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IACM Reiterates FD&C Colors Consumed at Safe Levels

Washington, DC, May 8, 2014 – Ensuring the safety of color ingredients used in the products consumers enjoy – and maintaining the public’s confidence in that safety – is the color industry’s primary goal. The International Association of Color Manufacturers (IACM), which represents both color manufacturers and consumer product companies that use color, understands that the safety of the food supply is of paramount importance to all consumers.

In response to a recent journal publication, IACM reiterates that FD&C colors have been thoroughly tested and are safe for use. Food companies are authorized to use FD&C colors in their products at levels consistent with good manufacturing practices (GMP).

Color additives are required to be approved by FDA and listed in the U.S. Code of Federal Regulations (CFR) before they may be used in products marketed in the U.S. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), a color additive is not to be listed unless data establish that the proposed use of the color additive is safe. Under 21 CFR 70.3(i), an additive is safe only if there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive. To establish with reasonable certainty that an additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, the additive’s toxicological data, and other relevant information, such as published literature, available to the Agency.

FD&C color additives are among the most tested food additives in the world. Additionally, in the US, every batch of FD&C color is analyzed and certified as safe for use by the FDA, and this testing is conducted before the batch can be used in any product sold in the US. FDA maintains acceptable daily intake levels (ADI) and reviews per capita intake levels based on the total pounds of color additive batch-certified by the agency. FDA compares an individual’s estimated daily intake (EDI) of the additive from all food sources to the ADI established by toxicological data as part of the review of the information relied on to support the proposed use of a color additive. At this time, per capita EDIs for the certified colors are below the ADIs established by toxicology studies.

In 2011, the FDA Food Advisory Committee, an expert panel of pediatricians, toxicologists, behavioral scientists, food scientists, and scientists in related fields, met for a two-day meeting to look at all of the available study data exploring color additive intake and hyperactive behavior. The Committee concluded, based on all available evidence, that there is no causal relationship between the intake of color additives and hyperactivity in children. Just earlier this year, FDA published a new method for determining the presence and concentrations of certified food colors in 44 food and beverage products. IACM supports FDA’s attempts to ensure that color additives are being consumed at levels that are safe, particularly for children.

We are confident in reassuring all consumers, including mothers of young children, that FD&C colors are safe ingredients and are used at appropriate levels in finished food products. Our industry remains vigilant about the safety of our products through additional testing and close monitoring of new scientific developments related to color additive safety. We will continue to work closely with regulatory authorities around the world to ensure that food colors are safe.

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The International Association of Color Manufacturers (IACM) is the trade association that represents the manufacturers and end-users of coloring substances that are used in foods, including natural and synthetic colors.