

Food and Drug Administration, HHS

§ 701.1

regulations without regard to the retail level effective date.

[47 FR 50451, Nov. 5, 1982; 48 FR 1707, Jan. 14, 1983; 48 FR 11427, Mar. 18, 1983, as amended at 48 FR 16664, Apr. 19, 1983; 48 FR 37624, Aug. 19, 1983]

EFFECTIVE DATE NOTE: See 48 FR 41579, Sept. 16, 1983, for a document announcing an interim stay of the effective date of certain provisions in paragraph (e)(3) of § 700.25.

§ 700.35 Cosmetics containing sunscreen ingredients.

(a) A product that includes the term “sunscreen” in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in section 201(g)(1) of the act. Sunscreen active ingredients affect the structure or function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun when used in conjunction with limiting sun exposure and wearing protective clothing. When consumers see the term “sunscreen” or similar sun protection terminology in the labeling of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. Consequently, the use of the term “sunscreen” or similar sun protection terminology in a product’s labeling generally causes the product to be subject to regulation as a drug. However, sunscreen ingredients may also be used in some products for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). To avoid consumer misunderstanding, if a cosmetic product contains a sunscreen ingredient and uses the term “sunscreen” or similar sun protection terminology anywhere in its labeling, the term must be qualified by describing the cosmetic benefit provided by the sunscreen ingredient.

(b) The qualifying information required under paragraph (a) of this sec-

tion shall appear prominently and conspicuously at least once in the labeling in conjunction with the term “sunscreen” or other similar sun protection terminology used in the labeling. For example: “Contains a sunscreen—to protect product color.”

[64 FR 27693, May 21, 1999]

EFFECTIVE DATE NOTE: At 64 FR 27693, May 21, 1999, § 700.35 was added, effective May 21, 2001. At 65 FR 36319, June 8, 2000, the effective date was delayed until Dec. 31, 2002.

PART 701—COSMETIC LABELING

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Subpart C—Labeling of Specific Ingredients

- 701.20 Detergent substances, other than soap, intended for use in cleansing the body.
- 701.30 Ingredient names established for cosmetic ingredient labeling.

AUTHORITY: 21 U.S.C. 321, 352, 361, 362, 363, 371, 374; 15 U.S.C. 1454, 1455.

SOURCE: 39 FR 10056, Mar. 15, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 701.1 Misbranding.

(a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or