AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

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]

§ 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.

§ 70.10 Color additives in standardized foods and new drugs.

(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 § 130.17 of this chapter.