

**§ 700.11**

**21 CFR Ch. I (4-1-13 Edition)**

(m) The term *all business trading names used by the establishment* means any name which is used on a cosmetic product label and owned by the cosmetic product manufacturer or packer, but is different from the principal name under which the cosmetic product manufacturer or packer is registered.

(n) The definitions and interpretations contained in sections 201, 601, and 602 of the act shall be applicable to such terms when used in the regulations in this subchapter.

(o) *System of commercial distribution* of a cosmetic product means any distribution outside the establishment manufacturing the product, whether for sale, to promote future sales (including free samples of the product), or to gage consumer acceptance through market testing, in excess of \$1,000 in cost of goods.

(p) *Filed screening procedure* means a procedure that is:

(1) On file with the Food and Drug Administration and subject to public inspection;

(2) Designed to determine that there is a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of the cosmetic product; and

(3) Which is subject, upon request by the Food and Drug Administration, to an audit conducted by the Food and Drug Administration at reasonable times and, where an audit is conducted, such audit shows that the procedure is consistently being applied and that the procedure is not disregarding reportable information.

(q) *Reportable experience* means an experience involving any allergic reaction, or other bodily injury, alleged to be the result of the use of a cosmetic product under the conditions of use prescribed in the labeling of the product, under such conditions of use as are customary or reasonably foreseeable for the product or under conditions of misuse, that has been reported to the manufacturer, packer, or distributor of the product by the affected person or any other person having factual knowledge of the incident, other than an alleged experience which has been determined to be unfounded or spurious

when evaluated by a filed screening procedure.

[39 FR 10054, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981]

**Subpart B—Requirements for Specific Cosmetic Products**

**§ 700.11 Cosmetics containing bithionol.**

(a) Bithionol has been used to some extent as an antibacterial agent in cosmetic preparations such as detergent bars, shampoos, creams, lotions, and bases used to hide blemishes. New evidence of clinical experience and photopatch tests indicate that bithionol is capable of causing photosensitivity in man when used topically and that in some instances the photosensitization may persist for prolonged periods as severe reactions without further contact with sensitizing articles. Also, there is evidence to indicate that bithionol may produce cross-sensitization with other commonly used chemicals such as certain halogenated salicylanilides and hexachlorophene. It is, therefore, the view of the Food and Drug Administration that bithionol is a deleterious substance which may render any cosmetic product that contains it injurious to users. Accordingly, any cosmetic containing bithionol is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Regulatory proceedings may be initiated with respect to any cosmetic preparation containing bithionol shipped within the jurisdiction of the act after March 15, 1968.

**§ 700.13 Use of mercury compounds in cosmetics including use as skinbleaching agents in cosmetic preparations also regarded as drugs.**

(a) Mercury-containing cosmetic preparations have been represented for many years as skin-bleaching agents or as preparations to remove or prevent freckles and/or brown spots (so-called age spots). Preparations intended for such use are regarded as drugs as well as cosmetics. In addition to such use as skin-bleaching agents, mercury compounds have also been widely used as preservatives in cosmetics such as