

FDA Revises Color Additives Requirements

The U.S. Food and Drug Administration (FDA) has revised its requirements for cochineal extract and carmine. This regulation is effective January 5, 2011. The names of these color additives will need to be declared on the labels of all food and cosmetic products that contain them. This final rule responds to reports of severe allergic reactions, including anaphylaxis, to foods and cosmetics containing these color additives and will allow consumers who are allergic to them to identify and thus avoid products that contain them

All affected products initially introduced or delivered for introduction into interstate commerce on or after this date shall fully comply, except as to any provisions that may be stayed by the filing of proper objections. Voluntary compliance with this final regulation, including making any required labeling changes, may begin immediately.

21 CFR Parts 73 and 101 are therefore amended as follows:

Section	Revisions to 21 CFR Part 73
<p>§ 73.100 Cochineal extract; carmine</p>	<p>Revise paragraph (d) to read as follows:</p> <p><i>(d) Labeling requirements. (1) The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of Sec. 70.25 of this chapter. (2) The label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine shall specifically declare the presence of the color additive by listing its respective common or usual name, "cochineal extract" or "carmine," in the statement of ingredients in accordance with Sec. 101.4 of this chapter.</i></p>
<p>§ 73.2087 Carmine</p>	<p>Revise paragraph (c) to read as follows:</p> <p><i>(c) Labeling. (1) The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of Sec. 70.25 of this chapter. (2) Cosmetics containing carmine that are not subject to the requirements of Sec. 701.3 of this chapter shall specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. For example: "Contains carmine as a color additive."</i></p>
Section	Revision to 21 CFR Part 101
<p>§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives</p>	<p>Revise paragraph (k)(2) to read as follows:</p> <p><i>(2) Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of this chapter to be declared by their respective common or usual names may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with -----" or "----- color," the blank to be filled in with the name of the color additive listed in the applicable regulation in part 73 of this chapter.</i></p>

[Full text of final rule in Federal Register](#)

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