

color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 22675, May 26, 1978; 52 FR 49586, Dec. 31, 1987]

§ 70.51 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of part 14 of this chapter, and particularly subpart H of that part.

§ 70.55 Request for scientific studies.

The Commissioner will consider requests by any interested person who desires the Food and Drug Administration to conduct scientific studies to support a petition for a regulation for a color additive. If favorably acted upon, such studies will be limited to pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its identi-

fication and determination in foods, drugs, or cosmetics, as the case may be. All requests for such studies shall be accompanied by the fee prescribed in § 70.19.

PART 71—COLOR ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.

- 71.1 Petitions.
- 71.2 Notice of filing of petition.
- 71.4 Samples; additional information.
- 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.
- 71.15 Confidentiality of data and information in color additive petitions.
- 71.18 Petition for exemption from certification.

Subpart B—Administrative Action on Petitions

- 71.20 Publication of regulation.
- 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.
- 71.25 Condition for certification.
- 71.26 Revocation of exemption from certification.
- 71.27 Listing and exemption from certification on the Commissioner's initiative.
- 71.30 Procedure for filing objections to regulations.
- 71.37 Exemption of color additives for investigational use.

AUTHORITY: 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b-360f, 360h-360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

SOURCE: 42 FR 15639, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 71.1 Petitions.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. The petition shall be submitted in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product). If any part of the material submitted is