Food and Drug Administration, HHS

§ 73.1030

oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500–550 °F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

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

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

(5) 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 label 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.


§ 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