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**International Color Manufacturers Association (IACM)**
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Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

October 25, 2006

Dear Administrator:

On behalf of the International Color manufacturers Association (IACM), I wish to thank the Environmental Protection Agency (EPA) for their comments on the test plan and robust summaries on 4,5-dihydro-5-oxo-1-(4 sulfophenyl)-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid trisodium salt, FD&C Yellow No. 5, Tartrazine (CAS No 1934-21-0).

The IACM serves is an industry consortium to coordinate testing activities for chemical substances under the Chemical Right-to-Know Program. Since 2000, the companies that are current members of IACM have supported the collection and review of available test data, development of test plans and robust summaries, and conducted additional testing.

Based on our initial recommendations and the peer-reviewed comments of the EPA, IACM is pleased to submit the following revised test plan and robust summaries for this substance. The revised test plan and robust summaries contain additional data on existing studies and the results of additional toxicity studies that are related to the questions and comments made by the EPA in its letter dated 05/20/2005. This letter contains responses to the specific comments made by the EPA. These responses taken together with the inclusion of new study data and other information constitute the key changes to the original test plan and robust summaries.

Based on these additional data, the IACM concludes that the current test plan and robust summaries for this food color is now complete. The experimental and model data for physiochemical properties, environmental fate, ecotoxicity, and human health endpoints are consistent and provide a comprehensive basis upon which to evaluate the hazard potential of FD&C Yellow No. 5. The U.S. Food and Drug

Administration approved FD&C Yellow No. 5 for use in food (CFR 21, Part 74.340).
In an EPA letter dated 19 October 2001 concerning HPV-sponsored chemicals that are recognized as GRAS by the Food and Drug Administration, it was pointed out that:

" It may well be, on the basis of experience gained over years of use, that most of the substances have little compelling evidence suggesting that testing is needed in the context of the HPV Challenge Program. Nonetheless, while this line of reasoning could have been used to support the recommendation not to test the substances in this category, the information was only provided as background; few examples, and no actual data, were cited."

Without prior guidance from EPA, the International Color Manufacturers Association felt responsible to report endpoint data for this substance. Most of these data have already been provided to the US Food and Drug Administration during their evaluation of FD&C Yellow No. 5 as a food additive.

Based on the long history of use of FD&C Yellow No. 5 as a food additive, the hazard assessments performed by the US FDA, and the current regulatory status for the addition of this substance to the food supply, there is no compelling evidence that this substance should be further tested for physiochemical properties and human health endpoints in the EPA Chemical "Right to Know" Program. We do, however, maintain that data on the environmental fate and ecotoxicity are relevant to the HPV Challenge program. In this context, we have sponsored the collection of additional ecotoxicity data to provide a robust database on ecotoxicity endpoints. We consider that the test plan and robust summaries for FD&C Yellow No. 5 are final and have no plans to provide additional data. The EPA comprehensive comments provided the necessary guidance to complete the test plan for this category. The collaboration between the IACM and the Environmental Protection Agency in the Chemical "Right to Know" Program has produced a hazard database that will be useful to the public for decades to come. Thank you for the opportunity to participate in such a program.

If you have any questions or comments concerning the contents of this letter, please feel free to contact me at any time (202-331-2325) or tadams@therobertsgroup.net.

Best regards,

Timothy B. Adams, Ph.D.

Technical Contact Person for IACM