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[Page 286-293]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 70--COLOR ADDITIVES

Subpart A--General Provisions

Sec.
70.3 Definitions.
70.5 General restrictions on use of color additives.
70.10 Color additives in standardized foods, new drugs, and antibiotics.
70.11 Related substances.
70.19 Fees for listing.

Subpart B--Packaging and Labeling

70.20 Packaging requirements for straight colors (other than hair dyes).
70.25 Labeling requirements for color additives (other than hair dyes).

Subpart C--Safety Evaluation

70.40 Safety factors to be considered.
70.42 Criteria for evaluating the safety of color additives.
70.45 Allocation of color additives.
70.50 Application of the cancer clause of section 721 of the act.
70.51 Advisory committee on the application of the anticancer clause.
70.55 Request for scientific studies.

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Source: 42 FR 15636, Mar. 22, 1977, unless otherwise noted.

Subpart A--General Provisions

Sec. 70.3 Definitions.

(a) Secretary means the Secretary of Health and Human Services.
(b) Department means the Department of Health and Human Services.
(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 Center for Food Safety and Applied Nutrition, 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 another substance) of imparting a color thereto. 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 transmittal of the color 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 definitions 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. 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 721 of the act, on the basis that it is used (or intended to be

[[Page 287]]

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 parts 73, 74, and 81 of this chapter, 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 with in 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 coal tar hair dyes intended for use in altering the color of the hair and which are, or which bear or contain, color additives

derived from coal tar 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. The exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, and it does not extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditions, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetic that alter the color of the hair.

(v) The terms externally applied drugs and externally applied cosmetics mean drugs or cosmetics applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

[42 FR 15636, Mar. 22, 1977, as amended at 61 FR 14478, Apr. 2, 1996]

Sec. 70.5 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 parts 73, 74, and 81 of this chapter, 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 parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

(c) Color additives for use in surgical sutures. 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 as a surgical suture 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 as a surgical suture, 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 parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

Sec. 70.10 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 part 71 of this chapter 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 Sec. 130.17 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 part 71 of this chapter.

(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 Sec. 130.17 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 part 71 of this chapter 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 part 71 of this chapter.

(3) Where a petition for a color additive must be filed in accordance with paragraph (b)(2) of this section, 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.

Sec. 70.11 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.

Sec. 70.19 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) of this section, 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

[[Page 290]]

under paragraph (a) or (b) of this section, 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 Sec. 80.35 for use in color additive mixtures shall be $250.00.

(k) Objections and request for public hearing under section 721(d) of the act or section 203(d)(2)(C) of Pub. L. 86-618 (74 Stat. 404; 21 U.S.C. 379e, 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 721(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, collectable at par at Washington, DC All deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 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.

[42 FR 15636, Mar. 22, 1977, as amended at 54 FR 24890, June 12, 1989; 61 FR 14478, Apr. 2, 1996]

Subpart B--Packaging and Labeling

Sec. 70.20 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 parts 170 through 189 of this chapter.

Sec. 70.25 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 this part and parts 71, 73, 74, 80, and 81 of this chapter. In addition to all other information required by the act, 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 limitations 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.

Subpart C--Safety Evaluation

Sec. 70.40 Safety factors to be considered.

In accordance with section 721(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.

Sec. 70.42 Criteria for evaluating the safety of color additives.

(a) In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the ``safe-for-use'' principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such

[[Page 292]]

general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

(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.

Sec. 70.45 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 721(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.

Sec. 70.50 Application of the cancer clause of section 721 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

[[Page 293]]

judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

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

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

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

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

Sec. 70.55 Request for scientific studies.

The Commissioner will consider requests by any interested person who desires the Food and Drug Administration to conduct scientific studies to support a petition for a regulation for a color additive. If favorably acted upon, such studies will be limited to pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its 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 Sec. 70.19.