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.

(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.

§73.1095 β-Carotene.

(a) Identity and specifications. (1) The color additive β-carotene shall conform in identity and specifications to the requirements of §73.75(a)(1) and (b).

(b) Uses and restrictions. The color additive β-carotene may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(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).

(b) Uses and restrictions. Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1075 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).

(b) Uses and restrictions. Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1070 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.

§73.1065 Citrus red no. 2.

(a) Identity and specifications. (1) The color additive citrus red no. 2 shall be an intense yellow color prepared by the decomposition of β-carotene and shall be of a purity such that it will meet the specifications for color additive mixtures for drug use.

(b) Uses and restrictions. The color additive citrus red no. 2 may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1060 Brilliant blue FCF.

(a) Identity and specifications. (1) The color additive brilliant blue FCF shall conform to the specifications for color additive mixtures for drug use.

(b) Uses and restrictions. Brilliant blue FCF may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1050 Red iron oxide.

(a) Identity and specifications. (1) The color additive red iron oxide shall conform to the requirements of §73.75(a)(1) and (b).

(b) Uses and restrictions. Red iron oxide may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1045 Violet no. 2.

(a) Identity and specifications. (1) The color additive violet no. 2 shall conform to the requirements of §73.75(a)(1) and (b).

(b) Uses and restrictions. Violet no. 2 may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1040 Brilliant blue 4B.

(a) Identity and specifications. (1) The color additive brilliant blue 4B shall be a bright blue color capable of being dispersed in water.

(b) Uses and restrictions. Brilliant blue 4B may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.

§73.1035 Carminic acid.

(a) Identity and specifications. (1) The color additive carminic acid shall be a red color extractable from the body of the female red spider, I. p. karschni, in a manner prescribed by the Food and Drug Administration.

(b) Uses and restrictions. Carminic acid may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(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.