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(c) Exemption from the general accidental overdose warning. The labeling for antiflatulent drug products containing simethicone identified in §332.10 and antacid/antiflatulent combination drug products provided for in §332.15, containing the active ingredients identified in §331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in §330.1(g) of this chapter that the labeling bear the general warning statement “In case of accidental overdose, seek professional assistance or contact a poison control center immediately.” The labeling must continue to bear the first part of the general warning in §330.1(g) of this chapter, which states, “Keep this and all drugs out of the reach of children.”


§ 332.31 Professional labeling.
(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.
(b) Professional labeling for an antiflatulent-antacid combination may contain information allowed for health professionals for antacids and antiflatulents.

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—First Aid Antibiotic Drug Products

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333.101 Scope.
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§ 333.110 First aid antibiotic active ingredients.

The product consists of any of the following active ingredients within the specified concentration established for each ingredient and in the specified dosage form:
§ 333.120 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration and in the specified dosage form, and the product is labeled in accordance with § 333.160.

(a) Combinations of antibiotic active ingredients. (1) Bacitracin-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base.

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B in a suitable ointment base.

(3) Bacitracin-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B in a suitable ointment base.

(4) Bacitracin zinc-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base.

(5) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, and 8,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B;

(6) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable ointment base.

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases.

(8) Bacitracin zinc-polymyxin B sulfate topical powder containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable base.

(9) Neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, 3.5 milligrams of neomycin and 5,000 units of polymyxin B in a suitable water miscible base.

(10) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin and 10,000 units of polymyxin B in a suitable vehicle.

(11) Oxytetracycline hydrochloride-polymyxin B sulfate ointment containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B in a suitable ointment base.

(12) Oxytetracycline hydrochloride-polymyxin B sulfate topical powder containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B with a suitable filler.

(b) Combinations of first aid antibiotic active ingredients and local anesthetic active ingredients. (1) Bacitracin ointment containing, in each gram, 500 units of bacitracin and any single generally

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recognized as safe and effective amine or “caine”-type local anesthetic active ingredient in a suitable ointment base.

(2) Bacitracin-neomycin sulfate-poly-
myxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:
   (i) 500 units of bacitracin, 3.5 milli-
grams of neomycin, 5,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient; or
   (ii) 400 units of bacitracin, 3.5 milli-
grams of neomycin, 5,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient.

(3) Bacitracin-polymyxin B sulfate
topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B and any single generally recognized as safe and effective amine or “caine”-type local anesthetic active ingredient in a suitable vehicle, packaged in a pressurized con-
tainer with suitable inert gases.

(4) Bacitracin zinc-neomycin sulfate-
polymyxin B sulfate ointment containing, in each gram, 400 units of bacitracin, 3 milli-
grams of neomycin, 8,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient; or
   (ii) 400 units of bacitracin, 3.5 milli-
grams of neomycin, 5,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient; or
   (iii) 500 units of bacitracin, 3.5 milli-
grams of neomycin, 5,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient; or
   (iv) 500 units of bacitracin, 3.5 milli-
grams of neomycin, 10,000 units of poly-
myxin B, and any single generally rec-
ognized as safe and effective amine or “caine”-type local anesthetic active ingredient;

(5) Bacitracin zinc-polymyxin B sul-
fate ointment containing, in each gram, 500 units of bacitracin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or “caine”-type local anesthetic active ingredient in a suitable ointment base.

(6) Neomycin sulfate-poly-
myxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or “caine”-type local anesthetic active ingredient in a suit-
able vehicle.

§ 333.150 Labeling of first aid anti-
biotic 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 “In-
dications,” the following: “First aid to help” [select one of the following: “prevent,” (“decrease” (“the risk of” or “the chance of”)), (“reduce” (“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 es-
tablished 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 mis-
branding and the prohibition in section 301(d) of the act against the introduc-
tion 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 warn-
ings 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.”
§ 333.160 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) Indications. The labeling of the product states, under the heading “Indications,” the indication(s) for each ingredient in the combination, as established in the “Indications” sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. 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.

(1) For permitted combinations identified in §333.120(a). The indications in §333.150 should be used.

(2) For permitted combinations identified in §333.120(b). In addition to the required indication identified in §333.150, the labeling of the product may state, under the heading “Indications,” the following additional indication: “First aid for the temporary relief of” (select one of the following: “pain,” “discomfort,” “pain or discomfort” or “pain and itching”) “in minor cuts, scrapes, and burns.”

(c) Warnings. The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) Directions. The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs. When the time intervals or age limitations for administrations of the individual ingredients differ, the directions...
for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

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.

(b) Athlete's foot. An infection of the feet caused by certain dermatophytic fungi.

(c) Dermatophyte. A fungus that invades and lives upon the skin or in the hair or nails.

(d) Fungus. Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.

(e) Jock itch. A chronic and recurrent infection caused by certain dermatophytic fungi; affects the upper inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.

(f) Ringworm. A skin infection caused by certain dermatophytic fungi.

§ 333.210 Antifungal active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Clioquinol 3 percent.

(b) Haloprogin 1 percent.

(c) Miconazole nitrate 2 percent.

(d) Povidone-iodine 10 percent.

(e) Tolnaftate 1 percent.

(f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio that provides a total undecylenate concentration of 10 to 25 percent.

(g) Clotrimazole 1 percent.

§ 333.250 Labeling of antifungal 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 an “antifungal.”

(b) Indications. The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1)(i) of this section and may contain the additional phrase listed in paragraph (b)(1)(ii) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (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.

(1) For products containing any ingredient identified in §333.210 labeled for the treatment of athlete's foot, jock itch, and ringworm. (i) Select one of the following: “Treats,” “For the treatment of,” “For effective treatment of,” “Cures,” “For the cure of,” “Cures up,” or “Proven clinically effective in the treatment of”) “most” (select one condition from any one or more of the following groups of conditions:

(A) “Athlete’s foot,” athlete’s foot (dermatophytosis),” “athlete’s foot (tinea pedis),” or “tinea pedis (athlete’s foot);”

(B) “Jock itch,” “jock itch (tinea cruris),” or “tinea cruris (jock itch);”

or
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(C) “Ringworm,” “ringworm (tinea corporis),” or “tinea corporis (ringworm).”

(ii) In addition to the information identified in paragraph (b)(1)(i) of this section, the labeling of the product may contain the following statement: “Relieves,” “For relief of,” “For effective relief of,” or “Soothes,” (select one or more of the following: “Itching,” “scaling,” “cracking,” “burning,” “redness,” “soreness,” “irritation,” “discomfort,” “chafing associated with jock itch,” “itchy, scaly skin between the toes,” or “itching, burning feet”).

(2) For products containing the ingredient identified in § 333.210(e) labeled for the prevention of athlete’s foot. (i) (Select one of the following: “Clinically proven to prevent,” “Prevents,” “Proven effective in the prevention of,” “Helps prevent,” “For the prevention of,” “For the prophylaxis (prevention) of,” “Guards against,” or “Prevents the recurrence of”) “most” (select one of the following: “Athlete’s foot,” “athlete’s foot (dermatophytosis),” “athlete’s foot (tinea pedis),” or “tinea pedis (athlete’s foot)”) “with daily use.”

(ii) In addition to the information identified in paragraph (b)(2)(i) of this section, the labeling of the product may contain the following statement: “Clears up most athlete’s foot infection and with daily use helps keep it from coming back.”

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

(1) For products containing any ingredient identified in § 330.210. (i) “Do not use on children under 2 years of age unless directed by a doctor.”

(ii) “For external use only.”

(iii) “Avoid contact with the eyes.”

(2) For products labeled according to paragraph (b)(1) of this section for the treatment of athlete’s foot and ringworm. “If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.”

(3) For products labeled according to paragraph (b)(1) of this section for the treatment of jock itch. “If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.”

(4) For products labeled according to paragraph (b)(2) of this section for the prevention of athlete’s foot. “If irritation occurs, discontinue use and consult a doctor.”

(5) For products containing the ingredient identified in § 333.210(a) labeled according to paragraph (b)(1) of this section. The following statements must appear in boldface type as the first warnings under the “Warnings” heading. (i) “Do not use on children under 2 years of age.” (This warning is to be used in place of the warning in paragraph (c)(1)(i) of this section.)

(ii) “Do not use for diaper rash.”

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

(1) For products labeled according to paragraph (b)(1) of this section for the treatment of athlete’s foot, jock itch, and ringworm. [Select one of the following: “Clean” or “Wash”] “the affected area and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.”

(2) For products labeled according to paragraph (b)(2) of this section for the prevention of athlete’s foot. “To prevent athlete’s foot,” (select one of the following: “clean” or “wash”) “the feet and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.”

(e) The word “physician” may be substituted for the word “doctor” in any
§ 333.350 Labeling of acne 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 an “acne medication,” “acne treatment,” “acne medication” (insert dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”), or “acne treatment” (insert dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”).

(b) **Indications.** The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in §333.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following:

(a) Benzoyl peroxide, 2.5 to 10 percent.

(b) Resorcinol, 2 percent, when combined with sulfur in accordance with §333.320(a).

(c) Resorcinol monoacetate, 3 percent, when combined with sulfur in accordance with §333.320(b).

(d) Salicylic acid, 0.5 to 2 percent.

(e) Sulfur, 3 to 10 percent.

(f) Sulfur, 3 to 8 percent, when combined with resorcinol or resorcinol monoacetate in accordance with §333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in §333.310(b) may be combined with sulfur identified in §333.310(f).

(b) Resorcinol monoacetate identified in §333.310(c) may be combined with sulfur identified in §333.310(f).
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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.

(1) "For the" (select one of the following: "management" or "treatment") "of acne."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any one or more of the following statements:

(i) (Select one of the following: "Clears," "Clears up," "Clears up most," "Dries," "Dries up," "Dries and clears," "Helps clear," "Helps clear up," "Reduces the number of," or "Reduces the severity of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "and allows skin to heal."

(ii) "Penetrates pores to" (select one of the following: "eliminate most," "control," "clear most," or "reduce the number of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iii) "Helps keep skin clear of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iv) "Helps prevent new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "from forming."

(v) "Helps prevent the development of new" (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

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

(1) For products containing any ingredients identified in § 330.310. The labeling states "Do not use if you have very sensitive skin or are sensitive to benzoyl peroxide."

(ii) The labeling states "When using this product avoid unnecessary sun exposure and use a sunscreen to avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dyed fabrics, which may be bleached by this product skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration."

(iii) The labeling states "Stop use and ask a doctor if skin irritation becomes severe."

(d) Directions. The labeling of the product contains the following information under the heading "Directions":

(1) For products applied containing any ingredient identified in § 330.310. The labeling states "[bullet] clean the skin thoroughly before applying this product [bullet] cover the entire affected area with a thin layer one to three times daily [bullet] because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor [bullet] if bothersome dryness or peeling occurs, reduce application to once a day or every other day."

(2) For products applied and left on the skin containing benzoyl peroxide identified in § 333.310(a).
§ 335.50 Labeling of antidiarrheal drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product either as an "antidiarrheal" or "for diarrhea."

(b) Indications. The labeling of the product states, under the heading "Use," one or more of the phrases listed in this paragraph (b), as appropriate. 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) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act.

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(i) 标签声明了在本节(d)(1)段中所述的指示。
(ii) 标签声明了"[bullet] 如果外出，使用本产品后请涂抹防晒霜。如果皮肤出现刺激或敏感性，应停止使用本产品并咨询医生。"

(3) 对于包含§333.310中列出的任何成分的产品。

产品，如肥皂和面膜等，可能会被应用和移除，并应包括适当的指示。所有含有过氧化苯甲酰的产品应包含在§333.310(d)(2)段中所述的指示。

(4) 附加指示。除上述要求在§333.310(d)(1)和(d)(2)段中所述外，产品可能包含以下附加指示："新用户敏感测试。在不影响的区域或皮肤上应用少量产品3天。如果未出现不适，请选择以下任一指示：'elsewhere on this label', 'above', or 'below')."