

At this time, the agency considers a phosphate buffered solution acceptable for emergency first aid eyewash products. The increased concentration of phosphates would not alter the pH range but could be more effective against an acid or alkali burn.

#### *G. Industrial Glare*

One comment briefly referred to emergency first aid eyewash solutions to treat industrial glare (i.e., from welder's arc) but did not provide any data to support this use. At this time, the agency is not including this use as an indication for these products without adequate supporting documentation. The agency requests interested parties to provide supporting data.

#### *H. Five to 15-gallon Container Plus Preservative Concentrate*

One comment explained that a 15-minute emergency eyewash requires 14 gallons (gal) of potable water and a 5-minute eyewash requires 9 1/2 gal of potable water. The comment stated that the unit would be filled with potable water and the preservative concentrate added. The comment offered that a concentrate will preserve 5 to 20 gal of potable water for up to 180 days. The comment further stated that potable eyewash units should be flushed and cleaned and the water and concentrate replaced every 60 days.

All emergency eyewash products must be able to meet monograph requirements, which include safety and effectiveness, a pH range of 6.6 to 7.4, and compliance with CGMPs. The agency is aware that there are preservative concentrates in the marketplace for use in potable eyewash units, as the comment noted. Under § 349.82(d)(3), the agency is proposing that the labeling contain the word "concentrate" in bold type. The labeling must provide adequate directions for adding the concentrate to potable water to obtain a solution that meets the requirements of § 349.22. The directions should also state that the concentrate should be added to potable water to have a fully constituted solution available in advance of an emergency. The agency is unaware of data to support the length of time that any particular preservative concentrate is safe and effective. Manufacturers of these products are advised to follow CGMPs.

#### *I. Labeling*

One comment proposed several labeling revisions under § 349.78. Under § 349.78(a), the comment added to the statement of identity the terms

"neutralizer" and "neutralizing solution."

As stated in section II.A of this document, the agency does not believe that the term "neutralize" properly describes the action of these products and, therefore, is not proposing this term or any variation of this term in the monograph.

Under § 349.78(b)(1) and (b)(2), the comment added the terms "acid" and "alkali." Under § 349.78(b)(5), the comment provided for indications for eyes that have been subjected to industrial glare such as welder's arc and "other workplace irritants." The comment argued that demulcents have a long history of use for soothing the burning sensation associated with welder's arc and other workplace irritants that dry the eye. The comment explained that this indication is an extension of § 349.60(b)(2), which provides for temporary relief due to exposure to the sun.

The agency agrees that if an emergency first aid eyewash will assist in the prevention of permanent damage to the eye(s) due to industrial glare, this indication should be included in the uses section of the labeling. However, as stated in section II.G of this document, the agency needs supporting documentation for this use.

The agency believes the term "particulate contamination" is a general term that could include the comment's request for an indication for "other workplace irritants." The agency agrees that there are potential instances in the industrial setting where particulate matter could cause eye damage and that an eyewash solution could alleviate the seriousness of the condition. Accordingly, the agency is proposing the terms "acid," "alkali," and "particulate contamination" in new § 349.82(b) as examples of causes of injury.

Under § 349.78(d)(3), the comment suggested the following directions for emergency first aid eyewash products:

*For eyewash products packaged in a container that also serves as an eyecup.* Remove safety seal and cap. Avoid contamination of rim of bottle. Place rim over affected eye, pressing tightly to prevent the escape of the liquid, and tilt the head backward. Open eyelid wide and rotate eyeball to ensure thorough bathing with the solution. Use only unopened bottle on the eyes. The comment explained that many large volume (up to 32 oz) first aid eyewash solutions are packaged in containers with wide flanged rims that fit over the eye.

The agency agrees that containers that also serve as eyecups should be addressed in the monograph and is

including this information, with a few modifications, in § 349.82(d)(1). The agency notes that eyecups generally promote retention of material that may be injurious to the eye instead of allowing the injurious material to be washed away and down the face. The use of eyecups in the setting of workplace irritants should be discouraged. The agency also obtained and reviewed representative current labeling for a number of these products (Ref. 17) to develop the labeling in this proposal.

### **III. The Agency's Proposal**

The agency tentatively concludes that the references support the safety and effectiveness of emergency first aid eyewash drug products to remove acid or alkali chemicals and that, in particular, immediate flushing of the eye with fluid is urgently needed to lessen the impact of the alkalis. The agency also acknowledges that burns from alkalis penetrate the ocular tissues rapidly and produce damages that are widespread, uncontrolled, and progressive. However, the agency does not believe that a chemical irritant should be counteracted with another chemical. The agency believes that immediate and copious irrigation with fluid is the most important step and that the amount of time prior to irrigation is a critical factor in determining the amount of residual damage.

The effectiveness of an emergency eyewash appears dependent upon the steady flow of copious amounts of fluid to the injured eye(s). Emergency first aid eyewashes serve as an interim step in first aid care by providing immediate flushing of the eye and allowing the accident victim to be transported to the facility's first aid station or a hospital while the flushing treatment is in progress. Accordingly, the agency is proposing to amend the final monograph for OTC ophthalmic drug products to include a section on emergency first aid eyewashes.

### **IV. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the