

**PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

**Subpart A—General Provisions**

Sec.

349.1 Scope.

349.3 Definitions.

**Subpart B—Active Ingredients**

349.10 Ophthalmic astringent.

349.12 Ophthalmic demulcents.

349.14 Ophthalmic emollients.

349.16 Ophthalmic hypertonicity agent.

349.18 Ophthalmic vasoconstrictors.

349.20 Eyewashes.

349.30 Permitted combinations of active ingredients.

**Subpart C—Labeling**

349.50 Labeling of ophthalmic drug products.

349.55 Labeling of ophthalmic astringent drug products.

349.60 Labeling of ophthalmic demulcent drug products.

349.65 Labeling of ophthalmic emollient drug products.

349.70 Labeling of ophthalmic hypertonicity drug products.

349.75 Labeling of ophthalmic vasoconstrictor drug products.

349.78 Labeling of eyewash drug products.

349.79 Labeling of permitted combinations of active ingredients.

349.80 Professional labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 53 FR 7090, Mar. 4, 1988, unless otherwise noted.

**Subpart A—General Provisions**

**§ 349.1 Scope.**

(a) An over-the-counter ophthalmic 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 part and each of the general conditions established in § 330.1.

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

**§ 349.3 Definitions.**

As used in this part:

(a) *Ophthalmic drug product*. A drug product, which should be sterile in ac-

cordance with § 200.50, to be applied to the eyelid or instilled in the eye.

(b) *Astringent*. A locally acting pharmacologic agent which, by precipitating protein, helps to clear mucus from the outer surface of the eye.

(c) *Buffering agent*. A substance which stabilizes the pH of solutions against changes produced by introduction of acids or bases from such sources as drugs, body fluids, tears, etc.

(d) *Demulcent*. An agent, usually a water-soluble polymer, which is applied topically to the eye to protect and lubricate mucous membrane surfaces and relieve dryness and irritation.

(e) *Emollient*. An agent, usually a fat or oil, which is applied locally to eyelids to protect or soften tissues and to prevent drying and cracking.

(f) *Eyewash, eye lotion, irrigating solution*. A sterile aqueous solution intended for washing, bathing, or flushing the eye.

(g) *Hypertonicity agent*. An agent which exerts an osmotic gradient greater than that present in body tissues and fluids, so that water is drawn from the body tissues and fluids across semipermeable membranes. Applied topically to the eye, a hypertonicity agent creates an osmotic gradient which draws water out of the cornea.

(h) *Isotonicity*. A state or quality in which the osmotic pressure in two fluids is equal.

(i) *Vasoconstrictor*. A pharmacologic agent which, when applied topically to the mucous membranes of the eye, causes transient constriction of conjunctival blood vessels.

**Subpart B—Active Ingredients**

**§ 349.10 Ophthalmic astringent.**

The active ingredient and its concentration in the product is as follows: Zinc sulfate, 0.25 percent.

**§ 349.12 Ophthalmic demulcents.**

The active ingredients of the product consist of any of the following, within the established concentrations for each ingredient:

(a) Cellulose derivatives:

(1) Carboxymethylcellulose sodium, 0.2 to 2.5 percent.

**§ 349.14**

- (2) Hydroxyethyl cellulose, 0.2 to 2.5 percent.
- (3) Hypromellose, 0.2 to 2.5 percent.
- (4) Methylcellulose, 0.2 to 2.5 percent.
- (b) Dextran 70, 0.1 percent when used with another polymeric demulcent agent in this section.
- (c) Gelatin, 0.01 percent.
- (d) Polyols, liquid:
  - (1) Glycerin, 0.2 to 1 percent.
  - (2) Polyethylene glycol 300, 0.2 to 1 percent.
  - (3) Polyethylene glycol 400, 0.2 to 1 percent.
  - (4) Polysorbate 80, 0.2 to 1 percent.
  - (5) Propylene glycol, 0.2 to 1 percent.
  - (e) Polyvinyl alcohol, 0.1 to 4 percent.
  - (f) Povidone, 0.1 to 2 percent.

[53 FR 7090, Mar. 4, 1988, as amended at 68 FR 32982, June 3, 2003]

**§ 349.14 Ophthalmic emollients.**

The active ingredients of the product consist of any of the following:

- (a) Lanolin preparations:
  - (1) Anhydrous lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.
  - (2) Lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.
- (b) Oleaginous ingredients:
  - (1) Light mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.
  - (2) Mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.
  - (3) Paraffin, up to 5 percent in combination with one or more other emollient agents included in the monograph.
  - (4) Petrolatum, up to 100 percent.
  - (5) White ointment, up to 100 percent.
  - (6) White petrolatum, up to 100 percent.
  - (7) White wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.
  - (8) Yellow wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

**21 CFR Ch. I (4-1-07 Edition)**

**§ 349.16 Ophthalmic hypertonicity agent.**

The active ingredient and its concentration in the product is as follows: Sodium chloride, 2 to 5 percent.

**§ 349.18 Ophthalmic vasoconstrictors.**

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

- (a) Ephedrine hydrochloride, 0.123 percent.
- (b) Naphazoline hydrochloride, 0.01 to 0.03 percent.
- (c) Phenylephrine hydrochloride, 0.08 to 0.2 percent.
- (d) Tetrahydrozoline hydrochloride, 0.01 to 0.05 percent.

**§ 349.20 Eyewashes.**

The active ingredient of the product is purified water. The product also contains suitable tonicity agents to establish isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

[68 FR 7921, Feb. 19, 2003]

**§ 349.30 Permitted combinations of active ingredients.**

The following combinations are permitted provided each active ingredient is present within the established concentration, and the product is labeled in accordance with § 349.79.

- (a) Any single ophthalmic astringent active ingredient identified in § 349.10 may be combined with any single ophthalmic vasoconstrictor active ingredient identified in § 349.18.
- (b) Any two or three ophthalmic demulcent active ingredients identified in § 349.12 may be combined.
- (c) Any single ophthalmic demulcent active ingredient identified in § 349.12 or any ophthalmic demulcent combination identified in paragraph (b) of this section may be combined with any single ophthalmic vasoconstrictor identified in § 349.18.
- (d) Any single ophthalmic astringent active ingredient identified in § 349.10