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SOURCE: 52 FR 47322, Dec. 11, 1987, unless otherwise noted.

Subpart A [Reserved]

Subpart B—First Aid Antibiotic Drug Products

§ 333.101 Scope.

(a) An over-the-counter first aid antibiotic 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 of the general conditions established in § 330.1.

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

§ 333.103 Definitions.

As used in this subpart:

First aid antibiotic. An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

[52 FR 47322, Dec. 11, 1987, as amended at 64 FR 403, Jan. 5, 1999]

§ 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:

(a) Bacitracin ointment containing, in each gram, 500 units of bacitracin in a suitable ointment base.

(b) Bacitracin zinc ointment containing, in each gram, 500 units of bacitracin zinc in a suitable ointment base.

(c) Chlortetracycline hydrochloride ointment containing, in each gram, 30 milligrams of chlortetracycline hydrochloride in a suitable ointment base.

(d) Neomycin sulfate ointment containing, in each gram, 3.5 milligrams of neomycin in a suitable water soluble or oleaginous ointment base.

(e) Neomycin sulfate cream containing, in each gram, 3.5 milligrams of neomycin in a suitable cream base.

(f) Tetracycline hydrochloride ointment containing, in each gram, 30 milligrams of tetracycline hydrochloride in a suitable ointment base.

[52 FR 47322, Dec. 11, 1987, as amended at 53 FR 18838, May 25, 1988; 64 FR 403, Jan. 5, 1999]

§ 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, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

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

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases.

(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 5,000 units of polymyxin B; or

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