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MEMORANDUM

April 14, 2011

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: FDA Food Advisory Committee Meeting on Certified Color Additives and Hyperactivity in Children

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On March 30 and 31, 2011, the Food Advisory Committee to the Food and Drug Administration (FDA) held a meeting entitled "Certified Color Additives and Hyperactivity in Children." This memorandum provides a brief summary of pertinent parts of the two-day meeting. Attached to this memorandum are copies of the following: Committee Charge and Questions, FAC Meeting Agenda, Committee Roster, a background document prepared by FDA staff, and a petition submitted by the consumer group Center for Science in the Public Interest (CSPI).

The committee concluded that the scientific evidence does not support a causal relationship between consumption of artificial colors and hyperactivity in children, but called for further research. The committee's recommendation makes it unlikely that FDA will take any regulatory action, such as requiring a warning statement, against artificial color additives.

The Food Advisory Committee thus affirmed the FDA's own conclusions. However, it should be noted that FDA's review of the scientific literature also concluded that artificial color additives may exacerbate symptoms in certain children with hyperactivity:

> Based on our review of the data from published literature, FDA concludes that a causal relationship between exposure to color additives and hyperactivity in children in the general population has not been established. For certain susceptible children with Attention

> Deficit/Hyperactivity Disorder and other problem behaviors, however, the data suggest that their condition may be exacerbated by exposure to a number of substances in food, including, but not limited to, synthetic color additives. Findings from relevant clinical trials indicate that the effects on their behavior appear to be due to a unique intolerance to these substances and not to any inherent neurotoxic properties.

FDA, Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children, p. 13.

Committee Charge

The committee was charged with considering available relevant data on a possible linkage between consumption of certified color additives in food and hyperactivity in children. The committee was also tasked with advising FDA as to what action, if any, is necessary to ensure consumer safety. For the specific questions posed to the committee, please see the attached "Committee Charge and Questions."

Committee Conclusions

The committee concluded that available evidence does not establish a causal relationship between the consumption of artificial color additives and hyperactivity in children. The committee voted against advising FDA to require additional labeling, such as a warning label, on foods containing artificial colors. However, the committee advised that additional studies are warranted.

March 30

Testimony

Mitchell Cheeseman, Ph.D., Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, FDA

Dr. Cheeseman gave a brief overview of the history of the issue, discussing the definition and use of color additives, the petition process, the certification process, and the review process for color additives. He stated that it is the responsibility of the petitioner to address safety issues, and that FDA requires "proof of a reasonable certainty that no harm will result from the proposed use of an additive."

Jessica P. O'Connell, J.D., Office of Chief Counsel, FDA

Ms. O'Connell focused her comments on the labeling of color additives. She explained that FDA does not have the authority to require labeling based on consumer interest alone, and that warning statements are only used to convey material facts about a food. Effects that are widely known or insignificant therefore do not require warning labels.

Michael Jacobson, Ph.D., Executive Director, Center for Science in the Public Interest

Dr. Jacobson discussed the petition filed by CSPI, which calls on FDA to ban 8 of the 9 artificial color additives approved for use in food in the United States. He stated that FDA has for too long ignored the evidence that consumption of artificial color additives causes harm. He asserted that the studies FDA cited in their review of artificial color additives were so flawed they should not have been funded. While acknowledging that the existing data is varied, he argued that since food dyes are not necessary and have no redeeming benefits, they should be removed from the food supply.

Shula Edelkind, (representing the Feingold Association)

Ms. Edelkind challenged existing studies and presented the findings from a Feingold Association-funded study. She stated that existing studies did not test the amounts of artificial colors actually consumed in typical diets, and asserted that the Feingold study demonstrated adverse effects of ingestion of artificial color additives. Ms. Edelkind asserted that natural food dyes, such as those used in the European Union (EU), should be used, and called for a ban on artificial color additives.

Bernie Weiss, Ph.D., University of Rochester

Dr. Weiss discussed the results of a study he conducted, specifically focusing on one of the study subjects – a 34-month old girl. He stated that after consuming artificial food dyes, the subject exhibited target behaviors such as a short attention span, whining, and throwing and breaking things. Dr. Weiss asserted that the evidence points to adverse behavioral effects associated with artificial color additives, and called for their elimination from the food supply.

Discussion Period

The following topics were discussed during the question and answer period:

- Historic approval of color additives and current activity;
- No observed effect versus no observed adverse effect;
- The batch certification process and FDA testing procedures;

- FDA's interactive review process;
- FDA action on petitions;
- Warning statements and allergen labeling;
- Information that qualifies as "material";
- The fact that consumer interest alone is not sufficient for FDA to require labeling;
- Percentage of children sensitive to color additives (varied data);
- Sample size and dosage in studies;
- The distinction between harm and effects;
- FDA's level of authority in mandating data and studies presented;
- Scientific proof of harmful effects versus public health concern;
- Lack of evidence that removal of dyes in EU improved children's health;
- Risk versus benefits of use of color additives;
- Criteria for evaluation of studies; and
- Weighted evidence and integrity of studies.

March 31

Testimony

Sean Taylor, Ph.D., Scientific Director, International Association of Color Manufacturers

Dr. Taylor asserted that there is no causal link between intake of artificial food colors and hyperactivity in children. He criticized both the methodology and the results of the Southampton Study, a recent study by Southampton University in England that found an association between consumption of certain artificial colors (including some not approved for use in food in the U.S.) combined with the preservative sodium benzoate and hyperactivity in children.. Dr. Taylor cited the benefits artificial colors provide to consumers and suggested that the market should decide whether they should continue to be used.

Jason Aungst, Ph.D., Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, FDA

Dr. Aungst discussed the medical definition of Attention Deficit Hyperactivity Disorder (ADHD), and how the disease is viewed by the medical establishment. He then presented a review of scientific data, which he believes indicates that certain children are predisposed to either food intolerance or hyperactivity. He concluded that food colors are not inherently neuro-toxic, but may, when consumed by a predisposed individual, produce negative symptoms. Finally, Dr. Aungst added that current FDA labeling requirements enable personal avoidance on artificial color additives, which must be listed by their specific common or usual name in a food's ingredients declaration.

Public Speakers

Several mothers testified regarding their perceptions of the negative effects of artificial colors on children. They suggested that avoidance of these products improved their children's lives. Another witness called to the committee's attention the disagreement over how ADHD is viewed within the medical establishment. A practitioner of non-western medicine recounted her negative experiences with the artificial color Red #40. Industry representatives encouraged the FDA to base their decision on sound science, and noted that a large portion of the population is not prone to adverse effects from consumption of artificial color additives.

Discussion Period

The following topics were discussed during the question and answer period:

- Ability of individual dyes to breach the blood-brain barrier; and
- Level of public concern regarding artificial color additives (FDA has received 7,900 public comments).

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We trust this information is useful. If you have any questions, please contact Julian Baer at (202) 789-1212 or jbaer@ofwlaw.com.

Attachments (5)

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