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VIA E-MAIL: grossm@cder.fda.gov

April 7, 2005

Ms. Mary C. Gross
Center for Drug Evaluation and Research (HFD-400)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Use of Color on Pharmaceutical Product Labels, Labeling and Packaging, Public Hearing [Docket No. 2005N-0036]

Dear Ms. Gross:

In response to the Food and Drug Administration, HHS, request for comments on *Use of Color on Pharmaceutical Product Labels, Labeling and Packaging*, Public Hearing [Docket No. 2005N-0036], American Regent, Inc., strongly opposes industry wide mandatory color-coding. We do, however, support the use of color differentiation with a company's product line. That should be a decision that should be made by the individual manufacturer and not by the FDA.

A standardized system of color-coding may create an association between color and a drug product. This association may lead to "recognizing" a product label rather than accurately reading a product label. This may cause a greater number of medication errors.

Color differentiation, where color is used to help distinguish one item from another or to make particular parts of a label stand out, may be used to *prevent* errors. Color is appealing to the eye and draws our attention.

American Regent recognizes that medication errors due to improper product identification are a rising concern throughout the healthcare community. However, we believe that mandatory color-coding or removal of all color from the products is not the answer to this difficult problem.

We thank you for this opportunity to express our position.

Very truly yours,

A handwritten signature in black ink, appearing to read "Walter Tozzi".

Walter Tozzi, R.Ph., M.S., M.B.A.
Director of Marketing and Professional Services

WT:jm