



UNITED STATES OF AMERICA
Federal Trade Commission
Washington, D.C. 20580

Division of Advertising Practices

February 24, 2014

Urvashi Rangan, Ph.D.
Executive Director
Michael Crupain, M.D., M.P.H.
Director
Food Safety & Sustainability Center
Consumers Union/Consumer Reports
101 Truman Avenue
Yonkers, NY 10703

Dear Dr. Rangan and Dr. Crupain:

Thank you for your January 21, 2014 letter to Chairwoman Ramirez regarding statements made by the American Beverage Association and two leading food coloring manufacturers about the safety of caramel coloring used in many foods and beverages. You express concern that these statements are misleading because they mischaracterize FDA's position on the safety of 4-MEI, a chemical byproduct found in some classes of caramel used for coloring and flavoring.

As you are aware, an important aspect of the Federal Trade Commission's mission is to prevent deceptive or unfair acts or practices in commerce, including false and misleading claims in food advertising.¹ The FTC shares jurisdiction over food marketing with the Food and Drug Administration and generally defers to FDA's expertise on matters of food safety. We have consulted with FDA staff about the regulatory framework governing color additives and FDA's review of the safety of caramel coloring. As your letter acknowledges, the exemption for substances "Generally Recognized as Safe" does not apply to caramel when used as a food color additive. However, FDA has evaluated the safety of caramel as part of its certification process for color additives, considering such factors as probable consumption or exposure from its use, cumulative effect in the diet, and evaluation by scientific experts, and has determined that caramel is safe for its intended use in foods generally.²

¹ Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

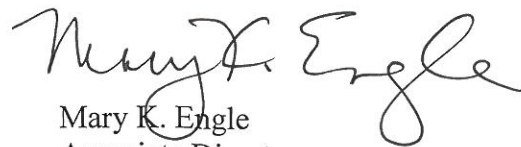
² See 21 C.F.R. §73.85 (FDA regulation listing caramel as a color additive permitted for use in foods generally); *see also* FDA, "For Industry: Color Additives: FDA's Regulatory Process and Historical Perspectives," *available online at* <http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives/default.htm> (explaining safety review and approval process for color additives).

We understand that FDA is currently reviewing the available data on the safety of 4-MEI, the chemical byproduct present in Class III and Class IV caramel coloring, and is reassessing potential consumer exposure to 4-MEI to determine what, if any, regulatory action needs to be taken. In the interim, FDA has indicated that it has “no reason to believe that there is any immediate or short-term danger presented by 4-MEI at the levels expected in food from the use of caramel coloring” and “is not recommending that consumers change their diets because of concerns about 4-MEI.”³

We recognize that marketing statements that caramel coloring is “Generally Recognized as Safe by the FDA” or “GRAS” may be technically inaccurate; however, as your letter acknowledges, color additives are subject to a high regulatory threshold for safety. Given that FDA has approved the safety of caramel as a color additive, and continues to allow its use in foods pending the outcome of the agency’s current review on the safety of 4-MEI, the staff does not believe that this matter warrants formal investigation or Commission action at this time.

We appreciate the excellent work that Consumers Union does to inform and protect consumers and hope you will continue to bring matters of concern to our attention. Please let us know whenever we can be of service. If you have any additional questions about this matter, feel free to contact Michelle Rusk, an attorney in the Division of Advertising Practices, at (202) 326-3148 or mrusk@ftc.gov.

Very truly yours,



Mary K. Engle
Associate Director
Division of Advertising Practices

³ See FDA, “Questions and Answers on Caramel Coloring and 4-MEI,” *available online at* <http://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/ucm364184.htm> (last updated Aug. 7, 2013).