§ 333.150 Labeling of first aid antibiotic drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “first aid antibiotic.”

(b) Indications. The labeling of the product states, under the heading “Indications,” the following: “First aid to help” [select one of the following: “prevent,” (“decrease” (“the risk of” or “the chance of”)), “guard against,” or “protect against”] [select one of the following: “infection,” “bacterial contamination,” or “skin infection”] “in minor cuts, scrapes, and burns.” Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.”

(2) For products containing chlortetracycline hydrochloride or tetracycline hydrochloride. “Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by doctor.”

(3) For any product containing bacitracin, bacitracin zinc, neomycin, neomycin sulfate, polymyxin B, and/or polymyxin B sulfate. “Stop use and consult a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops. Do not use if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by doctor.”

(d) Directions. The labeling of the product contains the following statements under the heading “Directions”:

(1) For ointment and cream products. “Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a sterile bandage.”

(2) For powder products. “Clean the affected area. Apply a light dusting of the powder on the area 1 to 3 times daily. May be covered with a sterile bandage.”

(3) For aerosol products. “Clean the affected area. Spray a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.”
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§ 333.203 Definitions.

As used in this part:
(a) Antifungal. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.

Subpart C—Topical Antifungal Drug Products

SOURCE: 58 FR 49898, Sept. 23, 1993, unless otherwise noted.

§ 333.201 Scope.

(a) An over-the-counter antifungal drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) Reference in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.203 Definitions.

As used in this subpart:
(a) Antifungal. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.