§ 349.70 Labeling of ophthalmic hypertonicity 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 “hypertonicity” (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 corneal edema.”

(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 §349.16:

(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) “Ask a doctor before use if you have [in bold type] narrow angle glaucoma.”

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

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

(5) “When using this product [in bold type] pupils may become enlarged temporarily.”

(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.”

§ 349.75 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 “vasoconstrictor (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) “Ask a doctor before use if you have [in bold type] narrow angle glaucoma.”

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

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

(5) “When using this product [in bold type] pupils may become enlarged temporarily.”

(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 irrigation,” or “eye irrigating solution.”