Food and Drug Administration, HHS

§ 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.”

(b) Indications. The labeling of the product under the heading “Indications” contains the following information: “Instil 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.”

(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”: “Instil 1 to 2 drops in the affected eye(s) up to four times daily.”

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