

§ 73.1030

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The labeling of the color-additive 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 requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1030 Annatto extract.

(a) *Identity and specifications.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 73.30(a)(1) and (b).

(2) Color additive mixtures for drug use made with annatto extract 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.* Annatto extract may be safely used for coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in § 73.30(a)(1)(ii) of this chapter.

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(d) *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.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 36994, July 19, 1977]

§ 73.1070 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate (CaCO₃).

(2) Color additive mixtures for drug use made with calcium carbonate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the United States Pharmacopeia XX (1980).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *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.

(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.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 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.

(d) *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.

§ 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) *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 requirement of section 721(c) of the act.

§ 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 drugs generally, including those intended for use in the area of the eye, 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.

(d) *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.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 33722, July 1, 1977]

§ 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) and (b).

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

(b) *Uses and restrictions.* Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* 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 § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives 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.

§ 73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity.* (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytyl 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