

December 14, 2010

Director, Regulations and Rulings Division
Alcohol and Tobacco Tax and Trade Bureau
Post Office Box 14412
Washington, DC 20044-4412

RE: TTB 2010-0008; Notice No. 111 – Disclosure of Cochineal Extract and Carmine in the Labeling of Wines, Distilled Spirits, and Malt Beverages

To Whom It May Concern:

On behalf of the International Association of Color Manufacturers (IACM), I am pleased to submit the following comments in response to the proposed rule, “Disclosure of Cochineal Extract and Carmine in the Labeling of Wines, Distilled Spirits, and Malt Beverages” 75 Fed. Reg. 212 (November 3, 2010). IACM is the international association of color additive manufacturers. IACM’s members manufacture and market colors that are incorporated into a wide range of foods, drugs and cosmetics. IACM members also produce colors that are currently permitted in foods and beverages certified as organic under the National Organic Program (NOP).

History of Use of Cochineal Extract and Carmine

Cochineal, carmine and cochineal extract have a long history of safe use. Discovered in Mexico by Spanish explorers in the 16th century, cochineal is now used in a variety of fruit drinks, candy, yogurt and some processed foods. Cochineal extract and carmine are listed for use in foods in amounts consistent with good manufacturing practice in 21 CFR 73.100 (2005). Food uses for carmine include popsicles, seafood, cheese, juices, alcohol beverages, cherries in fruit cocktails and strawberry milkshakes. Carmine is also used in a number of cosmetic products, including lipsticks, blush, nail polish and hair colors.

Labeling of Food and Cosmetic Products Containing Carmine and Cochineal Extract

On January 5, 2009, the Food and Drug Administration (FDA) published a final rule in the Federal Register that amended regulations to require the declaration of the color additives cochineal extract and carmine on the label of all food and cosmetic products in the United States (74 FR 207). The final rule is effective January 5, 2011. IACM did not oppose the requirement to declare cochineal extract and carmine in the labeling of products containing these color additives. Because beverage producers already voluntarily label their products, IACM concurred with FDA’s conclusion that the proposed labeling requirement would provide sensitized consumers sufficient information to avoid products containing these color additives.

Although carmine is widely consumed in foods and beverages, it has been rarely implicated in adverse reactions experienced by consumers. The typical low levels of carmine in foods and beverages limits oral exposure to this color additive. Thus, the likelihood of sensitization to carmine by ingestion is rather low. In many of the reported cases, the cause of sensitization to carmine was

topical exposure from the use of carmine-containing cosmetics or occupational exposure to carmine and not from ingestion of carmine-containing foods and beverages. Following sensitization, affected individuals would be sensitive to carmine and the amounts present in foods and beverages could elicit allergic reactions. It is not known whether all individuals with carmine sensitivity induced through topical use such as cosmetics containing the ingredients are sensitive to the ingestion of carmine in foods.

The IACM did take exception to any requirements the FDA might contemplate regarding the use of the term “insect” as the source of origin when labeling the use of carmine and cochineal. We further concurred with the agency’s observations that “information on the origin of these color additives is readily available to those consumers who want it. This information is provided in standard dictionaries under the definitions for the words “cochineal” and “carmine.” (emphasis added). IACM would also take exception to any labeling requirements by TTB as to the source of origin.

IACM does not oppose that alcohol beverage products containing the color additive cochineal extract or carmine must declare the presence of the additive using its respective common or usual name “cochineal extract” or “carmine”. Furthermore, IACM would support consistency with the recent label disclosure requirements issued by the FDA.

IACM asks for your consideration of extending the implementation date to a longer period, possibly 180-days after the date of the final rule, as opposed to the currently proposed 90-days. We continue to support voluntary labeling and do not anticipate that any additional costs of implementation will have a substantial economic impact on color additive manufacturers. However, we do believe that although there may be few alcohol beverage products containing cochineal, the smaller number of products does not lessen the burden of label reformulation by individual companies to meet the new requirements. Many small businesses are struggling to keep afloat in a sluggish economy with limited resources. IACM asks that TTB be sensitive to the unique economic times and provide a more reasonable transition period.

We are grateful for the opportunity to comment on this proposal and would be happy to provide any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Cox', written in a cursive style.

John Cox
General Counsel