

Act (21 U.S.C. 353(b)); (4) the product is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

Emergency first aid eyewash products and eye irrigating solutions that do not meet the previous criteria may not be marketed OTC pending evaluation of these products for the treatment of chemical burns and for irrigation of the eye(s) unless the product is the subject of an approved new drug application (NDA).

This analysis of impacts shows that the proposed rule is not economically significant under Executive Order 12866 and that the agency has undertaken important steps to reduce the burden to small entities. This analysis of impacts, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required by the Regulatory Flexibility Act. The agency will reassess the economic impact of this rulemaking in the preamble to the final rule.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as

defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or three hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

X. References

The following references are on display in the Dockets Management Branch (see **ADDRESSES**) under Docket No. 80N-145B and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. AP.
2. Comment 1.
3. Comment 2.
4. Comment 3.
5. Comment 4.
6. Comment 5.
7. Comment 6.
8. "External Disease and Cornea," 1989-1990, *Basic and Clinical Science Course*, American Academy of Ophthalmology, San Francisco, CA, pp. 130-133, 1989.
9. Potts, A. M., "Toxic Responses of the Eye," *Casarett and Doull's Toxicology: The Basic Science of Poisons*, 3d ed., Macmillan Publishing Co., New York, NY, pp. 478-485, 1986.
10. Raker, R. E., *Conn's Current Therapy 1990*, W. B. Saunders Co., Philadelphia, PA, p. 1035, 1990.
11. Dreisbach, R. H., and W. O. Robertson, "Emergency Management of Poisoning," *Handbook of Poisoning: Prevention, Diagnosis & Treatment*, 12th ed., Appleton & Lange, Norwalk, CT, pp. 28-29, 1987.
12. Siverston, K. T., "Ocular Toxicity," *Manual of Toxicologic Emergencies*, Year Book Medical Publishers, Inc., Chicago, IL, pp. 115-118, 1989.
13. Tapley, D. F. et al., "The Eyes," *The Columbia University College of Physicians and Surgeons Complete Home Medical Guide*, Crown Publishers, Inc., New York, NY, pp. 696-697, 1989.
14. Behrman, R. E., and V. C. Vaughan, "Injuries to the Eye," *Nelson Textbook of*

Pediatrics, 13th ed., W. B. Saunders Co., Philadelphia, PA, pp. 1472-1473, 1987.

15. "Occupational Health Guidelines for Ethyl Chloride," National Institute for Occupational Safety and Health, pp. 1-4, September 1978.

16. *Dorland's Illustrated Medical Dictionary*, 27th ed., W. B. Saunders Co., Philadelphia, PA, p.252, 1988, s.v. "buffer."

17. Comment 7.

List of Subjects in 21 CFR Part 349

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 349 be amended as follows:

PART 349—OPHTHALMIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 349 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 349.22 is added to subpart B to read as follows:

§ 349.22 Emergency first aid eyewashes.

These products contain water, agents to achieve the pH within a range of 6.6 and 7.4, and a suitable antimicrobial preservative agent. Additionally, they may contain tonicity agents to establish isotonicity with tears and agents for buffering the pH.

3. Section 349.82 is added to subpart C to read as follows:

§ 349.82 Labeling of emergency first aid eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one of the following: "Emergency first aid eyewash," "First aid eye rinse," or "Emergency eyewash."

(b) *Indications.* The labeling of the product states, under the heading "Uses", "for" [select one of the following: "flushing," or "irrigating"] "the eye to reduce chances of severe injury caused by acid, alkali, or particulate contamination".

(c) *Warnings.* In addition to the warnings in § 349.50 (the "Replace cap after using," warning in § 349.50(c)(1) should only be used if applicable), the labeling of the product contains the following warnings under the heading "Warnings" for all emergency eyewash products:

(1) "Do not use [in bold type] [bullet]¹ for injection [bullet] in intraocular surgery [bullet] internally [bullet] if

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.