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April 5, 2010

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I wanted to express my appreciation for your strong support for food safety, and urge your attention to an important, but under-appreciated, food safety concern. Recent studies have provided new evidence of the link between synthetic food dyes and hyperactivity in children. I urge you to review the citizen's petition filed by the Center for Science in the Public Interest on June 3, 2008 called, "Petition to Ban the Use of Yellow 5 and Other Food Dyes, in the Interim to Require a Warning on Foods Containing these Dyes, to Correct the Information the Food and Drug Administration Gives to Consumers On the Impact of These Dyes on the Behavior of Some Children, and to Require Neurotoxicity Testing of New Food Additives and Food Colors."

Attention Deficit Hyperactivity Disorder (ADHD) is an increasing concern in the United States. The Centers for Disease Control and Prevention estimates that 3 to 7% of American school children are affected by ADHD.¹ One study estimated that the annual societal cost of ADHD was between \$36 billion and \$52 billion in 2005.²

There is increasing evidence that artificial food dyes increase hyperactivity, reduce concentration, and exacerbate ADHD symptoms in children.

¹ Schab, David, and Nhi-Ha Trinh. "Do Artificial Food Colors Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials." *Developmental and Behavioral Pediatrics*. 25.6 (2004): 423-34.

² Pelham, W.E., E.M. Foster, and J.A. Robb. "The economic impact of attention-deficit/hyperactivity disorder in children and adolescents." *Journal of Pediatric Psychology*. 32.6 (2007): 711-27.

Indeed, a 2004 meta-analysis of numerous clinical studies concluded that dyes impair children's behavior.³ In addition, the British government funded two high-quality, large-scale studies of the impact of food dyes on children. These studies are particularly important, as they showed that food dyes had a statistically significant impact on the broader population of children, not just children suspected of being sensitive to dyes. In a double-blind, randomized study with 277 3-year-old children, the researchers concluded, "There is a general adverse effect of artificial food colouring and benzoate preservatives on the behaviour of 3 year old children which is detectable by parents but not by a simple clinic assessment."⁴ In a second randomized, double-blinded, placebo-controlled study published in 2007, artificial colors combined with a preservative had a statistically significant adverse affect on the behavior of a total of more than 200 3- and 8-9-year-olds.⁵

These studies provide powerful evidence that food dyes influence children's behavior. Based on its own two studies and the body of evidence stretching back to the 1970s, the British Food Safety Advisory Board called for a voluntary removal of most artificial colors by the end of 2009. Major corporations responded to that request, with Mars, Kraft, Kellogg, McDonald's, and other companies removing dyes from their British products. Subsequently, the European Union passed a law that will require a warning label on most foods that contain dyes beginning on July 20, 2010.

In 2008, the Center for Science in the Public Interest submitted a citizens petition asking the F.D.A to review the evidence, correct its educational materials, issue warning labels, and initiate a rule-making to ban food dyes. The petition and this letter only address eight synthetic food dyes that require FDA certification and are suspected of adversely affecting children. (One of the eight, Orange B, is rarely if ever used, while a ninth dye, Citrus Red 2, is used in minuscule amounts and only on a small fraction of orange skins.) I am concerned that the F.D.A. has not yet responded substantively to this almost two-year-old petition, and I look forward to a prompt response to this petition.

It is important that the F.D.A carefully consider the evidence regarding food dyes and children's behavior. Not only have food dyes been shown to harm behavior and educational performance, but they have no nutritional value or any other health benefit to consumers.

The F.D.A. should take action in order to ensure that consumers are informed of the risks due to artificial food dyes. Prominently labeled warnings on foods would allow parents to make

³ Schab, David, and Nhi-Ha Trinh. "Do Artificial Food Colors Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials." *Developmental and Behavioral Pediatrics*. 25.6 (2004): 423-34.

⁴ Bateman, B, J O Warner, E Hutchinson, et al. "The effects of a double blind, placebo controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children." *Archives of Disease in Childhood*. 89.6 (2004): 506-11.

⁵ McCann, Donna, Angelina Barrett, Alison Cooper, et al. "Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial." *Lancet*. 370.9598 (2007): 1560-567.

informed choices as consumers. A thorough review of the evidence by an authoritative science-based organization or agency, such as the Institute of Medicine, would help the country to better understand the evidence, and to shape public policy based on data.

Rule-making to ban synthetic dyes must be considered. Foods for children and infants should not include artificial dyes that might impact all children and vulnerable children in particular. While warning labels would help, they would not address the use of food dyes in food sold in restaurants and in vending machines. Furthermore, the British example shows that eliminating food dyes does not significantly affect sales or costs. There are 31 additional food colorings (derived from plants or animals) that can be easily substituted for the synthetic dyes.

We owe our children safe, healthy food that helps them to succeed at school and at home. I appreciate your attention to the increasing evidence that food dyes stand in the way of educational success, and look forward to prompt action by the F.D.A.

Sincerely,

A handwritten signature in blue ink that reads "Louise Slaughter". The signature is written in a cursive, flowing style.

Louise M. Slaughter
Member of Congress