

Effective date. This amendment shall become effective on August 7, 1974.

[SEAL] VERNON D. ACREE,
Commissioner of Customs.

Approved: July 29, 1974.

DAVID R. MACDONALD,
Assistant Secretary
of the Treasury.

[FR Doc.74-17952 Filed 8-6-74;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 8—COLOR ADDITIVES

Chromium-Cobalt-Aluminum Oxide
Pigment

The Commissioner of Food and Drugs, having evaluated the data in a petition (CAP 12) filed by Davis and Geck, Division of American Cyanamid Co., Danbury, CT 06813, and other relevant material, finds that chromium-cobalt-aluminum oxide pigment is safe under the conditions prescribed in this order for use in coloring linear polyethylene surgical sutures, U.S.P., for use in general surgery and that certification is not necessary for the protection of the public health.

Chromium-cobalt-aluminum oxide is currently provisionally listed in § 8.501 (f) (21 CFR 8.501(f)) for use in polyethylene surgical sutures only. There are no other color additive-petitions or progress reports, as required by the color additive regulations (21 CFR Part 8), for the use of chromium-cobalt-aluminum oxide in drugs. Accordingly, chromium-cobalt-aluminum oxide is being deleted from § 8.501(f), effective on the effective date of this order.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403; 21 U.S.C. 376 (b), (c) and (d)) and the transitional provisions accompanying the Color Additive Amendments of 1960 (sec. 203, 74 Stat. 404-407; 21 U.S.C. 376 note) and under authority delegated to the Commissioner (21 CFR 2.120), Part 8 is amended as follows:

§ 8.501 [Amended]

1. In § 8.501(f) by deleting "Chromium-cobalt-aluminum oxide" from the list of color additives.

2. By adding the following new section to Subpart F:

§ 8.6010 Chromium - cobalt - aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3 , 34-37 percent.

Cobalt, calculated as CoO , 29-34 percent.

Aluminum, calculated as Al_2O_3 , 29-35 percent.

Lead (as Pb), not more than 30 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 N hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, 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 U.S.P.

(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 Federal Food, Drug, and Cosmetic Act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing order may at any time on or before September 6, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order shall become effective October 7, 1974, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403; 21 U.S.C. 376 (b), (c), and (d)) and the transitional provisions accompanying the Color Additive Amendments of 1960 (Sec. 203, 74 Stat. 404-407; 21 U.S.C. 376 (note))

Dated: July 31, 1974.

SAM D. FINE,
Associate Commissioner
for Compliance.

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