

men of weight reduction based on caloric restriction, for patients in whom obesity is refractory to other measures.

(3) Complete labeling guidelines are available from the Food and Drug Administration.

(h) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which is not in accord with this regulation.

(39 FR 11680, Mar. 29, 1974, as amended at 41 FR 10885, Mar. 15, 1976; 55 FR 11573, Mar. 29, 1990)

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §310.504 was removed, effective Apr. 14, 1997.

§310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness when inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) Clinical investigations designed to obtain evidence that any aerosol drug preparation containing vinyl chloride as an ingredient, including propellant, is safe and effective for the purpose intended, must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

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(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

(39 FR 10830, Aug. 26, 1974, as amended at 55 FR 11573, Mar. 29, 1990)

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §310.505 was removed, effective Apr. 14, 1997.

§310.507 Aerosol drug products for human use containing 1,1,1-trichloroethane.

(a) Trichloroethane has been used in aerosol drug products as a solvent for the active ingredients and to reduce the vapor pressure of the propellants. It is potentially toxic to the cardiovascular system, i.e., can sensitize the heart to epinephrine. At a sufficiently large concentration, it is a potent anesthetic agent. Deaths associated with aerosol decongestant products intended to be inhaled and containing trichloroethane have been reported. Most of the deaths resulted from abuse or gross misuse of the preparations.

(b) The Food and Drug Administration finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of trichloroethane in aerosol drug products intended for inhalation either directly or indirectly. Any aerosol drug product containing trichloroethane and labeled, represented, or advertised for use by inhalation is a new drug and subject to regulatory proceedings unless it is the subject of a new drug application approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

(c) Clinical investigations designed to obtain evidence that any aerosol drug product containing trichloroethane and labeled, represented, or advertised for use by inhalation either directly or indirectly is safe and effective for the purposes intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Regulatory proceedings will be initiated with regard to any such drug within the jurisdiction of the act which

is not in accord with this regulation on January 16, 1978.

(42 FR 63387, Dec. 16, 1977, as amended at 55 FR 11573, Mar. 29, 1990)

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §310.507 was removed, effective Apr. 14, 1997.

§310.508 Use of certain halogenated salicylanilides as an inactive ingredient in drug products.

(a) Halogenated salicylanilides (tribromsalan (TBS, 3,4,5-tribromosalicylanilide), dibromsalan (DBS, 4, 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3', 4,3'-tetrachlorosalicylanilide (TC-SA)) have been used as active or inactive ingredients in a number of over-the-counter (OTC) drug products, largely antibacterial soaps, for antimicrobial, preservative, and other purposes. These halogenated salicylanilides are potent photosensitizers and can cause disabling skin disorders. In some instances the photosensitization may persist for prolonged periods as a severe reaction without further exposure to these chemicals. Safer alternative antimicrobial agents are available.

(b) These halogenated salicylanilides are not generally recognized as safe and effective for use as active or inactive ingredients in any drug products. Therefore, any drug product containing such a halogenated salicylanilide as an ingredient at any level for any purpose is a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act for which an approved new drug application pursuant to section 505 of the act and part 314 of this chapter is required for marketing.

(c) Clinical investigations designed to obtain evidence that any drug product containing a halogenated salicylanilide as an ingredient at any level for any purpose is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Any such drug product initially introduced into interstate commerce after December 1, 1975, that is not in