

March 23, 2010

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave.,
Silver Spring, MD 20993

Re: Docket FDA-2008-P-0349-0001/CP

Dear Dr. Hamburg:

The undersigned organizations are concerned that food dyes, which are widely used in the American food supply, impair children's behavior. In June 2008, the Center for Science in the Public Interest formally petitioned the Food and Drug Administration to ban most of the currently approved dyes (Blue 1, Blue 2, Green 3, Orange B, Red 3, Red 40, Yellow 5, and Yellow 6). We strongly endorse that petition and urge the FDA take swift action.

Many of the controlled studies conducted over the last three decades have demonstrated that synthetic dyes (usually tested as mixtures of several dyes) impair some children's behavior. In 2004, a meta-analysis of studies on dyes and behavior concluded that the effect of dyes on children was statistically significant, particularly with regard to parents' ratings.¹

Subsequent to the meta-analysis, two large studies funded by the British government found that mixtures of several dyes (administered together with the preservative sodium benzoate) adversely affected children's behavior.² Unlike most previous studies, the new studies tested children in the general population, not children whose parents suspected they were sensitive to dyes. As a result, the British government urged food manufacturers to stop using the tested colors, which companies apparently have done. Some of Britain's biggest supermarket chains—Tesco, Sainsbury's, ASDA, Marks & Spencer, and the Co-op—pledged to drop the dyes from their house-brand products. McDonald's, Nestlé, Kraft, Mars, Haribou, and Kellogg removed (or never used) those dyes from their foods in Britain, but not in the same foods in the United States.

Spurred by the British research, the European Union is requiring companies to put a warning label on most dyed foods beginning in July 2010. The notice will state that

¹ Schab D, Trinh N. Do Artificial Food Colors Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials. *J Dev Behav Pediatr.* 2004;25:423-34.

² McCann D, Barrett A, Cooper A et al. Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomized, double-blinded, placebo-controlled trial. *Lancet.* 2007(Nov 3);370:1560-7. Bateman B, Warner JO, Hutchinson E, 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.* 2004;89:506-11.

consumption of the food dye(s) “may have an adverse effect on activity and attention in children.”

In contrast to the European measures, the FDA has done nothing to protect children from food dyes. In fact, the FDA’s Web site has a pamphlet written by the food industry’s International Food Information Council that states “Although this theory was popularized in the 1970’s, well-controlled studies conducted since then have produced no evidence that food color additives cause hyperactivity or learning disabilities in children.”³

While the FDA denies that synthetic dyes affect children, the National Institute of Mental Health recognizes in its article on “What causes ADHD?” a “link between consumption of certain food additives like artificial colors or preservatives, and an increase in activity.”⁴ Likewise, the American Academy of Family Physicians states on its web site: “Studies have shown that certain food colorings and preservatives may cause or worsen hyperactive behavior in some children. Talk to your doctor about whether you need to make any changes to your child’s diet.”⁵

Given the preponderance of scientific evidence showing a link between food dyes and hyperactivity, the authoritative actions taken by the British and European Parliaments, and the lack of any health benefit of dyes, we urge the FDA to provide accurate information on its Web site, expedite its review of CSPI’s petition calling on the agency to protect children by banning the dyes, and, pending that, require a warning label on dyed foods.

Sincerely,

Consumer Federation of America
Feingold Association of the United States
Institute for Agriculture and Trade Policy
MomsRising
National Consumers League
Physicians for Social Responsibility
Prevention Institute
Science and Environmental Health Network

Please respond via Michael Jacobson, Ph.D., CSPI, mjacobson@cspinet.org; 202-777-8328; 1875 Connecticut Ave., #300, Washington, DC 20009.

cc: Michael Taylor, Jeffrey Farrar, Joshua Sharfstein, Jessica Leighton, Sharon Natanblut, Stephen Sundlof

³ <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm094211.htm#qahyper>

⁴ <http://www.nlm.nih.gov/health/publications/a-look-at-attention-deficit-hyperactivity-disorder/complete-publication.shtml>

⁵ <http://familydoctor.org/online/famdocen/home/children/parents/behavior/118.html#ArticleParsysMiddleColumn0007>