

this section is subject to regulatory action.

[40 FR 25171, June 17, 1985, as amended at 55 FR 11579, Mar. 29, 1990]

§ 310.530 Topically applied hormone-containing drug products for over-the-counter (OTC) human use.

(a) The term “hormone” is used broadly to describe a chemical substance formed in some organ of the body, such as the adrenal glands or the pituitary, and carried to another organ or tissue, where it has a specific effect. Hormones include, for example, estrogens, progestins, androgens, anabolic steroids, and adrenal corticosteroids, and synthetic analogs. Estrogens, progesterone, pregnenolone, and pregnenolone acetate have been present as ingredients in OTC drug products marketed for topical use as hormone creams. However, there is a lack of adequate data to establish effectiveness for any OTC drug use of these ingredients. Therefore, with the exception of those hormones identified in paragraph (e) of this section, any OTC drug product containing an ingredient offered for use as a topically applied hormone cannot be considered generally recognized as safe and effective for its intended use. The intended use of the product may be inferred from the product’s labeling, promotional material, advertising, and any other relevant factor. The use of the word “hormone” in the text of the labeling or in the ingredient statement is an implied drug claim. The claim implied by the use of this term is that the product will have a therapeutic or some other physiological effect on the body. Therefore, reference to a product as a “hormone cream” or any statement in the labeling indicating that “hormones” are present in the product, or any statement that features or emphasizes the presence of a hormone ingredient in the product, will be considered to be a therapeutic claim for the product, or a claim that the product will affect the structure or function of the body, and will consequently cause the product to be a drug.

(b) Any OTC drug product that is labeled, represented, or promoted as a topically applied hormone-containing product for drug use, with the excep-

tion of those hormones identified in paragraph (e) of this section, is regarded as a new drug within the meaning of section 201(p) of the act, for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use as a topically applied hormone-containing drug product 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) After March 9, 1994, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(e) This section does not apply to hydrocortisone and hydrocortisone acetate labeled, represented, or promoted for OTC topical use in accordance with part 348 of this chapter.

[58 FR 47610, Sept. 9, 1993]

§ 310.531 Drug products containing active ingredients offered over-the-counter (OTC) for the treatment of boils.

(a) Aminacrine hydrochloride, benzocaine, bismuth subnitrate, calomel, camphor, cholesterol, ergot fluid extract, hexachlorophene, ichthammol, isobutamben, juniper tar (oil of cade), lanolin, magnesium sulfate, menthol, methyl salicylate, oxyguinoline sulfate, petrolatum, phenol, pine tar, rosin, rosin cerate, sassafras oil, sulfur, thymol, triclosan, and zinc oxide have been present in OTC boil treatment drug products. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these or any other ingredient for OTC use for the treatment of boils. Treatment is defined as reducing the size of a boil or reducing an infection related to a boil. Treatment has involved the use of “drawing salves” for

these purposes. These “drawing salves” contained various ingredients. Based on evidence currently available, any OTC drug product offered for the treatment of boils cannot be considered generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, or promoted for the treatment of boils is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application or abbreviated application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application or abbreviated new drug application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any OTC boil treatment drug product 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) After May 7, 1991, any such OTC drug product that contains aminacrine hydrochloride, bismuth subnitrate, calomel, camphor, cholesterol, ergot fluid extract, hexachlorophene, isobutamben, juniper tar (oil of cade), lanolin, magnesium sulfate, menthol, methyl salicylate, oxyguinoline sulfate, petrolatum, phenol, pine tar, rosin, rosin cerate, sassafras oil, thymol, or zinc oxide initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(e) After May 16, 1994, any such OTC drug product that contains benzocaine, ichthammol, sulfur, or triclosan initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

(f) This section does not apply to drug products that contain benzocaine labeled, represented, or promoted for OTC topical use in accordance with part 348 of this chapter.

[58 FR 60336, Nov. 15, 1993]

§ 310.532 Drug products containing active ingredients offered over-the-counter (OTC) to relieve the symptoms of benign prostatic hypertrophy.

(a) The amino acids glycine, alanine, and glutamic acid (alone or in combination) and the ingredient sabal have been present in over-the-counter (OTC) drug products to relieve the symptoms of benign prostatic hypertrophy, e.g., urinary urgency and frequency, excessive urinating at night, and delayed urination. There is a lack of adequate data to establish general recognition of the safety and effectiveness of these or any other ingredients for OTC use in relieving the symptoms of benign prostatic hypertrophy. In addition, there is no definitive evidence that any drug product offered for the relief of the symptoms of benign prostatic hypertrophy would alter the obstructive or inflammatory signs and symptoms of this condition. Therefore, self-medication with OTC drug products might unnecessarily delay diagnosis and treatment of progressive obstruction and secondary infections. Based on evidence currently available, any OTC drug product containing ingredients offered for use in relieving the symptoms of benign prostatic hypertrophy cannot be generally recognized as safe and effective.

(b) Any OTC drug product that is labeled, represented, or promoted to relieve the symptoms of benign prostatic hypertrophy is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use to relieve the symptoms of benign prostatic hypertrophy 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.