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[Code of Federal Regulations]
[Title 21, Volume 1]
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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A--GENERAL

[PART 70 -- COLOR ADDITIVES](#)

Subpart B--Packaging and Labeling

Sec. 70.25 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by this part and parts 71, 73, 74, 80, and 81 of this chapter. In addition to all other information required by the act, labels for color additives, except those in a form suitable for coloring the human body, shall state:

human body, shall state:

(1) The name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture.

(2) A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."

(3) Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.

(4) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of a color additive, the label shall in addition provide directions for use of the color additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limitations shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: "Do not use in products used in the area of the eye"; "Do not use for coloring drugs for injection."

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

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