



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

SEP 23 2011

Jim Tozzi  
Center for Regulatory Effectiveness  
1601 Connecticut Avenue, Suite 500  
Washington, DC 20009

Dear Mr. Tozzi:

Thank you for your recent letter referencing a quotation from the Food and Drug Administration (FDA) that appeared in the recent World Trade Organization's (WTO) Panel Report in *United States—Measures Affecting the Production and Sale of Clove Cigarettes*. In your letter, you discuss your opinion of the relevance of this quotation to the possible regulation of menthol cigarettes.

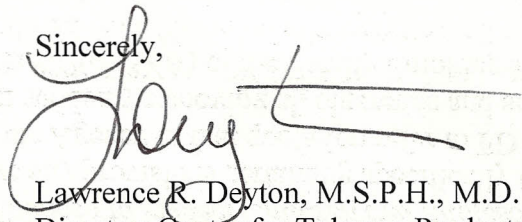
However, as the citation at the end of the quotation in the WTO report indicates, this FDA statement comes from the final rule issued by FDA on August 28, 1996, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,396, 44,413. That rule did not have any provisions pertaining specifically to menthol cigarettes, and the conclusions reached by the Agency in that quotation refer to FDA's concerns in 1996 about the possible consequences from suddenly removing all cigarettes and smokeless tobacco from the market at that time. Under Section 907(d)(3)(A) of the Family Smoking Prevention and Tobacco Control Act, the Secretary is prohibited from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products."

With respect to illicit trade and contraband, FDA is continuing to assess the potential impact and consulting with other regulatory and law enforcement agencies to ensure that any regulations the Agency might issue are designed to deter illicit trade, smuggling, and counterfeiting of tobacco products.

If you have further questions, please let us know. You might also be interested in the updates about FDA tobacco-related activities, available on our web site at:  
[www.fda.gov/TobaccoProducts/NewsEvents](http://www.fda.gov/TobaccoProducts/NewsEvents).

Thank you for sharing your concerns on this very important public health issue.

Sincerely,



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