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§ 349.75 Labeling of ophthalmic vasoconstrictor 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 ''redness reliever'' or ''vasoconstrictor (redness reliever)'' (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: ''Relieves redness of the eye due to 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 § 349.18:

(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 you have glaucoma, do not use this product except under the advice and supervision of a doctor.''

(3) ''Overuse of this product may produce increased redness of the eye.''

(4) ''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.

§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: ''eyewash,'' ''eye lotion,'' or ''eye irrigating solution.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' one of the following phrases:

(1) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to remove'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(2) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to help relieve'' (select one or more of the following: ''irritation,'' ''discomfort,'' ''burning,'' ''stinging,'' ''smarting,'' or ''itching'') ''by removing'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for all eyewash products:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''Obtain immediate medical treatment for all open wounds in or near the eyes.''

(3) ''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'':

(1) *For eyewash products intended for use with an eyecup.* Rinse cup with clean water immediately before each use. Avoid contamination of rim and inside surfaces of cup. Fill cup half full and apply the cup to the affected eye, pressing tightly to prevent the escape of the liquid, and tilt the head backward. Open eyelids wide and rotate eyeball to ensure thorough bathing with the wash or lotion. Rinse cup with clean water after each use.

(2) *For eyewash products intended for use with a nozzle applicator.* Flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle.

§ 349.79 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