

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.

(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 § 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.* (1) Where an application for a new drug is received and this