotine on a) consumer perception of nicotine strength and b) uptake and metabolism of nicotine.

5. Correlations between menthol content and consumer perceptions regarding a) taste, b) impact, c) nicotine strength, and d) product harm.

In accordance with FDA's request under section 904(b) of the act, you are also to submit documents and underlying scientific information developed since January 1, 1990 relating to the following topics:

6. Consumer perception studies around advertising and packaging of menthol cigarettes.
7. Marketing strategies by brand/subbrand of menthol cigarettes, including a) strategies targeted to particular demographic groups, b) strategies aimed at tobacco-naïve consumers, and c) strategies aimed at recruitment of former tobacco users.
8. Rates of users switching from menthol to nonmenthol cigarettes and vice versa.
9. Comparative rates of initiation for menthol and nonmenthol cigarettes.
10. Comparative rates of cessation for users of menthol and nonmenthol cigarettes.

In your production of documents we ask that each document be identified as responsive to one or more of the numbered topics above.

For the purposes of this 904(b) request, FDA requests only the final version, or in the absence of a final version, the most recent draft of each document. As such, please do not submit a) past iterations of a completed or more recent document, b) document duplicates, or c) near duplicates that only vary in minor ways (e.g. differences in addressee or changes in letterhead). Moreover, information responsive to this 904(b) request that has been previously provided to FDA under the 904(a)(4) requirement to submit certain tobacco health documents does not have to be re-submitted as long as the document can be fully referenced (e.g., by the file name and file extension, Bates number (begin Bates number to end Bates number), the date of submission, and relevant page numbers). However, information sufficient to fully identify the document must be provided in lieu of reproducing the document under this 904(b) submission.

Furthermore, FDA requests only the following types of documents:

- Interim or final reports, findings, analyses, assessments, and any other scientific evaluations of data relating to studies, surveys or other research activities (hereafter "scientific reports");
- Documents containing charts, tables, diagrams, and any other presentations of data that are the subject of research activities or that accompany scientific reports;
- All documents containing scientific protocols or design features of research activities, including discussions, analyses, or reviews of, or any other substantive commentary on, the design of research activities;
- All documents containing substantive, scientific, marketing, or health-related, analyses, reviews, discussions, assessments, or evaluations of, or commentary or recommendations related to, research activities, scientific reports or their underlying data. These analytical documents may take any form, including, but not limited to,

slide or powerpoint presentations, emails, memos, or handwritten notes, or handwritten annotations to scientific reports. Documents that do not add any additional information or analysis related to the scientific issues in the study should be excluded (e.g., transmittal documents).

FDA asks that data (e.g., spreadsheets, SAS datasets) be submitted in a file type and structured format that allows for meaningful review and analysis of the data. Where relevant, data submissions should be accompanied by the name and version of software used to create the file, names and definitions of variables, and copies of programs and macros needed to generate your analyses. Any data analyses that stratify scientific results by gender, race/ethnicity or age are to be included in your submission.

All information under section I(A) of this document is to be received by CTP no later than [3 months after date of the letter]. If you are a manufacturer of cigarettes and do not have any responsive documents to submit, or if you are a tobacco product manufacturer who does not manufacture and has not previously manufactured cigarettes, please inform FDA of this in writing no later than [3 months after date of the letter]. If you anticipate difficulties with this document production, please contact CTP within 30 days of receipt of this letter so that we may assist you in resolving any technical difficulties you may have and facilitate compliance with the above timeline.

The failure to provide information requested by FDA in accordance with FFDCA § 904(b) is a violation of the act and subject to regulatory and enforcement action by FDA.

B. Additional Requests

To provide additional background information for the TPSAC review--beyond the section 904(b) request--CTP also asks that you submit the following information:

11. Quantities of menthol and nicotine in the cigarette by brand/subbrand and by year between 2000 and 2010. Each brand/subbrand should be identified as a menthol or nonmenthol product.
12. Quantities of menthol and nicotine in the cigarette smoke, as determined by the Cambridge Filter/ISO test method using standard parameters as well as the intense smoking conditions set forth in Canadian regulations, by brand/subbrand and by year between 2000 and 2010. Each brand/subbrand should be identified as a menthol or nonmenthol product.
13. Please describe the manufacturing process by which menthol is introduced into your menthol cigarettes, including a) the source and type of menthol used, b) the presence or use of any menthol analogs, and c) the manufacturing stage at which menthol is introduced (e.g., placed on the foil in contact with the tobacco product, introduced as a flavor into the reconstituted tobacco).
14. CTP is aware that many tobacco products contain subliminal levels of menthol, while only certain products are marketed as menthol cigarettes. Please identify

the threshold (e.g., menthol content) at which you identify and market a product by reference to its menthol flavoring or characteristics.

15. Rationale for adding menthol to cigarettes not marketed as menthol cigarettes, and criteria for determining amount of menthol to be added.
16. Research on other chemical compounds structurally or functionally similar to menthol, including the rationale for identifying and using such compounds in cigarettes.

We ask that you submit all information responsive to section I(B) of this document to be received by CTP no later than [3 months after date of the letter].

II. Submission Instructions

Consistent with applicable statutes and regulations, the confidentiality of trade secret and confidential commercial information submitted to FDA pursuant to this request will be preserved.

We encourage you to submit your response in an electronic format on CD-ROM or DVD. Please see the attached document for guidance in preparing your electronic submission to CTP.

Your submission should be prominently identified with the label "FDA 04-2010 Menthol Request" and sent to the following address:

Center for Tobacco Products
Food and Drug Administration
Attn: Document Control Center
9200 Corporate Boulevard
Rockville, MD 20850

We look forward to your prompt response and appreciate your support of the TPSAC in their review and evaluation of this important topic. If you have questions regarding this document request, please contact Cristi Stark, Senior Regulatory Health Project Manager, at 301-796-9224 or TPSAC@fda.hhs.gov.

Sincerely,

Lawrence R. Deyton, M.D.
Director
Center for Tobacco Products

Electronic Submission Instructions

A. General Instructions

We request that you to submit your response in text-searchable PDF file(s) on a CD-ROM or DVD. The files should include a signed cover letter prominently identified as "FDA 04-2010 Menthol Request," and should also identify the software (name, version, and company) that you used to confirm the submission is free of viruses or other malware.

The CD-ROM or DVD media should be labeled with your company name, contact phone number, "FDA 04-2010 Menthol Request," submission date, and series number (e.g., "disc 1 of 2").

If you plan to submit PDF files, they should not contain any attached, embedded or bundled files. If your summary or any supplementary documents are scanned, you should verify the accuracy of optical character recognition and legibility of the document.

B. Instructions for Information Submitted under Section I(A)

For more information about the preferred organization and formatting of document submissions under section 904 of the act, please refer to FDA's guidance *Submission of Tobacco Health Documents*.

C. Instructions for Information Submitted under Section I(B)

To improve the organization and readability of the electronic submission we request that you include a well-structured table of contents and use bookmarks and hypertext links.

We suggest that the first level of detail in your table of contents be the numbered items in this information request. The second level of detail should describe the contents of each item (e.g., general summary, study description, study results).

In general, bookmarks should be provided for each item listed in the table of contents including all major section headings and subheadings. All tables, figures, publications, references, and appendices should also be bookmarked. Hypertext links should be used to connect text to supporting annotations, related sections, references, appendices, tables, or figures that are not located on the same page as the text. Hypertext links should be designated by blue text.