

Guidance for Industry

Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives Small Entity Compliance Guide

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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I. Introduction

On January 5, 2009, the Food and Drug Administration (FDA) published a final rule in the Federal Register that amended its regulations to require the declaration by name 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 on January 5, 2011, although FDA encourages manufacturers to have new labels printed that are in compliance with the new requirements so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements of the January 5, 2009 final rule set forth in 21 CFR parts 73 and 101 concerning the requirement for the declaration by name of the color additives cochineal extract and carmine on the label of all food and cosmetic products in the United States. These regulations are binding and have the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Division of Petition Review in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Questions and Answers

1. Is the presence of cochineal extract or carmine in food products intended for human use required to be declared on the label?

Yes. Cochineal extract or carmine must be declared on the label of all food products intended for human use, including butter, cheese, and ice cream, when present in the food (21 CFR 73.100 (d)(2)).

2. How must the presence of cochineal extract or carmine be listed on the label?

Cochineal extract or carmine must be listed on the label by its respective common or usual name, "cochineal extract" or "carmine." (21 CFR 73.100 (d)(2)).

3. Where must "cochineal extract or carmine be declared on the label?

Cochineal extract or carmine must be declared in the statement of ingredients in accordance with 21 CFR 101.4 (21 CFR 73.100 (d)(2)).

4. Are cosmetics containing carmine that are not subject to the requirements of 21 CFR 701.3 required to declare the presence of carmine on the label?

Yes. (21 CFR 73.2087 (c)(2)).

5. How must carmine be declared on the label of a cosmetic that is not subject to the requirements of 21 CFR 701.3?

Carmine must be declared prominently and conspicuously at least once in the labeling (21 CFR 73.2087 (c)(2)).

6. Can you provide an example of a label statement for a cosmetic that contains carmine?

The presence of carmine may be declared on the label in the following manner: "Contains carmine as a color additive." (21 CFR 73.2087 (c)(2)).

7. Can color additives for which individual declarations are required by applicable regulations in 21 CFR part 73 still be declared on the label as "Artificial Color," "Artificial Color Added," or "Color Added?"

No. These color additives must be declared by their respective common or usual names. (21 CFR 101.22(k)(2)).