

Information Request Regarding Menthol in Cigarettes
Justification for Emergency OMB Approval
May 18, 2010

As we discussed with OMB on March 22, 2010, CTP would like to pursue a request for emergency processing of an information collection regarding the public health impact of menthol in cigarettes. Under Section 907(e) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Family Smoking Prevention and Tobacco Control 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. Pursuant to Section 907(e), TPSAC must submit its report and recommendations to the Secretary of Health and Human Services (the Secretary) within one year of its formation, or March 23, 2011.

In order to provide TPSAC with the information it needs to carry out its statutory obligation, FDA is requesting that tobacco companies submit information pursuant to section 904(b) of the act. As FDA anticipates that the quantity and organization of the data received may take significant time to synthesize and analyze, FDA is also requesting that industry voluntarily provide summary and additional background information beyond the scope of section 904(b).

Although the deadline for the TPSAC report is March 23, 2011, TPSAC will not be able to meet this statutory deadline without an emergency clearance of this information collection. TPSAC was formed on March 23, 2010, and its initial meeting took place on March 30-31. Individuals from CTP reviewed all of the available published literature on menthol (more than 300 articles) and presented that information to the TPSAC members at this first meeting. However, there was limited information in the published literature and the Committee specifically identified the topics that are included in the industry request as information that is important for them to develop a report and recommendations. Since the initial TPSAC meeting, individuals at CTP have worked to formulate an information request that provides TPSAC the information it desires and that minimizes the burden to respondents. Given the committee’s deadline, we anticipate that TPSAC will need to receive synthesized data by October 1, 2010. CTP believes that it is necessary to receive responses to this information request by July 2010, at the latest as FDA anticipates that it will need significant time to organize, scan, code, analyze, and synthesize the information received. Therefore, we are requesting emergency processing and clearance of this information collection by May 17th so that we can issue the letter to industry requesting this information soon thereafter. Under this time frame, industry would have ample time to respond to the information request.

CTP believes that this information collection is an ideal candidate for emergency processing due to the time constraints mandated by the Tobacco Control Act. Under

normal clearance procedures, CTP could not likely be able to request this information until after October 1, 2010. As mentioned above, we need to request and receive information by July, 2010 in order for TPSAC to have this information for its analysis and review for developing its report and recommendations. All of the information requested will enable TPSAC to meet its statutory obligation to submit its report and recommendations on the impact of menthol in cigarettes on the public health by March 23, 2011. The corresponding supporting statement is attached. Thank you.