

April 6, 2011

Carolyn Jeletic  
Center for Food Safety and Applied Nutrition (HFS-04)  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
Docket No. FDA-2008-P-0349

**RE: FDA Food Advisory Committee Public Meeting March 30-31, 2011**

Dear Ms. Jeletic:

The Safe Color Coalition appreciates the opportunity to provide written comments to the FDA Food Advisory Committee on the topic of whether available relevant data demonstrate a link between children's consumption of synthetic color additives in food and adverse effects on behavior. The Safe Color Coalition consists of trade associations and companies representing the makers and users of synthetic colors. The Safe Color Coalition maintains the position that there is no causal link between synthetic colors and hyperactive behavior in children.

The goal of the Safe Color Coalition is to promote the use of sound scientific assessment principles when evaluating the safety of synthetic color additives so that consumer safety is assured while providing maximum flexibility for industry to formulate products with the best colorants for particular applications based on technological requirements.

**CSPI Petition**

As you know, a petition [1] to the FDA was filed by the Center for Science in the Public Interest (CSPI) in 2008 requesting that the agency revoke the approval of eight FD&C food colors [2]. CSPI has also requested that a warning label be placed on food and beverage products containing these eight food colors. CSPI based its requests upon two published studies [3], that contend that there is a link between the intake of synthetic food colors and hyperactive behavior in children. A thorough review of currently available scientific literature does not support CSPI's assertions.

The scientific evidence does not support the CSPI petition to the FDA. Reviews of several studies on hyperactivity and synthetic food colors have been conducted by US experts and international regulatory bodies; they have concluded that there is no causal link between the intake of synthetic food colors and hyperactivity among children. We encourage the FDA to continue to abide by its current guidance statement which indicates that **there is no causal link between the intake of synthetic food colors and childhood hyperactivity** [4]. Labels for US food products are required to indicate the presence of colors thus allowing concerned consumers to make informed decisions.

In Europe, the European Food Safety Authority (EFSA) reviewed the study sometimes referred to as the "Southampton Study" (McCann et al., 2007) upon which the CSPI primarily bases its request, and the agency found that it provides only limited evidence that the two different mixtures of synthetic colors and sodium benzoate tested in the study had a small but statistically significant effect on children selected from the general population. EFSA further indicated that the effects were not statistically significant for the two mixtures in the different age groups: 3/4 year olds and 8/9 year olds. Finally, EFSA indicated that the clinical significance of any reported effects remains

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unclear. As a result, EFSA concluded that the study was not of sufficient significance to warrant a change to the regulatory status of the colors tested. Because mixtures were tested and not individual additives, it is not possible to ascribe any of the observed effects to a particular color.

### **Safe Color Coalition Supports FDA Conclusion**

The Safe Color Coalition applauds the FDA for its initial response to the CSPI actions and the FDA's indication that the McCann study did not provide sufficient cause to change their conclusions that the FD&C colors are safe for the general population. Further, the Coalition appreciates the FDA's support for the conclusions reached by EFSA in their review of the study. As concluded by the FDA Food Advisory Committee last week, currently available scientific data do not demonstrate a need for any regulatory action to limit or restrict the use of these colors.

### **Safety of Synthetic Colors**

The companies involved in the Safe Color Coalition comply with the FDA regulations for certification and use of synthetic colors, the European requirements contained in European Directives and other international requirements for the use of synthetic colors. In addition, the members of the color industry have sponsored many safety studies, the results of which have been evaluated by the FDA and international regulatory bodies, including the Joint Expert Committee on Food Additives (JECFA) and EFSA. These studies confirm the safety of synthetic colors, and as a result these colors have been approved for use in food, beverage, and other products in the United States and globally for decades. Any color additive, whether an FD&C color or one exempt from certification [5], must meet all safety requirements by the FDA.

In addition, ongoing toxicology studies have been routinely conducted worldwide and reviewed by organizations such as the FDA, EFSA, and the World Health Organization (WHO) to assess the safety of synthetic food, drug and cosmetic colorants in various applications. Many articles have been written on assessing the safety of these colorants [6-11]. Some consumer groups have voiced concerns about safety and childhood hyperactivity attributed to some of the synthetic colors based on theories regarding an alleged link.

Although these theories were popularized in the 1970s, well-controlled studies [12] conducted since then have produced no evidence that food and drug color additives cause hyperactivity or learning disabilities in children. A Consensus Development Panel of the National Institutes of Health (NIH) concluded in 1982 that there was no scientific evidence to support the claim that colorings or other food additives cause hyperactivity [13] and that elimination diets should not be used universally to treat childhood hyperactivity, since there is no scientific evidence to predict which children may benefit [14].

As part of an overall re-assessment of the safety of all food additives, EFSA's Panel on food additives and nutrient sources added to food (ANS) has re-evaluated many food colors including the six synthetic colors used in the Southampton study [15], three of which have been thoroughly evaluated by the FDA and can be certified as FD&C Colors in the United States [16]. All of these synthetic colors are widely used by the global food industry and have been the subject of safety reviews by JECFA. All have been assigned a numerical Acceptable Daily Intake (ADI) by JECFA, which establishes the number of milligrams of the color an individual can consume per kilogram of body weight every day without adverse effect. The opinions expressed by the EFSA ANS Panel have upheld the safety of six of the synthetic colors and will allow for the continued use within the European marketplace.

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### **Colors Provide Benefits**

While they are not nutritional additives, color additives provide important benefits in foods. Color is one of the principal contributors to the palatability of foods. Also, during processing (heating, transport, storage, other manipulation), the inherent color in foods is often lost. This can have the effect of making otherwise nutritious foods appear unappealing. Therefore, color additives are used to replace color that is lost during the processing of foods [17].

Color additives also correct for natural color variation that occurs in foods. Consumer testing has shown that consumers will not purchase products or consume them if the color that they have is in any way unexpected. Color additives are therefore added to ensure an even, consistent appearance. While synthetic color additives can be replaced with non-synthetic ("natural") color additives in some cases, non-synthetic colors are not able to replace synthetic color additives in all applications due to their technical, regulatory, and color-shade limitations.

Synthetic colors tend to be very stable to light, heat, and oxidation which allows for long shelf life. Generally, the stability of many non-synthetic colors is typically lower than for the synthetic colors, the color variability from batch-to-batch can be greater than with synthetic colors and many non-synthetic colors can be very sensitive to pH. Additionally, some non-synthetic colors can impact flavor to the product unlike the synthetic colors. Non-synthetic colors can be used successfully in some food products that have short shelf lives and non-challenging manufacturing processes and product formulations. However, in applications where a long shelf life, similar flavor, and good batch-to-batch color reproducibility is needed, it would be very difficult to substitute non-synthetic colors for the synthetic colors currently used in these applications without having a significant impact on the shelf life and quality of many products on the market today.

Another consideration regarding the use of non-synthetic colors is the fact that there is a limited supply available for a number of these materials which could impact availability and cost if demand increased significantly due to replacement of synthetic colors. Additionally, some of the non-synthetic colors have only been approved by the FDA for very specific types of applications and may not be able to be used as a substitute for synthetic colors for broad application due to regulatory constraints.

If the FDA were to require the removal of synthetic color additives in foods in the United States, the economic impact could be immense. Synthetic color additives are safe, economical, and beneficial, and reformulating products such that they are still appealing to consumers and continue to meet acceptable quality standards is difficult, time-consuming, and expensive. This could result in higher food costs for consumers and a significant and unwarranted impact on the US food supply.

The Safe Color Coalition recommends that, given the extensive review done by FDA and the outcome of the discussions held by the FDA Food Advisory Committee, the FDA continue to confirm that the existing dataset supports the safety of synthetic colors and that there has been no causal link demonstrated to indicate that these colors cause hyperactive behavior in children. In addition, the FDA should recognize the technical benefits of synthetic colors as food additives. The current regulations requiring food products to clearly label colors contained in product marketed in the United States allow consumers to make informed choices and should not be revised at this time.

We appreciate the work of the FDA and the Food Advisory Committee in preparing and reviewing the data and materials which served as the basis for discussion at the March 30-31 meeting. The members of the Safe Color Coalition support the recommendations made by the FDA and would like

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to work with the FDA to address some of the points raised in the discussion, including the need for better exposure estimate and the desire for further studies.

If you have any questions about these comments or wish to discuss these issues further with members of the Safe Color Coalition, please contact Sean Taylor at 202-293-5800 or [staylor@vertosolutions.net](mailto:staylor@vertosolutions.net).

Sincerely,

Colorcon

Consumer Healthcare Products Association (CHPA)

Council for Responsible Nutrition (CRN)

Emerald Hilton Davis

Grocery Manufacturers Association (GMA)

International Association of Color Manufacturers (IACM)

International Food Additives Council (IFAC)

International Pharmaceutical Excipients Council of the Americas (IPEC Americas)

Snack Food Association (SFA)

## REFERENCES

1. CSPI Petition to Ban the Use of Yellow 5 and Other Food Dyes, in the Interim to Require a Warning on Foods Containing Those 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, 2008, FDA Docket 2008.P.0349.0001
2. FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, Orange B, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6
3. (a) McCann D, Barrett A, Cooper A et al. (2007) 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*, 370, 1560-1567; (b) Schab D, Trinh N. (2004) Do Artificial Food Colors Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials. *J Dev Behav Pediatr*. 25, 423-434.
4. <http://www.cfsan.fda.gov/~dms/foodic.html#qa>.
5. Colors that are exempt from certification include pigments derived from natural sources such as vegetables, minerals or animals. Nature derived color additives are typically more expensive than certified colors and may add unintended flavors to foods. Examples of exempt colors include annatto extract (yellow), dehydrated beets (bluish-red to brown), caramel (yellow to tan), beta-carotene (yellow to orange) and grape skin extract (red, green). <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm094211.htm>
6. Newsome, R. L. Food Colors—A Scientific Status Summary by the Institute of Food Technologists Expert Panel on Food Safety and Nutrition. *Food Technology* **1986**, 49-56.
7. *Catalog of Food Colors*; ILSI (Color Committee of the International Life Sciences Institute): Washington, DC, 1983; Vol. 1-3.
8. Food and Drug Administration. Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Foods. Red Book **1982**.
9. Joint FAO/WHO Expert Committee on Food Additives. Specification for the Identity and Purity and Toxicological Evaluation of Food Colors. FAO Nutr. Mtgs. Rept. Ser. No. 38B, WHO Food Add. **1966**, 66 (25).

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10. Joint FAO/WHO Expert Committee on Food Additives. Toxicological Evaluation of Some Food Colors, Emulsifiers, Stabilizers, Anti-Caking Agents and Certain Other Substances. FAO Nutr. Mtgs. Rept. Ser. No. 46A, WHO Food Add. **1969**, 70 (36).
11. Evaluation of Certain Food Additives. 21<sup>st</sup> Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Tech. Rep. Ser. 617, **1978**.
12. Food Advisory Committee Meeting Materials - Interim Toxicology Review Memorandum (Certified Color Additives) September 1, 2010
13. National Institutes of Health. Defined Diets and Childhood Hyperactivity: NIH Consensus Statement. 1982 (January 13-15).
14. FDA CFSAN Website - Food Color Facts <http://vm.cfsan.fda.gov/~lrd/colorfac.html>
15. Quinoline Yellow, Ponceau 4R, Allura Red, Azorubine (carmoisine), Tartrazine, Sunset Yellow
16. Allura Red (FD&C Red No. 40), Tartrazine (FD&C Yellow No. 5), Sunset Yellow (FD&C Yellow No. 6) are approved for use in food in the US; Quinoline Yellow (FD&C Yellow No. 10) is only approved for use in coloring drugs, cosmetics and contact lenses, but not food
17. Food Ingredients and Colors; International Food Information Council (IFIC) and U.S. Food and Drug Administration; November 2004; revised April 2010  
<http://www.fda.gov/Food/FoodIngredientsPackaging/ucm094211.htm>