DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Louise M. Slaughter
House of Representatives
Washington, D.C. 20515-3228

JUL 1 2003

Dear Ms. Slaughter:

Thank you for the letter of January 29, 2003, urging the Food and Drug Administration (FDA or the Agency) to ban FD&C Yellow No. 5 and 6. We are sorry to hear of your recent onset of allergies, including hives, asthma, and headaches, and hope that these problems are under control.

You stated that your doctors have told you that these problems are linked to the dyes in products you consume every day. It is difficult to draw definitive conclusions about the cause of allergic reactions because of the multitude of ingredients used in food and other products, the fact that some foods themselves cause allergic responses, and the variability of patients' responses when exposed to the same ingredient under different circumstances. We encourage you to have your doctors submit an adverse reaction report to FDA's MedWatch program, with documentation of the basis for their conclusions. Information on reporting adverse reactions to MedWatch is available on the Agency's website at: *http://www.fda.gov/medwatch/index.html.* We have enclosed a MedWatch form for your convenience.

A citizen petition is pending before FDA (Docket 01P-0345) requesting that FD&C Yellow No. 5 be removed from the lists of approved color additives for foods and drugs. The petition is currently under active consideration in FDA's Center for Food Safety and Applied Nutrition. As discussed with your staff, we will forward your letter to Docket 01P-0345, where it will be considered as the Agency evaluates the petition.

By way of background, under section 721 of the Federal Food, Drug, and Cosmetic (FD&C) Act, manufacturers or users of color additives must provide proof of a reasonable certainty that no harm will result from their intended uses of a color additive before going to market. When FDA makes a decision to list a color additive permanently for use in foods, drugs, cosmetics, or medical devices, it bases that decision on a fair evaluation of all the data before it, concerning the safety and suitability of the color additive under its intended conditions of use. The Agency, after such an evaluation of the data, listed Yellow No. 5 for use in food and ingested drugs in 1969, and for use in externally applied drugs and cosmetics in 1985, based on studies in laboratory animals fed high doses of the color additive. The listing for Yellow No. 5 can be found in the enclosed

LET

01P-0345

copies of Title 21 of the *Code of Federal Regulations,* section 74.705 (foods), section 74.1705 (drugs), and section 74.2705 (cosmetics).

FD&C Yellow No. 6 was listed for use in food, drugs, and cosmetics in 1986, following an evaluation of all of the data before the Agency, including a battery of lifetime ingestion studies. FDA also noted reports in the scientific and medical literature of rare adverse reactions to FD&C Yellow No. 6.

FDA recognizes that many individuals may be sensitive or allergic to one or more common foods or food ingredients, but that such foods or ingredients may have no adverse effect on the overwhelming majority of consumers. To ensure maximum flexibility in producing an ample food supply that provides a choice of products for each consumer, FDA's policy has allowed the use of substances that are shown to be safe for the general population, but that may, nevertheless, cause adverse response in a small sub-population of consumers. The key to this policy is that such foods must be appropriately labeled.

Section 403(i) of the FD&C Act requires the label of a food that is made from more than one ingredient to bear the common or usual name of each ingredient in the food. Thus, when FD&C Yellow No. 5 or No. 6 is added to food, it must be specifically declared in the ingredient statement of the food to which it is added (except for butter, cheese, and ice cream, which are exempted under section 403(k) of the FD&C Act.)

The hypothesis that exposure to food additives can lead to Attention Deficit Disorder (ADD) and other behavioral problems in children was advanced in the United States during the late 1960's and was tested by several studies during the 1970's. This hypothesis was the subject of a Congressional hearing in 1975. The results of the various studies were examined by a panel of experts under the National Advisory Committee on Hyperkinesis and Food Additives in 1980, and by a separate panel of the National Institutes of Health in 1982. Many studies at that time and since then have explored this hypothesis, but no sound studies have definitively proved it. Many studies show no correlation between exposure to color additives and ADD, and those that do show some correlation tend to rely on anecdotal observations. Should the Agency receive scientifically sound evidence that there is a correlation between ingestion of color additives and hyperactivity in children, FDA will take appropriate action. The Agency will continue to monitor the scientific literature and reports of adverse reactions (including the British study that you cited in your letter) to ensure that the food supply is safe.

More information on color additives can be found on FDA's website at:
www.cfsan.fda.gov/~dms/col-toc.html.

Thank you for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

Jane K. Chopko

for Amit K. Sachdev
Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch
5630 Fishers Lane, HFA-305
Rockville, MD 20852
Docket 01P-0345