§ 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 and its identification 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

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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.


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 in a foreign language, it shall be accompanied by an accurate and complete English translation. The petitioner shall state the post-office address in the United States to which published notices or orders issued or objections filed pursuant to section 721 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted the information. Any reference to published information offered in support of a color additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

<table>
<thead>
<tr>
<th>Name of petitioner</th>
<th>____________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-office address</td>
<td>____________________________</td>
</tr>
</tbody>
</table>

(Date)
Petitioner submits this pursuant to section 721(h)(l) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive as suitable and safe for use in or on subject to the conditions that

(Petitioner may propose a listing for general use in food, drugs, or cosmetics or, if such general listing is not believed suitable and safe, the petitioner shall describe the conditions under which he believes the additive can be safely used and for which it will be suitable. These conditions may include tolerance limitations, specifications as to the manner in which the additive may be added or used, and directions and other labeling or packaging safeguards that should be applied. The level of use proposed should not be higher than reasonably required to accomplish the intended color effect.)

Attached hereto, in triplicate (quadruplicate, if intended uses include uses in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the color additive, including chemical identity and composition of the color additive, its physical, chemical, and biological properties, and specifications prescribing its component(s) and identifying and limiting the reaction byproducts and other impurities.

The petition shall contain a description of the chemical and physical tests relied upon to identify the color additive and shall contain a full description of the methods used in, and the facilities and controls used for, the production of the color additive. These shall establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls, within reasonable limits, that do not affect the characteristics of the substance or the reliability of the controls may be specified.

The petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation of any straight color, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common or usual name and its complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition.

Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packaging operations for a color additive, the petitioner shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the color additive, the expiration period that will be employed as well as any packaging and labeling precautions needed to preserve stability.

B. The amount of the color additive proposed for use and the color effect intended to be achieved, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the color additive. If the color effect results or may reasonably be expected to result from use of the color additive in packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

Typewritten or other draft-labeling copy will be accepted for consideration of the petition provided final printed labeling identical in content to the draft copy is submitted as soon as available, and prior to the marketing of the color additive. The printed labeling shall conform in prominence and conspicuousness with the requirements of the act.

If the color additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance. If the safety data will not support the use of the amount of the color additive reasonably needed to accomplish the desired color effect, the requested tolerance will not be established. Petitioners are expected to propose the use of color additives in accordance with sound color chemistry.

C.1. A description of practicable methods to determine the pure color and all intermediates, subsidiary colors, and other components of the color additive.

2. A description of practicable methods to determine the amount of the color additive in any raw, processed, and/or finished food, drug, or cosmetic in which use of the color additive is proposed. (The tests proposed shall be those that can be used for food, drug, or cosmetic control purposes and can be applied with consistent results by any properly equipped laboratory and trained personnel.)

3. A description of methods for identification and determination of any substance formed in or on such food, drug, or cosmetic because of the use of the color additive. (If it
§ 25.30 or 25.32 of this chapter or an environ-
ment assessment under §25.40 of this chapter.

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will be retained but not filed. A petition shall be retained but shall not be filed if any of the data listed in the above form are lacking or are not set forth so as to be readily understood or if the prescribed fee has not been submitted. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or authorized agent, who is a resident of the United States.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier petition.

(g) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 721(b) of the act shall include with respect to each nonclinical study contained in the petition, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(h) [Reserved]

(i) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 721(b) of the act shall include statements regarding each such clinical investigation contained in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §§56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 56 of this chapter.

(j)(1) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to
Food and Drug Administration, HHS § 71.6

regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) or the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA or, if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

§ 71.2 Notice of filing of petition.

(a) Except where the petition involves a new drug, the Commissioner, within 15 days after receipt, will notify the petitioner of acceptance or non-acceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 721(d)(1) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. The date used for computing the 90-day limit for the purposes of section 721(d)(1) of the act shall be moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the information and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces.

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) Extension of time for studying petitions. If the Commissioner determines that additional time is needed to study the petition, the Commissioner shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.
§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the Federal Register or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in §20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in §20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §20.61 of this chapter.

(6) All records showing the Food and Drug Administration’s testing of or action on a particular lot of a certifiable color additive.
Food and Drug Administration, HHS

§ 71.20 Publication of regulation.

The Commissioner will forward for publication in the Federal Register, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 721(d)(1) of the act):

(a) A regulation listing in part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 721(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packaging requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) or the Poultry Products Inspection (PPIA) (21 U.S.C. 451 et seq.) for which the color additive has been found suitable and for which it may safely be employed.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its

§ 71.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to part 10 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

Subpart B—Administrative Action on Petitions

§ 71.20 Publication of regulation.
manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.


§ 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 has issued pursuant to section 721(b) of the act, even though the 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

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.
73.230 Fruit juice.
73.260 Vegetable juice.
73.275 Dried algae meal.
73.295 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

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

73.2030 Annatto.
73.2065 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 Guaiacuene.
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.