§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation is effective for other uses.

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in part 74 of this chapter. The Commissioner’s order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.
the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

#### Subpart A—Foods

Sec.  
73.1 Diluents in color additive mixtures for food use exempt from certification.  
73.30 Annatto extract.  
73.35 Astaxanthin.  
73.37 Astaxanthin dimethyl disuccinate.  
73.40 Dehydrated beets (beet powder).  
73.50 Ultramarine blue.  
73.75 Canthaxanthin.  
73.85 Caramel.  
73.90 β-Apo-8′-carotenal.  
73.95 β-Carotene.  
73.100 Cochineal extract; carmine.  
73.125 Sodium copper chlorophyllin.  
73.140 Toasted partially defatted cooked cottonseed flour.  
73.160 Ferrous gluconate.  
73.165 Ferrous lactate.  
73.169 Grape color extract.  
73.170 Grape skin extract (enocianina).  
73.185 Haematococcus algae meal.  
73.200 Synthetic iron oxide.  
73.205 Fruit juice.  
73.260 Vegetable juice.  
73.275 Dried algae meal.  
73.285 Tagetes (Aztec marigold) meal and extract.  
73.300 Carrot oil.  
73.315 Corn endosperm oil.  
73.340 Paprika.  
73.345 Paprika oleoresin.  
73.350 Mica-based pearlescent pigments.  
73.352 Paracoccus pigment.  
73.355 Phaffia yeast.  
73.450 Riboflavin.  
73.500 Saffron.  
73.575 Titanium dioxide.  
73.585 Tomato lycopene extract; tomato lycopene concentrate.  
73.600 Turmeric.  
73.615 Turmeric oleoresin.

#### Subpart B—Drugs

Sec.  
73.1001 Diluents in color additive mixtures for drug use exempt from certification.  
73.1010 Alumina (dried aluminum hydroxide).  
73.1015 Chromium-cobalt-aluminum oxide.  
73.1025 Ferric ammonium citrate.  
73.1030 Annatto extract.  
73.1070 Calcium carbonate.  
73.1075 Canthaxanthin.  
73.1085 Caramel.  
73.1095 β-Carotene.  
73.1100 Cochineal extract; carmine.  
73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).  
73.1150 Dihydroxyacetone.  
73.1162 Bismuth oxychloride.  
73.1200 Synthetic iron oxide.  
73.1298 Ferric ammonium ferrocyanide.  
73.1299 Ferric ferrocyanide.  
73.1326 Chromium hydroxide green.  
73.1327 Chromium oxide greens.  
73.1329 Guanine.  
73.1350 Mica.  
73.1550 Talc.  
73.1575 Titanium dioxide.  
73.1645 Aluminum powder.  
73.1646 Bronze powder.  
73.1647 Copper powder.  
73.1991 Zinc oxide.

#### Subpart C—Cosmetics

Sec.  
73.2030 Annatto.  
73.2085 Caramel.  
73.2087 Carmine.  
73.2095 β-Carotene.  
73.2110 Bismuth citrate.  
73.2120 Disodium EDTA—copper.  
73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).  
73.2150 Dihydroxyacetone.  
73.2162 Bismuth oxychloride.  
73.2180 Guaiaculene.  
73.2190 Henna.  
73.2250 Iron oxides.  
73.2298 Ferric ammonium ferrocyanide.  
73.2299 Ferric ferrocyanide.  
73.2326 Chromium hydroxide green.  
73.2327 Chromium oxide greens.