Food and Drug Administration, HHS

§ 73.1100 Cochineal extract; carmine.  
(a) Identity and specifications. (1) The color additives cochineal extract and carmine shall conform in identity and specifications to the requirements of §73.100(a) (1) and (2).  
(2) Color additive mixtures for drug use made with carmine and cochineal extract may contain only those carmines that are exempt from the certification requirements of section 721(c) of the act.

§ 73.1085 Caramel.  
(a) Identity and specifications. (1) The color additive caramel shall conform in identity and specifications to the requirements of §73.85(a) (1), (2), and (3) and (b).  
(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.  
(b) Uses and restrictions. Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.  
(c) Labeling requirements. The labeling of the color additive carmine may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

§ 73.1095 β-Carotene.  
(a) Identity and specifications. (1) The color additive β-carotene shall conform in identity and specifications to the requirements of §73.95(a)(1) and (b).  
(2) The diluents in color additive mixtures for drug use containing β-carotene are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring ingested drugs.  
(b) Uses and restrictions. The color additive β-carotene may be safely used in coloring ingested drugs generally in amounts consistent with good manufacturing practice.  
(c) Labeling requirements. The labeling of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of §70.25 of this chapter.

§ 73.1075 Canthaxanthin.  
(a) Identity and specifications. (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of §73.75(a)(1) and (b).  
(2) Color additive mixtures for ingested drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.  
(b) Uses and restrictions. Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.  
(c) Labeling requirements. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(a) Identity. (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytol ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) Specifications. Potassium sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

- Moisture, not more than 5.0 percent.
- Nitrogen, not more than 5.0 percent.
- pH of 1 percent solution, 9 to 11.
- Total copper, not less than 4 percent and not more than 6 percent.
- Free copper, not more than 0.25 percent.
- Iron, not more than 0.5 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 5 parts per million.
- Ratio, absorbance at 405 μm to absorbance at 630 μm, not less than 3.4 and not more than 3.9.
- Total color, not less than 75 percent.

(c) Uses and restrictions. Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied drugs.

- Volatile matter (at 34.6 °C for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.
- Residue on ignition, not more than 0.4 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 3 parts per million.
- Iron (as Fe), not more than 25 parts per million.
- 1,3-dihydroxy-2-propanone, not less than 98 percent.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.