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IACM Pleased with Results of FDA Exposure Study on FD&C Colors

WASHINGTON, D.C. (August 27, 2014) – The International Association of Color Manufacturers (IACM) is pleased with the US Food and Drug Administration’s findings that all exposure estimates for FD&C colors are well below the acceptable daily intake levels previously identified by the FDA. The study estimated exposure for each FD&C color additive for the US population aged 2 years or more, and for specific age groups including children aged 2-5 years, and teenage boys aged 13-18 years using a peer-reviewed HPLC method developed by the FDA. The FDA unveiled the results of the study in a poster displayed at the American Chemical Society’s annual meeting in San Francisco earlier this month.

This study is the result of the recommendation by the FDA Food Advisory Committee (FAC), convened in March 2011. FDA requested that the FAC consider the available relevant data on a possible association between children’s consumption of FD&C color additives in food and behavioral effects. The FAC concluded that a causal link between children’s consumption of FD&C color additives and behavioral effects had not been established, and a warning label was unnecessary to ensure the safe use of the color additives. However, the advisory committee recommended further research, including a comprehensive exposure assessment for these color additives, especially for children.

IACM understands that FDA will also be estimating exposure using 14-day food consumption data as well as reassessing the safety studies conducted on FD&C color additives to determine if additional safety studies are needed before issuing a publication in a peer reviewed journal early next year.

“We are pleased that FDA has undertaken such a comprehensive study on FD&C colors additives and confirmed that exposure to these colors is well below the acceptable daily intake levels,” said IACM Executive Director Sarah Codrea. “This work, in combination with recent work undertaken by the European Food Safety Authority (EFSA) also finding that consumer exposure estimates are well below acceptable daily intake levels, reinforces our industry’s view that when used at the levels needed to achieve an appropriate technical effect, these colors do not pose safety concerns.”

“We also look forward to hearing more on the results and FDA’s next steps from FDA chemist Diana Doell, Ph.D., who will be presenting on this topic at IACM’s upcoming [Global Color Conference](#) in Chicago, IL,” Codrea continued.

IACM will continue to support efforts to maintain the safe use of colors in the United States and globally. The color industry takes its responsibility for consumer safety seriously and has sponsored many safety studies, the results of which have been evaluated by the FDA and international regulatory bodies, including JECFA and EFSA. These studies continue to confirm the safety of synthetic colors, and as a result various coloring dyes have been approved for use in food, beverage, and other products globally.

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The International Association of Color Manufacturers (IACM) is a trade association that represents the manufacturers and end-users of coloring substances that are used in foods, drugs, and cosmetics. Our association includes members that produce and use both certified and exempt from certification colors. For more information on our services and products, please visit www.iacmcolor.org.

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