Characterization of Menthol

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Introduction

- Philip Morris USA agrees with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers and is addictive.

- Smokers are far more likely to develop serious diseases, like lung cancer, than non-smokers.

- There is no safe cigarette.

- It can be very difficult to quit smoking, but this should not deter smokers who want to quit from trying to do so.

- To reduce the health effects of cigarette smoking, the best thing to do is to quit.

Apply equally to menthol and non-menthol cigarettes.
Written Submission on Menthol

- 164 pages
- Hundreds of references
- Topics covered
  1. Design, Fabrication, and Testing of Menthol Cigarettes
  2. Marketing of Menthol Cigarettes
  3. Health Effects of Menthol Cigarettes as Compared with Non-Menthol Cigarettes
  4. Total Exposure Study
  5. Mechanistic Studies on the Sensory, Desensitization, and Local Anesthetic Effects of Menthol
  6. Menthol Cigarettes and Smoking Initiation
  7. Menthol Smoking Prevalence and Dependence
  8. Menthol and Smoking Cessation
Use of Menthol in Consumer Products

- **Long history of safe use**
  - Use in foods
    - FDA GRAS ¹
    - Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives ²
    - Flavor and Extract Manufacturers Association ³
  - Use in other products
    - Approved by the FDA for use in other products, including as an inactive ingredient in nicotine replacement therapy products such as nicotine inhalation system ⁴

PM USA’s Use of Menthol in Cigarettes

- Menthol is a flavor
- It is used to address the taste preferences of some adult smokers
- PM USA only adds menthol to the flavor recipes of cigarettes labeled as menthol cigarettes
Sources of Menthol

- *l*-menthol
  - Most commonly identified as menthol
  - Most abundant in nature
  - Associated with minty flavor and cooling
  - Obtained from mint oils
  - Produced by synthetic means
  - Incoming supplier shipments to PM USA are tested to meet quality standards

*Mentha arvensis*

USDA, http://plants.usda.gov
Manufacturing of Menthol Cigarettes

- Typical methods of menthol application to cigarettes
  - Tobacco
  - Filter
  - Packaging

- Regardless of the point of application, menthol distributes itself among the components of the packed cigarette
Ventilation (12-13 mm from mouth end)

Tobacco

Cigarette Paper

Plug wrap

Tipping Paper

Filter
Cellulose acetate with plasticizer
Cigarettes are designed to meet adult smokers’ taste preferences.

Strength of taste (Adult Smoker Panels)

Menthol in smoke
(as measured by smoking machine)

At equivalent tar levels, the strength of taste of menthol cigarettes increases with the increase of menthol in smoke.
PM USA Menthol Cigarettes

31 PM USA menthol brand styles - Cambridge filter smoking method (formerly known as FTC method)

Data from Table 1.3 of ALCS submission, June 30, 2010
Quantity of Menthol

- The amount of menthol added to menthol cigarettes is determined by
  - Consumer taste preferences
  - PM USA Product Integrity Guidelines
Product Integrity Toxicological Evaluation

- **Extensive evaluation process**
  - Comprehensive literature review
  - Chemical analysis
  - Smoke chemistry
  - *In-vitro* and *in-vivo* tests

- **Evaluation of**
  - Ingredients
  - Product and package components
  - Manufacturing processes
  - Integrated product designs
Toxicological Studies Using Menthol Cigarettes

- Toxicological properties of menthol and non-menthol cigarettes evaluated in
  - Smoke chemistry
  - Cytotoxicity
  - Mutagenicity
  - Rodent inhalation
  - Mouse skin painting
- Numerous peer-reviewed publications

The weight of the scientific evidence from this evaluation process shows that the addition of menthol to cigarettes does not increase the inherent risks of cigarette smoking
## Epidemiological Studies Comparing Health Effects of Menthol vs. Non-Menthol Cigarettes

<table>
<thead>
<tr>
<th>Study authors, date, page no.</th>
<th>Health outcome investigated</th>
<th>Study design</th>
<th>Number of subjects</th>
<th>Menthol associated with increased risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hebert &amp; Kabat, 1988, p.986</td>
<td>Esophageal cancer</td>
<td>Case-control</td>
<td>Cases = 312; Controls = 462</td>
<td>NO</td>
</tr>
<tr>
<td>Hebert &amp; Kabat, 1989, p. 41</td>
<td>Esophageal cancer</td>
<td>Case-control</td>
<td>Cases = 311; Controls = 462</td>
<td>NO</td>
</tr>
<tr>
<td>Kabet &amp; Hebert, 1991, p. 6511</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 1044; Controls = 1324</td>
<td>NO</td>
</tr>
<tr>
<td>Kabet &amp; Hebert, 1994, p. 183</td>
<td>Oropharyngeal cancer</td>
<td>Case-control</td>
<td>Cases = 276; Controls = 1265</td>
<td>NO</td>
</tr>
<tr>
<td>Sidney, et al., 1995, p. 727</td>
<td>Lung cancer</td>
<td>Cohort</td>
<td>Menthol: 3654 Non-menthol: 8107</td>
<td>YES in men only, (RR=1.45; 95% CI 1.03-2.02)</td>
</tr>
<tr>
<td>Carpenter, et al., 1999, p. 114</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 337; Controls = 478</td>
<td>NO</td>
</tr>
<tr>
<td>Brooks, et al., 2003, p. 609</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 643; Controls = 4110</td>
<td>NO</td>
</tr>
<tr>
<td>Stellman, et al., 2003, p. 294</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 3448; Controls = 8151</td>
<td>NO</td>
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<tr>
<td>Jockel, et al., 2004, p. 33</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 1004; Controls = 1004</td>
<td>NO</td>
</tr>
<tr>
<td>Pletcher, et al., 2006, p. 1919</td>
<td>Coronary calcification, pulmonary function decline</td>
<td>Longitudinal, prospective</td>
<td>Menthol: 972 Non-menthol: 563</td>
<td>NO</td>
</tr>
<tr>
<td>Murray et al., 2007, p. 101</td>
<td>Mortality from coronary heart disease, cardiovascular disease, lung cancer, and all causes</td>
<td>Prospective</td>
<td>Menthol: 1216 Non-menthol: 4665</td>
<td>NO</td>
</tr>
<tr>
<td>Etzel, et al., 2008, p. 261</td>
<td>Lung cancer</td>
<td>Case-control</td>
<td>Cases = 491; Controls = 497</td>
<td>NO</td>
</tr>
</tbody>
</table>
Summary

- Menthol is a flavor used in cigarettes
- PM USA only adds menthol to the flavor recipes of cigarettes labeled as menthol cigarettes
- Menthol is used in cigarettes to address the taste preferences of some adult smokers
- Menthol increases the strength of taste of cigarettes
- The addition of menthol does not increase the inherent risks of cigarette smoking