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trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(a) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(b) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

§ 5.7 Wrapped fish fillets.

(a) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of section 403(e) (2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking: *Provided*, That:

(1) The outside container bears a label declaration of the total net weight; and

(2) The individual packages bear a conspicuous statement "To be weighed at time of sale" and a correct statement setting forth the weight of the wrapper; and

Provided further, That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare ----- ounce," the blank being filled in with the correct average weight of the wrapper used.

(b) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this section shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

§ 5.8 Bananas, wrapped clusters (consumer units).

(a) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e) (2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing: *Provided*, That:

(1) The master carton or container bears a label declaration of the total net weight; and

(2) The individual packages bear a conspicuous statement "To be weighed at the time of sale" and a correct statement setting forth the weight of the wrapper; and

Provided, further, That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(b) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

PART 8—COLOR ADDITIVES

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AUTHORITY: The provisions of this Part 8 issued under secs. 701, 706, 52 Stat. 1055 as amended; 74 Stat. 399; 21 U.S.C. 371, 376.

Subpart A—Definitions and Procedural and Interpretative Regulations

SOURCE: The provisions of this Subpart A appear at 28 F.R. 6439, June 22, 1963, unless otherwise noted.

§ 8.1 Definitions and interpretations.

(a) "Secretary" means the Secretary of Health, Education, and Welfare.

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) "Act" means the Federal Food, Drug, and Cosmetic Act as amended.

(e) "Color Certification Branch" means the unit established within the Food and Drug Administration located in the Bureau of Scientific Standards and Evaluation, charged with the responsibility for the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) A "color additive" is any material, not exempted under section 201(t) of

the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the color being transmitted to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as "color additives"; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a "color additive." Food ingredients as authorized by a definition and standard of identity prescribed by regulations pursuant to section 401 of the act are "color additives," where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." An ingested drug the intended function of which is to impart color to the human body is a "color additive." For the purposes of this part, the term "color" includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not "color additives."

(g) For a material otherwise meeting the definition of "color additive" to be exempt from section 706 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely from its aiding, retarding, or otherwise affecting directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a "color additive" and is not exempt.

(i) "Safe" means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term "straight color" means a color additive listed in Subparts C, D, E, F, G, and H of this part, and includes lakes and such substances as are permitted by the specifications for such color.

(k) The term "mixture" means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term "lake" means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or

stabilizing, or may be a functional component of an article intended for coloring the human body.

(n) The term "substratum" means the substance on which the pure color in a lake is extended.

(o) The term "pure color" means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term "batch" means a homogeneous lot of color additive or color additive mixture produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(r) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term "package" means the immediate container in which a color additive or color additive mixture has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color additive mixtures for household use containing less than 15 percent pure color, when two or more containers of 3 ounces each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(u) The "hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article

bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.

[28 F.R. 6439, June 22, 1963, as amended at 29 F.R. 14983, Nov. 5, 1964]

NOTE: By order of the Commissioner, 28 F.R. 6449, June 22, 1963, a transitional period of 2 years is granted for "coal-tar" hair dyes in commercial use which would not be exempt under paragraph (u) of this section.

§ 8.2 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as cholinesterase inhibition) produced by such substance.

§ 8.3 Color additives in standardized foods, new drugs, and antibiotics.

(a) *Standardized foods.* (1) Where a petition is received for issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a color additive

in the standardized food, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the safety of the color additive (if such information has not previously been submitted and safety of the color additive for the intended use has not been already established), and the petition must show also that the use of the color additive in the standardized food would be in conformance with section 401 of the act or with the terms of a temporary permit issued under § 10.5 of this chapter.

(2) If a petition for a definition and standard of identity contains a proposal for a color additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a color additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(3) A regulation will not be issued allowing the use of a color additive in a food for which a definition and standard of identity is established, unless its issuance is in conformance with section 401 of the act or with the terms of a temporary permit issued under § 10.5 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the color additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

(b) *New drugs and antibiotics.* (1) Where an application for a new drug or for certification of an antibiotic drug is received and this application proposes, for coloring purposes only, the inclusion of a color additive, the provisions of the regulations in this part shall apply with respect to the information that must be submitted about the safety of the color additive, if such information has not previously been submitted and safety of the color additive for the intended use has not already been established.

(2) If an application for a new drug or certification of an antibiotic drug inferentially contains a proposal for a color additive regulation, and the applicant fails to designate it as such, the Commissioner, upon determining that the application includes a proposal for a color additive regulation, shall so notify the applicant and shall thereafter proceed in accordance with the regulations in this part.

(3) Where a petition for a color additive must be filed in accordance with subparagraph (2) of this paragraph, the date of filing of the color additive petition shall be considered as the date of filing of the new-drug application or the request for certification of the antibiotic drug.

§ 8.4 Petitions proposing regulations for color additives.

(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. 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 706 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:

 Name of petitioner ----- (Date)
 Post-office address -----
 Name of color additive and proposed use.-----

Commissioner of Food and Drugs,
 Food and Drug Administration,
 Department of Health, Education, and
 Welfare,
 Washington 25, D.C.

Dear Sir:

Petitioner submits this pursuant to section 706(b) (1) 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 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 packing 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 is the petitioner's view that any such method would not be needed, under the terms of the section 706(b)(5)(A)(iv), a statement shall be submitted in lieu of methods as to the basis for such view.)

D. Full reports of investigations made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

E. Complete data which will allow the Commissioner to consider, among other things, the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additive; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet including, but not limited to food additives and pesticide chemicals for which tolerances or exemptions from tolerances have been established.

F. Proposed tolerances and other limitations on the use of the color additive, if tolerances and limitations are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary (including supporting data to establish the safety of the intended use).

H. If submitting a petition to alter an existing regulation issued pursuant to section 706(b) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

I. The prescribed fee of \$----- for admitting the color additive to listing is enclosed (unless there is an advance deposit adequate to cover the fee).

Yours very truly,

(Petitioner)
By -----
(Indicate authority)

(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.

§ 8.5 Notification 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 nonacceptance 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 706(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. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug or certifiable antibiotic, notification to the petitioner will be made in accordance with § 8.3(b) (3).

(b) The Commissioner will cause to be published in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

§ 8.6 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 706(d) (1) of the act):

(a) A regulation listing in Subpart C, D, E, F, G, or H of this part the color additive on the appropriate list or lists as provided under section 706(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.

(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 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.

§ 8.7 Samples.

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 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. The date used for computing the

90-day limit for the purposes of section 706(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 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.

§ 8.8 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 and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 8.6 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

§ 8.9 Confidentiality of petition.

Data in a petition regarding any method or process entitled to protection as a trade secret will be held confidential

and not revealed, unless it is necessary to do so in the record of an administrative hearing preliminary to possible judicial proceedings under section 706 of the act. Data in the petition will not be revealed to persons other than the petitioner and persons engaged in the enforcement of the act beyond that which is necessary to comply with section 706(d)(1) (notice of the regulation proposed) and 706(b)(1) (order acting on the petition).

§ 8.10 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 judgement 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 706(b) of the act, even though the regulation is effective for other uses.

§ 8.11 Allocation of color additives.

Whenever, in the consideration of a petition or a proposal to list a color additive or to alter an existing listing, the data before the Commissioner fail to show that it would be safe to list the color additive for all the uses proposed or at the levels proposed, the Commissioner will notify the petitioner and other interested persons by publication in the FEDERAL REGISTER that it is necessary to allocate the safe tolerance for the straight color in the color additive among the competing needs. This notice shall call for the presentation of data by all interested persons on which the allocation can be made in accordance with section 706(b)(8) of the act. The time for acting upon the petition shall be stayed until such data are presented, whereupon the time limits shall begin to run anew. As

promptly as possible after presentation of the data, the Commissioner will, by order, announce the allocation and the tolerance limitations.

§ 8.12 Advisory committee on the application of the cancer clause.

(a) Any person who will be adversely affected by any action or proposed action applying the cancer clause may at any time, before or within 30 days after the publication of the Commissioner's order taking such action, request the referral of the matter to an advisory committee for a report and recommendations. Such request shall be made in writing to the Commissioner and shall be accompanied by an advance deposit for fees prescribed by § 8.50.

(b) The Commissioner may, at any time, upon his own initiative refer any such matter to an advisory committee for a report and recommendations. In case the Commissioner on his own initiative deems it necessary to refer a proposal to an advisory committee, he shall, in writing, so inform the person filing the petition, if any there be.

§ 8.13 Appointment of advisory committee.

(a) Whenever the referral of a petition or proposal to an advisory committee is requested, or the Commissioner otherwise deems such referral necessary, the Commissioner will request the National Academy of Sciences to select qualified experts willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in biology, medicine, physiology, toxicology, pharmacology, veterinary medicine, or other appropriate science to qualify them on the subject matter to be referred to them. The Commissioner will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(b) Each advisory committee shall consist of not less than three experts qualified in the subject matter to be referred to the committee and of adequately diversified professional background. The Commissioner may specify a larger number to serve. He shall appoint one member of the committee as chairman, and the chairman shall be the spokesman of the committee for re-

ceiving and forwarding reports and other functions of the committee.

(c) The Commissioner shall appoint the experts so selected and fix their compensation at not to exceed \$75.00 a day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their places of residence. Subsistence expenses shall not exceed \$25.00 per day.

§ 8.14 Procedure for advisory committee.

(a) The Commissioner shall submit to the chairman of the committee the petition, if any there be; all pertinent data on which he based the issuance, amendment, or repeal of any regulation in question; and other such relevant information as is available. When the Commissioner submits a proposal to an advisory committee, he shall inform the petitioner, if any there be, and furnish him with copies of material other than the petition that is furnished the committee. The chairman of the committee shall acknowledge receipt of the information and readiness of the committee to act. The date of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. Copy of this acknowledgment shall be forwarded to the petitioner, if any there be, by the chairman of the committee.

(b) A secretariat to the advisory committees will be established by the Commissioner. The secretariat shall furnish members of the committee with copies of the proposal or petition and any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so advise the Commissioner. Such meetings shall be held in Washington, D.C., or at such other place as the Commissioner shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(c) As soon as practicable, the advisory committee shall make an independent study of the data, and not later than 60 days after receipt of the proposal or petition (unless the time has been extended as provided in paragraph

(d) of this section), the chairman shall certify to the Commissioner the report and recommendations of the committee, including any minority report, together with all underlying data and a statement of the reasons or basis for the recommendations, and shall return the petition or proposal. The report will include copies of all material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. A copy of the report of the advisory committee will be supplied to any person who has filed a petition or requested the referral to the advisory committee.

(d) If at any time within 60 days the chairman believes that the advisory committee needs more time, he shall so inform the Commissioner in writing, in which case he shall make the certification contemplated by section 706(b)(5)(C)(ii) of the act within the additional 30 days. The Commissioner shall in turn notify the petitioner.

(e) Within 30 days after receipt of the committee report, the Commissioner shall confirm or modify any order theretofore issued by him or shall issue an order acting on the proposal if no order has been issued.

(f) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion as to the member who may best represent the committee at a hearing, if one occurs.

(g) More than one petition or proposal may be handled by a committee concurrently.

(h) A person who has filed a petition or who has requested the referral of a proposal to the advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have a right to consult with the committee in connection with the petition or proposal. Such persons shall notify the chairman and if practicable make appointments through him. The report of the committee shall show the names of persons other than committee members discussing proposals or petitions with the committee. Except for discussions with authorized persons the committee shall not disclose data originating with a petitioner prior to publication of a regulation.

§ 8.15 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 Subpart C, E, or G of this part. 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.

§ 8.16 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 8.17 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in Subpart C, D, E, F, G, or H of this part.

§ 8.18 Request for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture that has not been exempted from the certification procedure by order of the Commissioner may make formal objections and request an order providing such exemption. Such a request shall be accompanied by full facts on which such a request is based. The request shall furnish reasonable grounds for the desired finding including specifically why such certification is not necessary for the protection of the public health.

§ 8.19 Procedure for filing objections to regulations.

(a) Objections under section 706(d) of the Act and section 203(d) (2) (C) of

Public Law 86-618 (74 Stat. 404; 21 U.S.C. 376, note) shall be submitted in quintuplicate to the Hearing Clerk of the Department and shall be accompanied by a filing fee as specified in § 8.50. Each objection to a provision of the regulation shall be separately numbered.

(b) A statement of objections shall not be accepted for filing if:

(1) It is received for filing more than 30 days after the date of publication of the order in the FEDERAL REGISTER; or

(2) It fails to establish that the objector is adversely affected by the regulation; or

(3) It does not specify with particularity the provisions of the regulation to which objection is taken; or

(4) It does not state reasonable grounds for each objection raised. Grounds which it is reasonable to conclude are capable of being established by reliable evidence at the hearing and which if proved would call for changing the provisions specified in the objections will be deemed reasonable grounds.

(5) The fee is not submitted.

(c) If the statement of objections may not be filed, the Commissioner shall inform the objector of the reasons.

§ 8.20 Notice of public hearing.

If the objections and statement filed by any person, when they are considered with the record in the proceeding (including any reply to the objections that the petitioner may have filed), show that the person filing the objections will be adversely affected and that the grounds stated in support of the objections are reasonable, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place where the hearing will be held, specify the time within which appearances must be filed, and specify the time (not earlier than 30 days after the date of the notice) when the hearing will start. The hearing shall convene at the place and time announced in the notice, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing.

§ 8.21 Hearing procedure.

Public hearings will be conducted in accordance with the rules provided in § 120.15 through § 120.28 of this chapter.

§ 8.22 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 8.51 unless the person has established with the Food and Drug Administration an advance deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 8.51 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 8.23 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in Subpart C, E, or G of this part.

(2) The name of a lake shall be the name derived in the manner described in Subpart B of this part.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the

name described in subparagraph (1), (2), or (3) of this paragraph, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 8.27 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date _____
Commissioner of Food and Drugs,
Food and Drug Administration,
Department of Health, Education, and
Welfare,
Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in Subpart C, E, or G)

Batch number _____
(Manufacturer's number)

Batch weighs _____ pounds

Batch manufactured by _____
at _____

(Name and address of actual manufacturer)
How stored pending certification _____

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____

(State proposed uses)

Required fee, \$_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed) _____

By _____

(Title)

(2) *Request for certification of a batch of color additive lake.*

Date _____
 Commissioner of Food and Drugs,
 Food and Drug Administration,
 Department of Health, Education, and
 Welfare,
 Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color _____
 Batch number _____

(Manufacturer's number)

Batch weighs _____ pounds

Name of color used _____

Quantity _____ pounds

Lot number _____

(When certification of the lake for use in foods is requested)

Precipitant used _____

Substratum used _____

Quantity _____ pounds

Batch manufactured by _____

at _____

(Name and address of actual manufacturer)

How stored pending certification _____

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in _____

(State proposed uses)

Required fee, \$_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed) _____

By _____

(Title)

(3) Request for certification of a repack of a batch of certified color additive.

Date _____
 Commissioner of Food and Drugs,
 Food and Drug Administration,
 Department of Health, Education, and
 Welfare,
 Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color _____

(As listed in regulations and as certified; or repacker's name, if a mixture)

Original lot number _____

Certified color content _____

This color obtained from _____

Batch number _____

Batch weighs _____ pounds

How stored pending certification _____

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested for use in _____

(State proposed uses)

Required fee, \$_____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed) _____

By _____

(Title)

(4) Request for certification of a batch of color additive mixture.

Date _____
 Commissioner of Food and Drugs,
 Food and Drug Administration,
 Department of Health, Education, and
 Welfare,
 Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____

(Manufacturer's trade name)

Batch number _____

(Manufacturer's number)

Weight of hatch _____ pounds

Volume of batch _____ gallons

(If liquid)

Batch manufactured by _____

Constituents of the mixture:

1. Color(s). (List separately each color and each lot number.)

Name of color as certified

Lot number

Quantity used (in pounds)

Obtained from

2. List of diluents. (List separately each diluent.)

Name of diluent

Quantity used

By weight

By volume (if liquid)

Batch mixed as follows _____

(Describe in detail)

How stored pending certification -----

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested for use in -----

(State proposed uses)

Required fee, \$----- (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed) -----

By -----

(Title)

§ 8.23 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Held under the control of the person requesting certification until certified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the person requesting certification of such batch.

(5) Be accompanied by any label or labeling intended to be used.

§ 8.24 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not be used until the requested certificate has been issued.

[28 F.R. 6439, June 22, 1963, as amended at 29 F.R. 14983, Nov. 5, 1964]

§ 8.25 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been

certified, the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(b) The person requesting certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 8.31 and 8.32, except that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

[29 F.R. 14983, Nov. 5, 1964]

§ 8.26 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

§ 8.27 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with § 8.22 appears to contain no untrue statement of a material fact;

(2) Such color additive conforms to the specifications and any other conditions set forth therefor in Subpart C, E, or G of this part.

(3) The batch covered by such request otherwise appears to comply with

the regulations in this part, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by Subpart C, E, or G of this part, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 8.22, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal.

§ 8.28 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 8.26; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 8.26; or

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Upon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§ 130.14–130.26 of this chapter.

§ 8.29 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall

be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color additive was used as an ingredient, or for use in preparing a batch of a mixture for which exemption from certification has been authorized, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any color additive covered thereby if the package in which such color additive was closed for shipment or delivery is opened. After such expiration such color additive shall be considered to be from a batch that has not been certified, except that such color additive shall not be so considered when the package is opened; (1) and such color additive is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic; (2) for the purpose of certifying a batch made by repackaging such color; (3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient; or (4) for the purpose of preparing a batch of a mixture for which exemption from certification has been authorized; or (5) when

the package is reopened solely for re-packaging by the person to whom such certificate was issued.

(e) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 8.32 to appear thereon.

(f) A certificate shall not be effective with respect to a package of color additive, and such color additive shall be considered to be from a batch that has not been certified if:

(1) Such package has not been sealed in accordance with § 8.31;

(2) Such package has been sealed in accordance with § 8.31 and the seal has been broken, intentionally or accidentally, unless such seal has been broken for the purpose of using color additive in accordance with § 8.25, or, such package has been opened by a duly authorized representative of the Administration or Department in the performance of his official duties, and he has immediately resealed the package in conformance with § 8.31.

(g) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such color additive is used in any manner other than that for which it was certified.

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all certificates for existing batches and portions of batches of such a color additive theretofore issued under such revoked or amended regulations shall cease to be effective; and any such lots of the color additive shall be regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformance with the new regulations. When a certificate thus ceases to be effective for a color additive, any certificates previously issued for a color additive mixture containing that color additive shall cease to be effective on the same date. Use of such color additive or color additive mixture after such specified date without the new certificate in preparing food, drugs, or cos-

metics will result in such food, drugs, or cosmetics being adulterated. When a certified color additive has been used in food, drugs, or cosmetics and the status of the color additive is thereafter changed by amendment or revocation of its listing or specification regulations, such food, drugs, and cosmetics will not be regarded as adulterated by reason of the use of such color additive, unless the hazard to health is such that existing stocks of the foods, drugs, or cosmetics cannot be safely used, in which cases findings to that effect will be made and regulations appropriate for such special cases will be issued.

§ 8.30 Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in Subpart C, E, or G, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restrictions prescribed in Subparts A and B.

(b) *Color additive mixtures exempted from certification.* A color additive mixture prepared from a previously certified batch of one or more straight colors, with or without any diluent that has been listed in Subpart D, F, or H for use in mixtures, shall be exempt from batch certification if the straight color used has not changed in composition in any manner whatsoever since its certification and if it is simply mixed with the approved diluents for exempt mixtures. The label of such color additive mixtures shall not bear the lot number assigned by the Food and Drug Administration to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

(c) *Additions to the list of diluents.* A person requesting additions to the list of diluents authorized for the purposes described in paragraphs (a) and (b) of this section shall submit a petition in accordance with the provisions of § 8.4. Each such petition shall be accompanied by the fee prescribed in § 8.50, unless there is an advance deposit to be used for prepayment of such fees.

NOTE: The provisions of § 8.30 with respect only to diluents for use in cosmetic color

additive mixtures were stayed, until a regulation is effected listing safe diluents for cosmetic use, including cosmetics which color the human body, 29 F.R. 18495, Dec. 29, 1964.

§ 8.31 Packaging requirements for straight colors (other than hair dyes).

Straight colors shall be packaged in containers which prevent changes in composition. Packages shall be sealed so that they cannot be opened without breaking the seal. An unavoidable change in moisture content caused by the ordinary and customary exposure that occurs in good storage, packing, and distribution practice is not considered a change in composition. If the packaging material is a food additive it shall be authorized by an appropriate regulation in Part 121 of this chapter.

§ 8.32 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by Subparts A and B of this part. Labels for color additives, except those in a form suitable for coloring the human body, shall state:

(1) The name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture.

(2) A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."

(3) Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.

(4) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of a color additive, the label shall in addition provide directions for use of the color additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limita-

tions shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: "Do not use in products used in the area of the eye"; "Do not use for coloring drugs for injection."

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

§ 8.33 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized.

(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.

§ 8.34 Safety factors to be considered.

In accordance with section 706(b) (5) (A) (iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested. The various species of experimental animals used in the tests shall conform to good pharmacological practice.

§ 8.35 General principles of evaluating the safety of color additives.

(a) In reaching a decision on any petition filed under section 706 of the act, the Commissioner will give full consideration to the specific biological properties of the color additive and the adequacy of the methods employed to demonstrate its safety for the proposed use. When considering color additives for food, for drugs, and for cosmetic uses that involve ingestion, the Commissioner will be guided by the principles and procedures for establishing the safety of food additives provided in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to all levels and patterns of consumption of the color additive specified or reasonably to be anticipated. For the purposes of this section, the principles for evaluating safety of additives set forth in the above-mentioned publications will apply to any substance that may properly be classified as a color additive as defined in section 201(t) of the act.

(b) The safety for external color additives will normally be determined by

tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application. The Commissioner may waive any of such tests if data before him otherwise establish that such test is not required to determine safety for the use proposed.

(c) Upon written request describing the proposed use of a color additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 8.36 Application of the cancer clause of section 706 of the act.

(a) *Color additives that may be ingested.* Whenever (1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or (2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether 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; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

(b) *Color additives that will not be ingested.* Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the

possibility of carcinogenesis is appropriate for the evaluation of the 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.

§ 8.37 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 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 § 8.50.

§§ 8.38–8.49 [Reserved]

§ 8.50 Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of \$3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be \$3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be \$2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a \$600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less \$1,800.00 if the petition is covered by paragraph (a) or (b) of this section, and less \$1,600.00, if the petition is covered by paragraph (c), shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of \$1,800.00 for a petition filed under paragraph (a) or (b), and \$1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color additive has been listed, any request for an amendment or additional tolerance shall be accompanied by a deposit of \$1,800.00 for use in the items specified in paragraphs (a) and (b) of this section, or \$1,600.00 for use in items specified in paragraph (c) of this section.

(j) The fee for services in listing a diluent under § 8.30 for use in color additive mixtures shall be \$250.00.

(k) Objections and request for public hearing under section 706(d) of the act or section 203(d) (2) (C) of Public Law 86-618 (74 Stat. 404; 21 U.S.C. 376, note) shall be accompanied by a filing fee of \$250.00.

(l) In the event of a referral of a petition under this section to an advisory committee, all costs related thereto (including personal compensation of committee members, travel materials, and other costs) shall be borne by the person or organization requesting the referral, such costs to be assessed on the basis of actual cost to the Government: *Provided*, That the compensation of such costs shall include personal compensation of advisory committee members at a rate not to exceed \$75.00 per member per day.

(m) In the case of requests of referrals to advisory committees, a special advance deposit shall be made in the amount of \$2,500.00. Where required, further advance in increments of \$2,500.00 each shall be made upon request of the Commissioner of Food and Drugs. All deposits for referrals to advisory committees in excess of actual expenses shall be refunded to the depositor.

(n) All requests for pharmacological or other scientific studies shall be accompanied by an advance deposit of \$5,000.00. Further advance deposits shall be made upon request of the Commissioner of Food and Drugs when necessary to prevent arrears in such cost. Any deposits in excess of actual expenses will be refunded to the depositor. If a request is denied the advance deposit will be refunded less such costs as are incurred for review of the request.

(o) The person who files a petition for judicial review of an order under section 706(d) of the act shall pay the costs of preparing a transcript of the record on which the order is based.

(p) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D.C., whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(q) The Commissioner of Food and Drugs may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(r) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner of Food and Drugs to waive or refund the fees.

§ 8.51 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case

of each request for certification submitted in accordance with § 8.22(j) (1) and (2), shall be 15 cents per pound of the batch covered by such requests, but no such fee shall be less than \$100.00.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 8.22(j) (3) and (4) shall be:

<i>Weight of batch</i>	<i>Fees</i>
100 pounds or less..	\$6.00
Over 100 pounds but not over 1,000 pounds..	\$6.00 plus 4 cents for each pound over 100 pounds.
Over 1,000 pounds..	\$42.00 plus 1 cent per pound for each pound in excess of 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D.C., whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than \$5.00.

§§ 8.52–8.100 [Reserved]

Subpart B—General Specifications and General Restrictions for Color Additives for Use in Foods, Drugs, and Cosmetics

§ 8.101 General restrictions on use of color additives.

(a) *Color additives for use in the area of the eye.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in the area of the eye, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Subparts E, F, G, and H of this part, even though such color additive is certified and/or listed for other uses.

(b) *Color additives for use in injections.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in injections unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in injections, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Subparts E and F of this part, even though such color additive is certified and/or listed for other uses.

[28 F.R. 6448, June 22, 1963]

Subpart C—Listing of Color Additives for Food Use Subject to Certification

§ 8.201 Citrus Red No. 2.

(a) *Identity and specifications.* (1) The color additive Citrus Red No. 2 is principally 1-(2,5-dimethoxyphenylazo)-2-naphthol. It conforms to the general specifications in § 8.110 of this part and the following specific requirements:

Volatile matter (at 100° C.), not more than 0.5 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Uncombined intermediates, not more than 0.05 percent.

Subsidiary dyes, not more than 2.0 percent.
Pure dye, not less than 98 percent.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (b) (1) of this section:

(i) Volatile solvents that leave no residue after application to the orange.

(ii) Salts of fatty acids meeting the requirements of § 121.1071 of this chapter.

(iii) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Uses and restrictions.* (1) The color additive shall be used only for coloring the skins of oranges that are not intended or used for processing (or, if so used, are designated in the trade as "packing-house elimination"), and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with the color additive shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(c) *Labeling requirements.* The label or labeling of the color additive shall bear, in addition to the other information required by the act and § 8.32 of the regulations in this Part 8:

(1) The statement (or its equivalent) "To be used only for coloring skins of oranges."

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(d) *Certification.* All batches of this color additive shall be certified in accordance with the regulations promulgated under Subpart A of this Part 8.

[28 F.R. 5082, May 22, 1963]

Subpart D—Listing of Color Additives for Food Use Exempt From Certification

§ 8.300 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not

changed in composition since certification. If a specification for a particular diluent is not set forth in this Subpart D, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under

the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under Part 121 of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

Substance	Definition and specification	Restrictions
Castor oil.....	As set forth in U.S.P. XVI.	Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction.

(b) *Special use—*(1) *Diluents in color additive mixtures for marking food—*(i) *Inks for marking gum and confectionery.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
n-Butyl alcohol.....		No residue in finished confectionery or gum.
Cetyl alcohol.....	As set forth in N.F. XI.	Do.
Cyclohexane.....		
Ethyl cellulose.....	As set forth in § 121.1087 of this chapter.	Do.
Ethylene glycol monoethyl ether.....		Do.
Isobutyl alcohol.....		Do.
Isopropyl alcohol.....		Do.
Polyoxyethylene sorbitan monooleate (polysorbate 80).....	As set forth in § 121.1009 of this chapter.	
Polyvinyl acetate.....	Molecular weight, minimum 2,000.	
Polyvinylpyrrolidone.....	As set forth in § 121.1139 of this chapter.	
Rosin and rosin derivatives.....	As set forth in § 121.1059 of this chapter.	
Shellac, purified.....	Food grade.	

(ii) *Inks for marking fruit and vegetables.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Acetone.....	As set forth in N.F. XI.	No residue.
Alcohol, SDA-3A.....	As set forth in 26 CFR Part 212.	Do.
Benzoin.....	As set forth in U.S.P. XVI.	
Copal, Manila.....		
Ethyl acetate.....	As set forth in N.F. XI.	Do.
Ethyl cellulose.....	As set forth in § 121.1087 of this chapter.	Do.
Methylene chloride.....		
Polyvinylpyrrolidone.....	As set forth in § 121.1139 of this chapter.	
Rosin and rosin derivatives.....	As set forth in § 121.1059 of this chapter.	
Silico dioxide.....	As set forth in § 121.1058 of this chapter.	
Terpene resins, natural.....	As set forth in § 121.1059 of this chapter.	Not more than 2 percent of the ink solids.
Terpene resins, synthetic.....	Polymers of α - and β -pinene.....	

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

Alcohol, denatured, formula 23A (26 CFR Part 212), Internal Revenue Service.

Damar gum (resin).
Diethylene glycol distearate.
Dioctyl sodium sulfosuccinate.
Ethyl cellulose (as identified in § 121.1087 of this chapter).
Ethylene glycol distearate.
Japan wax.
Limed rosin.
Naphtha.

Pentaerythritol ester of fumaric acid-rosin adduct.

Polyethylene glycol 6000 (as identified in § 121.1057 of this chapter).

Polyvinyl alcohol.

Rosin and rosin derivatives (as identified in § 121.1059 of this chapter).

[29 F.R. 13893, Oct. 8, 1964; redesignated 29 F.R. 15287, Nov. 14, 1964]

§ 8.301 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth) molasses, corn-steep liquor, and a maximum of 0.3 percent ethoxyquin. The algae are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used or intended for use to enhance the yellow color of chicken skins and egg yolks and to supplement the vitamin A content of feeds low in natural carotenoids.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is adequately supplemented with xanthophyll and carotenes and meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 121.202 of this chapter.

(c) *Labeling requirements.* The label and labeling of the color additive and any premixes prepared therefrom shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and other regulations in this chapter:

(1) The name of the color additive.

(2) A statement of the concentrations of xanthophyll, carotenes, and ethoxyquin contained therein.

(3) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(d) *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 certification requirements of section 706(c) of the act.

[26 F.R. 5919, July 1, 1961, as amended at 26 F.R. 7544, Aug. 15, 1961]

§ 8.302 β -Apo-8'-carotenal.

(a) *Identity.* (1) The color additive is β -apo-8'-carotenal.

(2) Diluents in color additive mixtures: Color additive mixtures made with β -apo-8'-carotenal may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act; or, if they are food additives, are authorized for a specific use or uses under the provisions of Part 121 of this chapter.

(b) *Specifications.* β -Apo-8'-carotenal conforms to the following specifications:

Physical state—Solid.

1 percent solution in chloroform—Clear.

Melting point (decomposition)—136°C.—140°C. (corrected).

Loss of weight on drying—not more than 0.2 percent.

Residue on ignition—not more than 0.2 percent.

Lead (Pb)—not more than 10 parts per million.

Arsenic (As)—1 part per million.

Assay (spectrophotometric)—96–101 percent.

(c) *Uses and restrictions.* The color additive may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β -apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods standardized pursuant to section 401 of the act where the use of added color is not authorized.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act and other regulations in this chapter:

(1) The name of the color additive, β -apo-8'-carotenal, and its quantity.

(2) The names of all other ingredients.

(3) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) (1) of this section.

(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 certification requirement of section 706(c) of the act.

[28 F.R. 3382, Apr. 6, 1963]

§ 8.303 Caramel.

(a) *Identity.* (1) The color additive caramel is the amorphous, dark-brown

material resulting from the carefully controlled heat treatment of the food-grade carbohydrates listed in this subparagraph (liquid caramel may be dehydrated).

Dextrose.
Invert sugar.
Lactose.
Malt sirup.
Molasses.
Starch hydrolysates and fractions thereof.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) **Acids:**

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) **Alkalis:**

Ammonium hydroxide.
Potassium hydroxide.
Sodium hydroxide.

(iii) **Salts:** Ammonium, sodium, or potassium carbonate (including bicarbonate), phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in § 121.1120 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures made with caramel may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act; or, if they are food additives, are authorized for a specific use or uses under the provisions of Part 121 of this chapter.

(b) **Specifications.** Caramel conforms to the following specifications:

Lead (Pb), not more than 10 parts per million.

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

Mercury (Hg), not more than 0.1 part per million.

(c) **Uses and restrictions.** Caramel may be used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act and the use of added color is not authorized by such standards.

(d) **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 certification requirement of section 706(c) of the act.

[28 F.R. 6498, June 25, 1963]

§ 8.304 β -Carotene.

(a) **Identity.** (1) The color additive is β -carotene prepared synthetically or obtained from natural sources.

(2) Diluents in color additive mixtures: Color additive mixtures made with β -carotene may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act; or, if they are food additives, are used only as prescribed in regulations in Part 121 of this chapter.

(b) **Specifications.** β -Carotene conforms to the following specifications:

Physical state—Solid.

1% solution in chloroform—Clear.

Loss of weight on drying, not more than 0.2%.

Residue on ignition, not more than 0.2%.

Lead (Pb), not more than 10 parts per million.

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

Assay (spectrophotometric) 96%–101%.

(c) **Uses and restrictions.** The color additive may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) **Labeling requirements.** The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom 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 therefore batches thereof are exempt from the certification requirement of section 706(c) of the act. [28 F.R. 13488, Dec. 13, 1963; 28 F.R. 13745, Dec. 12, 1963]

§ 8.305 Annatto extract.

(a) **Identity.** (1) The color additive annatto extract is an extract prepared from annatto seed. *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants

listed in subdivision (i) and (ii) of this subparagraph:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats.

The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under subdivision (ii) of this subparagraph. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures made with annatto extracts may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act, or, if they are food additives, are authorized for a specific use or uses under the provisions of Part 121 of this chapter.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, conforms to the following specifications:

(1) Arsenic (As)—Not more than 3 parts per million.

Lead (Pb)—Not more than 10 parts per million.

(2) When solvents listed under paragraph (a) (1) (ii) are used, it shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Part 121 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act and the use of added color is not authorized by such standards.

(d) *Labeling.* In addition to all other information required by the act, labels of annatto extract and color additive mixtures prepared therefrom shall bear information showing that the color is derived from annatto seed, and shall

declare all ingredients, with the exception of residues of solvents listed in paragraph (a) (1) (ii), by their specific common or usual names.

(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 certification requirements of section 706(c) of the act.

[28 F.R. 6351, June 20, 1963]

§ 8.306 Tagetes (Aztec marigold) meal.

(a) *Identity.* The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(b) *Specifications.* Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tagetes erecta* L. or from plant material or flowers of any other species of plants.

(c) *Uses and restrictions.* The color additive tagetes (Aztec marigold) meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in subparagraph (1) of this paragraph; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 121.202 of this chapter.

(d) *Labeling requirements.* The label and labeling of the color additive and any premixes prepared therefrom shall bear, in addition to the other information required by the act and other regulations in this chapter:

(1) The name of the color additive.

(2) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(3) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(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 certification requirements of section 706(c) of the act. [28 F.R. 10749, Oct. 5, 1963]

§ 8.315 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures made with toasted partially defatted cooked cottonseed flour may contain as diluents only those substances that, if used in foods, are not food additives within the meaning of section 201(s) of the act; or if they are food additives, are used only as prescribed in regulations in Part 121 of this chapter.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour conforms to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million (0.045 percent by weight).

(c) *Uses and restrictions.* Toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 8.32.

(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 certification requirement of section 706(c) of the act. [29 F.R. 1801, Feb. 6, 1964, as amended at 29 F.R. 13319, Sept. 25, 1964]

Subpart—Provisional Regulations

AUTHORITY: The provisions of this Subpart issued under Title II of Public Law 86-618, sec. 203(c), (d); 74 Stat. 405; 21 U.S.C., note under 376.

NOTE 1: §§ 9.1 to 9.3 of this chapter shall continue in effect, insofar as they are not inconsistent with the following provisional regulations, until new regulations for the enforcement of section 706 of the Federal Food, Drug, and Cosmetics Act basic color additives amendments of 1960 can be proposed and made effective, 25 F.R. 9759, Oct. 12, 1960.

§ 8.501 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additives Amendments of 1960 (sec. 203(b), 74 Stat. 405; 21 U.S.C. 376, note). Except for color additives for which petitions have been filed, progress reports are required by July 1, 1964, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in Part 9 of this chapter.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

	Closing date	Restrictions
FD&C Green No. 1 (§ 9.21 of this chapter).....	July 1, 1965	
FD&C Green No. 2 (§ 9.22 of this chapter).....	do	
FD&C Green No. 3 (§ 9.23 of this chapter).....	do	
FD&C Yellow No. 5 (§ 9.40 of this chapter).....	do	
FD&C Yellow No. 6 (§ 9.41 of this chapter).....	do	
FD&C Red No. 2 (§ 9.61 of this chapter).....	do	
FD&C Red No. 4 (§ 9.63 of this chapter).....	do	
FD&C Blue No. 1 (§ 9.80 of this chapter).....	do	
FD&C Blue No. 2 (§ 9.81 of this chapter).....	do	
FD&C Violet No. 1 (§ 9.90 of this chapter).....	do	
Lakes (FD&C) (§ 9.100 of this chapter).....	do	

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
D&C Green No. 5 (§ 9.103 of this chapter)	July 1, 1965	
D&C Green No. 6 (§ 9.104 of this chapter)	do	
D&C Green No. 8 (§ 9.106 of this chapter)	Apr. 1, 1965	
D&C Yellow No. 7 (§ 9.130 of this chapter)	do	§ 8.503 of this chapter.
D&C Yellow No. 8 (§ 9.131 of this chapter)	do	Do.
D&C Yellow No. 10 (§ 9.133 of this chapter)	July 1, 1965	
D&C Yellow No. 11 (§ 9.134 of this chapter)	do	
D&C Red No. 5 (§ 9.150 of this chapter)	do	External use only.
D&C Red No. 6 (§ 9.151 of this chapter)	July 1, 1965	
D&C Red No. 7 (§ 9.152 of this chapter)	do	
D&C Red No. 8 (§ 9.153 of this chapter)	Apr. 1, 1965	§ 8.503 of this chapter.
D&C Red No. 9 (§ 9.154 of this chapter)	do	Do.
D&C Red No. 10 (§ 9.155 of this chapter)	do	Do.
D&C Red No. 11 (§ 9.156 of this chapter)	do	Do.
D&C Red No. 12 (§ 9.157 of this chapter)	do	Do.
D&C Red No. 13 (§ 9.158 of this chapter)	do	Do.
D&C Red No. 17 (§ 9.162 of this chapter)	July 1, 1965	
D&C Red No. 19 (§ 9.164 of this chapter)	do	Do.
D&C Red No. 21 (§ 9.166 of this chapter)	Sept. 1, 1965	
D&C Red No. 22 (§ 9.167 of this chapter)	do	
D&C Red No. 27 (§ 9.172 of this chapter)	do	
D&C Red No. 28 (§ 9.173 of this chapter)	do	
D&C Red No. 30 (§ 9.175 of this chapter)	July 1, 1965	
D&C Red No. 31 (§ 9.176 of this chapter)	Apr. 1, 1965	
D&C Red No. 33 (§ 9.178 of this chapter)	July 1, 1965	Do.
D&C Red No. 34 (§ 9.179 of this chapter)	Apr. 1, 1965	
D&C Red No. 36 (§ 9.181 of this chapter)	July 1, 1965	
D&C Red No. 37 (§ 9.182 of this chapter)	do	Do.
D&C Red No. 39 (§ 9.184 of this chapter)	July 1, 1965	External use only.
D&C Orange No. 4 (§ 9.201 of this chapter)	Apr. 1, 1965	§ 8.503 of this chapter.
D&C Orange No. 5 (§ 9.202 of this chapter)	Sept. 1, 1965	Do.
D&C Orange No. 10 (§ 9.207 of this chapter)	do	
D&C Orange No. 11 (§ 9.208 of this chapter)	do	
D&C Orange No. 17 (§ 9.214 of this chapter)	July 1, 1965	Do.
D&C Brown No. 1 (§ 9.230 of this chapter)	do	External use only.
D&C Blue No. 4 (§ 9.240 of this chapter)	do	
D&C Blue No. 6 (§ 9.242 of this chapter)	do	
D&C Blue No. 7 (§ 9.243 of this chapter)	Apr. 1, 1965	
D&C Blue No. 9 (§ 9.245 of this chapter)	July 1, 1965	Surgical suture use only.
D&C Black No. 1 (§ 9.260 of this chapter)	July 1, 1965	External use only.
D&C Violet No. 2 (§ 9.270 of this chapter)	Apr. 1, 1965	
Lakes (D&C) (§ 9.280 of this chapter)		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Ext. D&C Yellow No. 1 (§ 9.301 of this chapter)	Apr. 1, 1965	
Ext. D&C Yellow No. 3 (§ 9.303 of this chapter)	July 1, 1965	
Ext. D&C Yellow No. 7 (§ 9.307 of this chapter)	Apr. 1, 1965	
Ext. D&C Red No. 8 (§ 9.347 of this chapter)	July 1, 1965	
Ext. D&C Red No. 15 (§ 9.354 of this chapter)	do	
Ext. D&C Red No. 24 (§ 9.363 of this chapter)	do	
Ext. D&C Green No. 1 (§ 9.400 of this chapter)	Apr. 1, 1965	
Ext. D&C Violet No. 2 (§ 9.411 of this chapter)	July 1, 1965	
Ext. D&C Orange No. 3 (§ 9.422 of this chapter)	do	
Lakes (Ext. D&C) (§ 9.440 of this chapter)		

(d) [Reserved]

(e) *Color additives provisionally listed for food use on the basis of prior commercial sale but which have not been nor are now subject to certification.*

	Closing date	Restrictions
Beet juice	Jan. 1, 1966	
Beet powder	do	
Calcium carbonate	do	
Carbon black (prepared by the "impingement" or "channel" process)	do	
Carmin	do	
Carminic acid	do	
Carrot oil	do	

	Closing date	Restrictions
Cochineal.....	Jan. 1, 1966	In processing of black olives.
Ferrous gluconate.....	do.....	
Grape skin extract.....	do.....	Pet foods only.
Iron oxides.....	do.....	
Paprika and paprika oleoresin.....	do.....	Limit of 0.4 percent.
Riboflavin.....	do.....	
Saffron (<i>Crocus sativus</i> L.) and its oleoresin.....	do.....	0.5-percent in salt for animal feed.
Titanium dioxide.....	do.....	
Turmeric and curcumin.....	do.....	
Ultramarine blue.....	do.....	
Xanthophyll.....	do.....	

(f) *Color additives provisionally listed for drug use on the basis of prior commercial sale but which have not been nor are now subject to certification.* The color additives listed in this paragraph are listed only for the uses and purposes commercially employed prior to July 12, 1960. Thus, a color additive used only in drugs for external application is not provisionally listed for internal drug use.

	Closing date	Restrictions
Alumina.....	Jan. 1, 1966	Polyethylene surgical suture use only.
Calcium carbonate.....	do.....	
Carbon black ("channel" or "impingement" process).....	do.....	As a component of iron pyrogallol color additive for surgical suture use only.
Carminic acid.....	do.....	
Chromium-cobalt-aluminum oxide.....	do.....	Surgical suture use only.
Cochineal.....	do.....	
Ferric ammonium citrate.....	do.....	Do.
Fustic.....	do.....	
Iron oxides.....	do.....	
Logwood.....	do.....	
Pyrogallol.....	do.....	
Talc.....	do.....	
Titanium dioxide.....	do.....	

(g) *Color additives provisionally listed for cosmetic use on the basis of prior commercial sale but which have not been nor are now subject to certification.* The color additives provisionally listed in this paragraph are so listed only for the uses and purposes commercially employed prior to July 12, 1960. Thus, a color additive previously used for coloring cosmetics to be applied to portions of the body other than the eye area (as defined in § 8.1(s)) is not provisionally listed for eye-area use.

	Closing date	Restrictions
Aluminum benzoate.....	Jan. 1, 1966	
Aluminum hydroxide.....	do.....	
Aluminum powder.....	do.....	
Aluminum silicate (including hydrated aluminum silicate).....	do.....	
Aluminum stearate.....	do.....	
Annatto.....	do.....	
Azulen.....	do.....	
Barium sulfate (blanc fixe).....	do.....	
Bentonite.....	do.....	
Bismuth oxychloride.....	do.....	
Bone black.....	do.....	
Bronze powder.....	do.....	
Calcium carbonate.....	do.....	
Calcium stearate.....	do.....	
Calcium sulfate.....	do.....	
Carmel.....	do.....	
Carbon black (prepared by the "impingement" or "channel" process).....	do.....	
Carmine.....	do.....	
Carminic acid.....	do.....	
Carotene.....	do.....	
Charcoal.....	do.....	
Chlorophyll copper complex and chlorophyllin copper complex.....	do.....	
Chromium hydroxide green.....	do.....	
Chromium oxide greens.....	do.....	

	Closing date	Restrictions
Cochineal.....	Jan. 1, 1966	
Copper, metallic powder.....	do.	
Cornstarch.....	do.	
Dihydroxyacetone.....	do.	
Ferric ferrocyanide (iron blue).....	do.	
Ferric hydroxide (hydrated iron oxide).....	do.	
Gold.....	do.	
Graphite.....	do.	
Guaanine (pearl essence).....	do.	
Iron oxides.....	do.	
Kaolin.....	do.	
Lithium stearate.....	do.	
Magnesium aluminum silicate.....	do.	
Magnesium carbonate.....	do.	
Magnesium oxide.....	do.	
Magnesium stearate.....	do.	
Magnesium trisilicate.....	do.	
Manganese violet (probably $2(\text{NH}_4)_2\text{Mn}_2(\text{P}_2\text{O}_7)_3$).....	do.	
Mica.....	do.	
Silicic acid.....	do.	
Silicon dioxide (silica).....	do.	
Silk, powdered.....	do.	
Talc.....	do.	
Tin oxide.....	do.	
Titanium dioxide.....	do.	
Ultramarine blue.....	do.	
Ultramarine green.....	do.	
Ultramarine pink.....	do.	
Ultramarine red.....	do.	
Ultramarine violet.....	do.	
Zinc carbonate.....	do.	
Zinc oxide.....	do.	
Zinc stearate.....	do.	

[28 F.R. 317, Jan. 11, 1963; 28 F.R. 452, Jan. 12, 1963, as amended at 28 F.R. 2674, Mar. 19, 1963; 28 F.R. 7183, July 12, 1963; 28 F.R. 7424, July 20, 1963; 28 F.R. 7936, Aug. 3, 1963; 28 F.R. 8309, Aug. 14, 1963; 28 F.R. 8460, Aug. 17, 1963; 28 F.R. 10816, Oct. 9, 1963; 28 F.R. 12161, Nov. 15, 1963; 28 F.R. 14311, Dec. 27, 1963; 29 F.R. 1615, Jan. 31, 1964; 29 F.R. 3621, Mar. 21, 1964; 29 F.R. 5393, Apr. 22, 1964, 29 F.R. 7421, June 9, 1964, 29 F.R. 9379, July 9, 1964; 29 F.R. 16983, Dec. 12, 1964; 29 F.R. 17089, Dec. 15, 1964]

§ 8.502 Termination of provisional listings of color additives.

(a) *Ext. D&C Yellow Nos. 9 and 10.* These colors cannot be produced with any assurance that they do not contain β -naphthylamine as an impurity. While it has been asserted that the two colors can be produced without the impurity named, no method of analysis has been suggested to establish the fact. β -Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in products to be used in contact with the skin. The Commissioner of Food and Drugs, having concluded that such action is necessary to protect the public health, hereby terminates the provisional listing of Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10 (§§ 9.309 and 9.310 of this chapter).

(b) (1) *D&C Red Nos. 8, 9, 10, 19, 33, 37; D&C Yellow No. 7; D&C Orange Nos. 3, 4, 5, and 17.* Subacute studies have established that these colors are toxic substances, unsafe for unrestricted use in drugs and cosmetics.

(2) *D&C Red Nos. 11, 12, and 13.* These colors are chemically related to D&C Red No. 10, being the calcium, barium, and strontium salts of the same dye, and are chemically indistinguishable from D&C Red No. 10 in the analysis of a product in which such colors have been used. They therefore must be subject to the same restrictions imposed on D&C Red No. 10.

(3) *D&C Yellow No. 8.* This color is chemically and pharmacologically related to D&C Yellow No. 7, and therefore must be subject to any restriction imposed on that color.

The Commissioner of Food and Drugs, having concluded that such action is necessary for the protection of the public health, hereby terminates the provisional listing for the colors named in this section for unrestricted use in drugs and cosmetics. These colors are now listed in Part 9 of this chapter as follows:

D&C Red No. 8 (§ 9.153 of this chapter).
D&C Red No. 9 (§ 9.154 of this chapter).
D&C Red No. 10 (§ 9.155 of this chapter).
D&C Red No. 11 (§ 9.156 of this chapter).

D&C Red. No. 12 (§ 9.157 of this chapter).
 D&C Red. No. 13 (§ 9.158 of this chapter).
 D&C Red. No. 19 (§ 9.164 of this chapter).
 D&C Red No. 33 (§ 9.178 of this chapter).
 D&C Red No. 37 (§ 9.182 of this chapter).
 D&C Yellow No. 7 (§ 9.130 of this chapter).
 D&C Yellow No. 8 (§ 9.131 of this chapter).
 D&C Orange No. 3 (§ 9.200 of this chapter).
 D&C Orange No. 4 (§ 9.201 of this chapter).
 D&C Orange No. 5 (§ 9.202 of this chapter).
 D&C Orange No. 17 (§ 9.214 of this chapter).

(c) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion:

(1) Groups of 50 rats are being fed diets containing FD&C Red No. 1 at levels of 5 percent, 2 percent, 1 percent, 0.5 percent, and 0 percent. At this stage of the tests, which have now been in progress for from 15 months to 18 months, 116 animals from the 250 being fed FD&C Red No. 1 at various levels and 27 of the 100 controls have died. Of these, 11 being fed at the 5 percent level, 16 being fed at the 2 percent level, 11 being fed at the 1 percent level, and 2 being fed at the 0.5 percent level, have shown liver damage. None of the controls that have died have shown liver damage.

(2) Groups of 100 mice are being fed diets containing 2 percent, 1 percent, 0.5 percent, and 0.1 percent FD&C Red No. 1, with 400 mice as controls. All mice on dosage levels of 2 percent and 1 percent died before the seventieth week. Gross liver damage has been observed in all groups fed at the 0.5 percent diet and above.

(3) Groups of 4 dogs are being fed diets containing 2 percent, 1 percent, 0.25 percent, and 0 percent FD&C Red No. 1. Three of the dogs on the 2 percent dosage level died before 32 weeks; the other is living. Three of the dogs on the 1 percent dosage level died or were sacrificed within 13 months. All deceased or sacrificed dogs have shown liver damage grossly and/or microscopically. Deceased dogs on the 1 percent and 2 percent dosage level showed poor physical condition.

The Commissioner of Food and Drugs, having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 1 (§ 9.60 of this chapter) for use in foods, drugs, and cosmetics.

(d) *FD&C Red No. 4.* Feeding tests of

this color additive have been conducted with three species:

(1) Rats of the Osborne-Mendel and Sprague-Dawley strains were fed FD&C Red No. 4 for 2 years at levels of 5 percent, 2 percent, 1 percent, and 0.5 percent of the diet. No effect was found.

(2) Mice of the C3Hf and C57BL strains were fed FD&C Red No. 4 for 2 years at levels of 2 percent and 1 percent of the diet. No effect was found.

(3) Dogs were fed FD&C Red No. 4 at levels of 2 percent and 1 percent of the diet. Adverse effects were found at both levels in the urinary bladder and in the adrenals. Three dogs of five fed on the 2-percent level died after 6 months, 9 months, and 5½ years on the test. Two of the dogs on the 2-percent level and all five of the dogs on the 1-percent level survived to the completion of the 7 year study.

The Commissioner of Food and Drugs has concluded that the data available to him do not permit the establishment of a safe level of use of this color additive for a long period of time in food and in ingested drugs and cosmetics. In order to protect the public health, the Commissioner hereby terminates the provisional listing of FD&C Red No. 4 (§ 9.63 of this chapter) for use in food and in drugs and cosmetics that may be ingested. The Commissioner does not find that the facts now before him require a prohibition of the use of FD&C Red No. 4 in drugs and cosmetics which are not ingested and the provisional listing with respect to these uses remains in effect.

[25 F.R. 9760, Oct. 12, 1960, as amended at 25 F.R. 10600, Nov. 5, 1960, 25 F.R. 11214, Nov. 26, 1960, 26 F.R. 7579, Aug. 16, 1961, 29 F.R. 16893, Dec. 11, 1964]

§ 8.503 Temporary tolerances.

Two-year chronic rat feeding studies, including histopathology, of D&C Red. No. 9 and D&C Red. No. 10 have been completed. A final determination of the status of these colors for ingestion must await chronic feeding studies with a nonrodent species. However, pharmacologists of the Food and Drug Administration have concluded, on the basis of chronic feeding studies with the rat, that a no-effect level of feeding of 100 parts per million will be accepted pending chronic feeding studies with a nonrodent species. Since the subacute toxicity of the two colors is of the same order of subacute toxicity as the other nine colors listed in § 8.502(b) (1), it can be assumed

for the purpose of temporary tolerances that the same no-effect level of feeding for the nine colors is also 100 parts per million. Data have been submitted which indicate that the maximum amount of the color additives listed in paragraph (a) of this section likely to be ingested daily from lipstick will correspond to about 0.1 part per million in the daily diet. On this basis, it is not inconsistent with the protection of the public health to allow, during this transitional period, continued use of these products in lipstick and in other products that may be ingested in the amounts specified in this section.

(a) Pursuant, therefore, to the authority in § 203(d)(1)(C) of the Color Additives Amendments of 1960, temporary tolerances are established for the following color additives:

D&C Orange No. 3 (§ 9.200 of this chapter).
 D&C Orange No. 4 (§ 9.201 of this chapter).
 D&C Orange No. 5 (§ 9.202 of this chapter).
 D&C Orange No. 17 (§ 9.214 of this chapter).
 D&C Red No. 8 (§ 9.153 of this chapter).
 D&C Red No. 9 (§ 9.154 of this chapter).
 D&C Red No. 10 (§ 9.155 of this chapter).
 D&C Red No. 11 (§ 9.156 of this chapter).
 D&C Red No. 12 (§ 9.157 of this chapter).
 D&C Red No. 13 (§ 9.158 of this chapter).
 D&C Red No. 19 (§ 9.164 of this chapter).
 D&C Red No. 33 (§ 9.178 of this chapter).

These color additives are therefore retained on the provisional list for use in lipstick with a temporary tolerance for each such color additive or combination of color additives of not more than 6 percent pure dye by weight of each lipstick. These color additives and D&C Yellow No. 7, D&C Yellow No. 8, and D&C Red No. 37 are retained without tolerance restrictions for externally applied drugs and cosmetics.

(b) The colors named in this paragraph may safely be used, during the transitional period, in drug products and in such other preparations subject to ingestion as mouth washes and dentifrices, where total usage reasonably to be expected to be ingested does not contribute more than 1 part per million of any such color additive or combination of color additives to the human diet. Therefore to meet this limitation the following colors are retained on the provisional list of color additives for use in drug products for internal use, mouth washes, dentifrices, and proprietary products, under a temporary tolerance, provided that in no instance shall such color additives contribute more than 0.75 milligram of the color additive, ex-

pressed as pure dye, to the amount of the product reasonably expected to be ingested in 1 day.

D&C Orange No. 3 (§ 9.200 of this chapter).
 D&C Orange No. 4 (§ 9.201 of this chapter).
 D&C Orange No. 5 (§ 9.202 of this chapter).
 D&C Red No. 8 (§ 9.153 of this chapter).
 D&C Red No. 12 (§ 9.157 of this chapter).
 D&C Red No. 19 (§ 9.164 of this chapter).
 D&C Red No. 33 (§ 9.178 of this chapter).
 D&C Red No. 37 (§ 9.182 of this chapter).
 [26 F.R. 7579, Aug. 16, 1961]

§ 8.510 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list (§ 8.502(a)) are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b)(1) Certificates issued heretofore for the color additive designated FD&C Red No. 1 (§ 9.60 of this chapter) are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

(c) Certificates issued heretofore for the color additive designated FD&C Red No. 4 (§ 9.63 of this chapter) and of all mixtures containing this color additive are cancelled effective 180 days after the date of the publication of this order insofar as food and ingested drugs and cosmetics are concerned, and use of this color additive in the manufacture of food and ingested drugs and cosmetics after that date will result in adulteration. The certificates shall continue in effect for the use of this color additive in drugs and cosmetics which are not ingested. The Commissioner finds that no action needs to be taken to remove food and ingested drugs and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acutely toxic substance and that it is used only in small amounts in food and ingested drugs and cosmetics.
 [25 F.R. 11214, Nov. 26, 1960, as amended at 29 F.R. 16983, Dec. 11, 1964]

§ 8.515 Limitation of certificates.

Certificates issued heretofore for color additives being retained on the provisional list in § 8.503, but under tolerance and usage restrictions, are hereby limited to those uses and under those conditions imposed by that section. Use of such color additives in any other manner after December 1, 1960, in drugs or cosmetics will result in adulteration. Any color additive certified under such tolerance and usage restrictions after October 12, 1960, shall bear a label statement of the name of the color additive and of the tolerance and use limitations applicable to it.

[25 F.R. 9761, Oct. 12, 1960]

Subpart E—Listing of Color Additives for Drug Use Subject to Certification

§ 8.4070 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1-4-di-*p*-toluidino anthraquinone. It conforms to the general specifications of § 8.120 (Subpart B) and the following specific requirements:

Volatile matter (at 135° C.), not more than 2.0 percent.

Water-soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 210° C.

(b) *Uses and restrictions.* The color additive may be safely used for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The quantity of the color additives does not exceed 0.75 percent by weight of the suture material.

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

(3) The listing of D&C Green No. 6 for the purposes described in paragraph (b) of this section is not to be construed as a listing for any other use.

(c) *Labeling.* The color additive shall bear labeling complying with the regulations under Subpart A of this part.

(d) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under Subpart A of this part.

[27 F.R. 12829, Dec. 28, 1962; 28 F.R. 71 Jan. 3, 1963]

Subpart F—Listing of Color Additives for Drug Use Exempt From Certification

§ 8.6000 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this Subpart F, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs*—(1) *General use.* Diluents listed in § 8.300(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured.....	As set forth in 26 CFR, Part 212....	In color coatings for pharmaceutical forms; no residue.
Cetyl alcohol.....	As set forth in N.F.XI.....	
Isopropyl alcohol.....		
Polyoxyethylene (20) sorbitan mono- stearate (Polysorbate 60).....	As set forth in § 121.1030 of this chapter.	
Polyoxyethylene (20) sorbitan tri- stearate (Polysorbate 65).....	As set forth in § 121.1008 of this chapter.	
Polysorbate 80.....	As set forth in § 121.1009 of this chapter.	
Polyvinyl-pyrrolidone.....	As set forth in § 121.1139 of this chapter.	
Sorbitan monooleate.....		
Sorbitan monostearate.....	As set forth in § 121.1029 of this chapter.	
Sorbitan trioleate.....		

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in § 8.300(b) (1) (i) and the following:

Ethyl lactate.

Polyoxyethylene sorbitan monolaurate (20).

(b) *Externally applied drugs.* Diluents listed in paragraph (a) (1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol-----	As set forth in N.F. XI.
Ethyl cellulose-----	As set forth in § 121.1087 of this chapter.

Hydroxyethyl cellulose.

Hydroxypropyl cellulose. As set forth in § 121.1160 of this chapter.

[29 F.R. 13893, Oct. 8, 1964; redesignated 29 F.R. 15287, Nov. 14, 1964]

§ 8.6001 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Diluents in color additive mixtures: Diluents in color additive mixtures for drug use containing synthetic iron oxide shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Specifications.* Synthetic iron oxide conforms to the following specifications, calculated on the basis of elemental iron content:

Copper (Cu), not more than 65 p.p.m.

Lead (Pb), not more than 8 p.p.m.

Arsenic (As) not more than 3 p.p.m.

Vanadium (Va), not more than 50 p.p.m.

Chromium (Cr), not more than 40 p.p.m.

Cobalt (Co), not more than 300 p.p.m.

Mercury (Hg), not more than 2 p.p.m.

Manganese (Mn), not more than 0.40 percent.

(c) *Uses and restrictions.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally: *Provided*, That if the color additive is used in ingested drugs, the amount consumed in accordance with labeled or prescribed dosages does not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Label requirements.* The label of the color additive and any mixtures intended in whole or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act and other regulations in this chapter:

(1) The name of the color additive, synthetic iron oxide.

(2) A statement of the concentration of synthetic iron oxide, as elemental iron, contained therein.

(3) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(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 certification requirements of section 706(c) of the act. [28 F.R. 3693, Apr. 16, 1963]

NOTE: § 8.6001 was stayed in its entirety at 28 F.R. 5719, June 12, 1963.

§ 8.6002 Caramel.

(a) *Identity and specifications.* (1) The color additive caramel shall conform in identity and specifications to the requirements of § 8.303(a) (1), (2), and (3) and (b).

(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart F as safe and suitable in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(c) *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 certification requirement of section 706(c) of the act. [28 F.R. 8309, Aug. 14, 1963]

§ 8.6003 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 8.305(a) (1) and (b).

(2) The diluents in color additive mixtures for drug use containing annatto extract shall be limited to those listed in subpart F of this Part as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Annatto extract may be used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* In addition to all other information required by the act, labels of annatto extract and mixtures prepared therefrom shall bear

information showing the color is derived from annatto seed and shall declare all ingredients by their specific names with the exception of residues of solvents listed in § 8.305(a) (1) (ii).

(d) *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 certification requirements of section 706(c) of the act. [28 F.R. 10202, Sept. 18, 1963]

§ 8.6004 β -Carotene.

(a) *Identity and specifications.* (1) The color additive β -carotene shall conform in identity and specifications to the requirements of § 8.304 (a) (1) and (b).

(2) The diluents in color additive mixtures for drug use containing β -carotene are limited to those listed in Subpart F of this Part 8 as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* β -Carotene may be used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 8.32.

(d) *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 certification requirements of section 706(c) of the Act. [29 F.R. 3003, Mar. 5, 1964]

Subpart G—Listing of Color Additives for Cosmetic Use Subject to Certification [Reserved]

Subpart H—Listing of Color Additives for Cosmetic Use Exempt From Certification [Reserved]

PART 9—COLOR CERTIFICATION

Subpart A—General

- Sec.
9.1 Definitions.
9.2 General specifications for straight colors.
9.3 Mixtures that may be certified.

Subpart B—Straight Colors and Specifications for Their Certification for Use in Food, Drugs, and Cosmetics

- 9.20 General.

- Sec.
9.21 FD&C Green No. 1.
9.22 FD&C Green No. 2.
9.23 FD&C Green No. 3.
9.40 FD&C Yellow No. 5.
9.41 FD&C Yellow No. 6.
9.61 FD&C Red No. 2.
9.62 FD&C Red No. 3.
9.80 FD&C Blue No. 1.
9.81 FD&C Blue No. 2.
9.90 FD&C Violet No. 1.
9.100 Lakes (FD&C).

Subpart C—Straight Colors and Specifications for Their Certification for Use in Drugs and Cosmetics

- 9.101 General.
9.103 D&C Green No. 5.
9.104 D&C Green No. 6.
9.105 D&C Green No. 7.
9.106 D&C Green No. 8.
9.130 D&C Yellow No. 7.
9.131 D&C Yellow No. 8.
9.133 D&C Yellow No. 10.
9.134 D&C Yellow No. 11.
9.150 D&C Red No. 5.
9.151 D&C Red No. 6.
9.152 D&C Red No. 7.
9.153 D&C Red No. 8.
9.154 D&C Red No. 9.
9.155 D&C Red No. 10.
9.156 D&C Red No. 11.
9.157 D&C Red No. 12.
9.158 D&C Red No. 13.
9.159 D&C Red No. 14.
9.162 D&C Red No. 17.
9.163 D&C Red No. 18.
9.164 D&C Red No. 19.
9.166 D&C Red No. 21.
9.167 D&C Red No. 22.
9.169 D&C Red No. 24.
9.172 D&C Red No. 27.
9.173 D&C Red No. 28.
9.174 D&C Red No. 29.
9.175 D&C Red No. 30.
9.176 D&C Red No. 31.
9.178 D&C Red No. 33.
9.179 D&C Red No. 34.
9.180 D&C Red No. 35.
9.181 D&C Red No. 36.
9.182 D&C Red No. 37.
9.183 D&C Red No. 38.
9.184 D&C Red No. 39.
9.200 D&C Orange No. 3.
9.201 D&C Orange No. 4.
9.202 D&C Orange No. 5.
9.205 D&C Orange No. 8.
9.207 D&C Orange No. 10.
9.208 D&C Orange No. 11.
9.211 D&C Orange No. 14.
9.212 D&C Orange No. 15.
9.213 D&C Orange No. 16.
9.214 D&C Orange No. 17.
9.230 D&C Brown No. 1.
9.240 D&C Blue No. 4.
9.242 D&C Blue No. 6.
9.243 D&C Blue No. 7.
9.245 D&C Blue No. 9.
9.260 D&C Black No. 1.