

J-590 [Revised]

From Lake Charles, LA, via Baton Rouge, LA; Greene County, MS; to Montgomery, AL.

* * * * *

Issued in Washington, DC, on February 12, 2003.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 03-3965 Filed 2-18-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 349**

[Docket No. 80N-145B]

RIN 0910-AA01

Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Proposed Amendment of Final Monograph for Over-the-Counter Ophthalmic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) ophthalmic drug products to include OTC emergency first aid eyewash drug products. These products are used to flush or irrigate the eye to remove acid and alkali chemicals or particulate contamination. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by May 20, 2003. Submit written or electronic comments on the agency's economic impact determination by May 20, 2003. Please see section IX of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Marina Y. Chang, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 1988 (53 FR 7076), FDA published a final monograph for OTC ophthalmic drug products in part 349 (21 CFR part 349). The monograph provides for eyewash drug products in § 349.20, but does not include emergency first aid eyewash drug products because there were no submissions or comments on these products during the rulemaking process.

After the final monograph was published, the agency received a request for an advisory opinion (Ref. 1) concerning the status of a product used for emergency first aid treatment of chemical burns of the eyes and skin. This product was described as a sterile phosphate buffered solution containing sodium phosphate, USP and monobasic potassium phosphate, NF, preserved with edetate disodium, USP 1:2,000 and benzalkonium chloride, USP 1:5,000, for use immediately following a chemical burn to thoroughly flush the eyes and skin for the express purpose of removing the chemical irritant, and to relieve the discomfort and burning caused by the irritating chemical prior to seeking medical treatment.

As a result, the agency published a request for data and information on this category of drugs in the **Federal Register** of December 5, 1989 (54 FR 50240). The agency stated that it was unaware of sufficient data to make a determination as to the safety, effectiveness, and proper labeling of these ophthalmic drug products. Specifically, the agency noted that the majority of these products: (1) Are not intended to be marketed directly to individual consumers; (2) are often packaged in large volume containers not normally found at the retail level of distribution, especially for OTC ophthalmic drug products; (3) may be stored for long periods of time under different environmental conditions; (4) may be marketed in different types of containers and closure systems; and (5) may be used with plumbed, nonplumbed, self-contained emergency eyewash, or shower equipment/stations. The agency noted it was not aware of all of the various labeling formats, labeling statements, and formulations of all the various emergency first aid eyewash products.

In response to the request for data and information, three manufacturers and one manufacturer's association provided submissions (Refs. 2 through 7) that included several journal articles in support of the safety and effectiveness of products that provide immediate emergency care by neutralization and

dilution to the most serious burns due to strong acids and alkalis. The submitted literature explained that acid burns cause instantaneous coagulation of protein and result in limited damage, whereas strong alkalis penetrate the ocular tissues rapidly and produce damage that is widespread, uncontrolled, and progressive (Ref. 8). The literature (Ref. 2) included a quote from the National Institute of Occupational Safety and Health occupational health guidelines which states: "If (chemical) gets into the eyes, wash eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately." The comment included an excerpt from the regulations of the Occupational Safety and Health Administration (OSHA) entitled "Requirements for Medical and First Aid" (42 CFR 1910.151). This portion of the OSHA regulations assures that workers exposed to injurious corrosive materials be provided with "suitable facilities for quick drenching or flushing of the eye." One manufacturer also provided sample labeling of several marketed products (Ref. 5).

II. Comments Received and the Agency's Responses**A. Neutralization**

Three comments addressed the term "neutralization." One comment stated that it removed this term from the principal display panel of its product's labeling and replaced it with "Wash/Flush" because the latter term better expressed the action of the product. Another comment considered the term "neutralization" to be relative and not absolute. The third comment believed that neutralizing was part of the action of the product and provided a chart demonstrating the buffering capacity of a neutralizer solution towards strong acids and bases versus purified water (Ref. 7).

The agency reviewed available medical literature (Refs. 8 through 15) and found the treatment of choice for acid and alkali burns listed in this literature to be copious and continuous irrigation of the area with water or a pH balanced solution for at least 20 to 30 minutes. According to the American Academy of Ophthalmology (Ref. 8), "Specific neutralizing agents are not useful; simple dilution (with water or saline solution) is the most effective and practical way of neutralizing strong chemicals." *Casarett and Doull's Toxicology: The Basic Science of Poisons* (Ref. 9) states: "Attempts to obtain some special buffered solution or