§ 310.526 Drug products containing active ingredients offered over-the-counter (OTC) for external use as hair growers or for hair loss prevention.

(a) Amino acids, aminobenzoic acid, ascorbic acid, benzoic acid, biotin and all other B-vitamins, dexamethasone, estradiol and other topical hormones, jojoba oil, lanolin, nucleic acids, polysorbate 20, polysorbate 60, sulfanilamide, sulfur 1 percent on carbon in a fraction of paraffinic hydrocarbons, tetracaine hydrochloride, urea, and wheat germ oil have been marketed as ingredients in OTC drug products for

§ 310.527 Camphorated oil drug products.

(a) Historically, camphorated oil (also known as camphor liniment), a solution of 20 percent camphor in cottonseed oil, has been marketed as an over-the-counter (OTC) drug product for various uses, primarily as a topical counterirritant or liniment. A large number of accidental ingestions of camphorated oil, often mistaken for castor oil, cod liver oil, mineral oil, olive oil, cough medicine, or other drug products, have been reported and toxicity has often resulted, primarily in infants and young children. Because of the potential hazard for poisoning to occur, the benefit from using any drug product containing camphor in oil or from using any camphor-containing drug product that is labeled as “camphorated oil” or “camphor liniment,” or any similar name such as “camphor oil” or “camphorated liniment,” for any use, is insignificant when compared to the risk. Based upon the adverse benefit-to-risk ratio, camphorated oil, any drug product containing camphor that is represented, suggested, or purported to be camphorated oil, such as a product labeled “camphor liniment,” “camphor oil,” “camphorated liniment,” or any similar name, cannot be considered generally recognized as safe.

(b) Any drug product containing sweet spirits of nitre is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is a new drug within the meaning of section 201(p) of the act for which an approved new drug application under 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 sweet spirits of nitre for any use 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 drug product containing sweet spirits of nitre in interstate commerce after June 27, 1980, that is not in compliance with this section is subject to regulatory action.