FDA Requires Label Declaration of Color Additives --
Cochineal Extract and Carmine

On January 5, 2009, the Food and Drug Administration (“FDA”) published a final rule amending its color additive regulations for cochineal extract and carmine to require that these additives be declared by their common or usual names rather than as “artificial color” on the labels of all food and cosmetic products that contain them. The purpose of the rule is to enable individuals with sensitivities to cochineal extract and carmine to avoid products containing these additives, as well as to enable consumers and healthcare professionals to more quickly identify sensitivities to these additives. The final rule takes effect January 5, 2011.

Cochineal is a dye made from dried and ground female bodies of the insect Dactylopius coccus costa, and contains approximately 10% carminic acid. Carmine is the aluminum or calcium-aluminum lake formed by precipitating carminic acid onto an aluminum hydroxide substrate using aluminum or calcium cation as the precipitant. Carmine is used in foods such as popsicles, strawberry milk drinks, port wine cheese, artificial crab/lobster products, cherries in fruit cocktails, and lumpfish eggs/caviar, and in a range of cosmetic products. Cochineal extract is used in fruit drinks, candy, yogurt, and some processed foods; it is not permitted for use as a color additive in cosmetics.

In 2006, FDA issued a proposed rule to mandate more specific labeling of the presence of these additives in response to reports of severe allergic reactions, including anaphylaxis, to cochineal extract and carmine-containing food and cosmetics. The proposed rule also responded, in part, to a citizen petition from the Center for Science in the Public Interest (“CSPI”), which requested that FDA take action to protect consumers allergic to these two additives. Previously, FDA regulations permitted the declaration of these additives by general language such as “Artificial Color” or “Color Added.”

The final rule adopts the proposed rule published by FDA on January 30, 2006. Specifically:

- FDA amends its color additive regulations in 21 C.F.R. § 73.100 to require the label of foods intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine to specifically declare the presence of these additives by listing the common or usual name, “cochineal extract” or “carmine” in the statement of ingredients.
- FDA amends its food labeling regulations in 21 C.F.R. § 101.22(k)(2) to disallow generic declaration of color additives for which individual declaration is required by applicable regulations in part 73.

FDA amends the color additive regulation governing the use of carmine in cosmetics -- 21 C.F.R. § 73.2087 -- to require the specific declaration of the presence of carmine prominently and conspicuously at least once in the labeling.

Legal authority for FDA regulations prescribing the safe use of color additives in food, drugs, and cosmetics comes from section 721(b) of the Federal Food, Drug and Cosmetic Act (“FDCA”). Additionally, FDA invokes section 403(x) of the FDCA, which authorizes the agency to require disclosure of a coloring determined by regulation to be, bear, or contain a food allergen (other than a major food allergen).

The regulations, as amended by this final rule, will be effective January 5, 2011. All covered products “initially introduced or initially delivered for introduction into interstate commerce” on or after that date must comply with the rule.³ Product on its way to customers or already sitting on retail shelves at that time will not need to be compliant. Although the effective date is still “some time away, FDA encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover.”⁴

Finally, any person who is adversely affected by the final rule may file objections with FDA within 30 days of the issuance of the final rule -- by February 4, 2009. An objecting party must specify with particularity the provision of the final rule it finds objectionable, state the grounds for its objections, and request a public hearing upon such objections.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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