

diligence hearing shall have the burden of proof at the hearing.

§ 60.46 Administrative decision.

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and to the requesting party, the applicant, and the petitioner.

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 and new drugs.
- 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.

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e.

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

Subpart A—General Provisions

§ 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