

§ 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.

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§ 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

may be combined with any single ophthalmic vasoconstrictor active ingredient identified in §349.18 and any single ophthalmic demulcent identified in §349.12 or ophthalmic demulcent combination identified in paragraph (b) of this section.

(e) Any two or more emollient active ingredients identified in §349.14 may be combined as necessary to give the product proper consistency for application to the eye.

Subpart C—Labeling

§349.50 Labeling of ophthalmic drug products.

(a) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this part.

(b) Where applicable, indications in this part 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. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this part, 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) The labeling of the product contains the following warnings, under the heading “Warnings”:

(1) *For ophthalmic drug products packaged in multi-use containers.* “To avoid contamination, do not touch tip of container to any surface. Replace cap after using.”

(2) *For ophthalmic drug products packaged in single-use containers.* “To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.”

(3) *For ophthalmic drug products containing mercury compounds used as a preservative.* “This product contains (name and quantity of mercury-containing ingredient) as a preservative. Do not use this product if you are sensitive to” (select one of the following: “mercury”

or “(insert name of mercury-containing ingredient) or any other ingredient containing mercury).”

§349.55 Labeling of ophthalmic astringent 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 “astringent” (select one of the following: “eye” or “ophthalmic”) “(insert dosage form, e.g., drops).”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following phrase: “For the temporary relief of discomfort from minor eye irritations.”

(c) *Warnings.* In addition to the warnings in §349.50, the labeling of the product contains the following warnings under the heading “Warnings” for products containing any ingredient identified in §349.10:

(1) “If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.”

(2) “If solution changes color or becomes cloudy, do not use.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

§349.60 Labeling of ophthalmic demulcent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a “lubricant” or “demulcent (lubricant)” (select one of the following: “eye” or “ophthalmic”) “(insert dosage form, e.g., drops).”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” one or more of the following phrases:

(1) “For the temporary relief of burning and irritation due to dryness of the eye.”

(2) “For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.”