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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 349

[Docket No. 80N-145B]

Over-the-Counter Ophthalmic Drug Products for Emergency First Aid Use; Safety and Efficacy Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for ingredients contained in eyewash drug products used for emergency first aid treatment of chemical burns of the eye(s). The agency will review the submitted data to determine whether these products are generally recognized as safe and effective for their labeled uses. This notice also describes the agency's general regulatory policy governing the marketing of over-the-counter (OTC) emergency first aid eyewash drug products during the pendency of this review. This request is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Data and information to be submitted by June 4, 1990.

ADDRESSES: Submissions should be sent to the Division of OTC Drug Evaluation (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In 1972, FDA established the OTC drug review to evaluate all drugs sold OTC. The final regulations providing for the OTC drug [illegible] § 330.10) were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). The agency appointed 17 advisory review panels to evaluate safety and effectiveness data of active ingredients found in OTC drug products. An advisory review panel, the Advisory Review Panel on OTC Ophthalmic Drug Products (Ophthalmic Panel), reviewed OTC ophthalmic drug products.

In its report on OTC ophthalmic drug products (published in the **Federal Register** of May 6, 1980; 45 FR 30002), the Ophthalmic Panel, in a general discussion of eyewashes, stated that eyewashes, eye lotions, and eye irrigating solutions are used to dilute or remove irritants such as foreign bodies, pollen, and noxious chemicals from the eye (45 FR 30046). The Panel mentioned that eyewashes, eye lotions, and eye irrigating solutions are not only used by consumers for cleaning and washing irritants from the eyes, but they are also used for the emergency flushing of chemicals or foreign bodies from the eye(s) in homes, places of work, first aid stations, clinics, and hospitals (45 FR 30047). The Panel recognized that these products are important components of first aid and emergency kits in industrial settings, clinics, and hospitals. In addition to their emergency first aid use, the Panel noted that irrigating fluids are used by medical personnel for irrigation following diagnostic procedures and for postoperative irrigation. Even though the Panel was aware of the existence and use of emergency first aid eyewashes and irrigating solutions, it did not consider these products further for these uses because no submissions were made by any company for these products or uses.

Following the publication of the Panel's report, no comments were submitted on the use of emergency first aid eyewashes or irrigating solutions. Accordingly, these products were not discussed in the tentative final monograph for OTC ophthalmic drug products that was published in the **Federal Register** of June 28, 1983 (48 FR 29788) or in the final rule that was published in the **Federal Register** of March 4, 1988 (53 FR 7076).

After the final rule was published, the agency received a request for an advisory opinion (Ref. 1) regarding the status of a product used for emergency first aid treatment of chemical burns of the eyes and the skin. The product was described as a sterile phosphate buffered solution containing sodium phosphate, U.S.P. and monobasic postassium phosphate, NF, preserved with edetate disodium, U.S.P. 1:2000 and benzalkonium chloride, U.S.P. 1:5000, 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. Noting that the final monograph for OTC ophthalmic drug products (21 CFR Part 349) is silent regarding the use of emergency first aid eyewashes for the treatment of chemical burns, the requester questioned how this product, which has a long marketing history, is to be regulated. The requester recommended that no regulatory action be considered until the problem has been resolved and a decision has been made by the agency as to how this type of product is to be regulated.

The agency is aware that a need exists for eyewash products for emergency first aid treatment of chemical burns (including acid and alkali burns). These products would be considered drugs just as eyewash products in the ophthalmic drug products final monograph are considered drugs. (See discussion of the drug status of eyewash products in comment 2 in the tentative final monograph at 48 FR 29789.)

A number of these eyewash products for emergency first aid treatment of chemical burns have been marketed prior to the effective date of the ophthalmic drug products final monograph. However, the agency currently has little data on which to make a determination as to the safety, effectiveness, and labeling of these products. The agency is aware 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 nonplumbed, plumbed, self-contained emergency eyewash, or shower equipment/stations.

etc. The agency is not aware of all of the various labeling formats and labeling statements or the formulations of all the various eyewash products that are offered for emergency first aid ophthalmic use.

The agency is also aware that a number of these products are initially used without medical supervision like other OTC drug products. The agency believes these products could be regulated under the existing monograph for OTC ophthalmic drug products.

The agency is also aware that ophthalmic irrigating solutions are used by medical personnel for irrigating the eye(s) following diagnostic procedures and for postoperative irrigation. The agency believes that professional labeling for such uses of these products could be addressed in the existing monograph for OTC ophthalmic drug products.

Accordingly, FDA invites the submission of data, published and unpublished, and any other information pertinent to all active ingredients in eyewash drug products used for emergency first aid treatment of chemical burns of the eyes. These data and information will facilitate the agency's review and aid in its determination as to whether these OTC drugs for human use are generally recognized as safe and effective and not misbranded under their recommended conditions of use, and will provide all interested persons an opportunity to present for consideration the best data and information available to support the stated claims for these products. Any relevant data and information on eyewash ingredients that may have been submitted to earlier rulemakings should be resubmitted to facilitate the agency's review of this class of drug products. Even though the final monograph for OTC ophthalmic drug products (21 CFR Part 349) became effective on March 6, 1989, any data submitted pursuant to this call-for-data notice will be reviewed and addressed as part of the agency's ongoing review of all OTC drug products. If appropriate, as determined by the agency's review of any submitted data, the agency will proposed to amend the final monogram for OTC ophthalmic drug products to include eyewashes for emergency first aid treatment of chemical burns of the eye(s) and eye irrigating solutions for use following diagnostic procedures and for postoperative irrigation.

Under the agency's general regulatory policy governing the marketing of OTC drug products that do not have an approved new drug application (NDA) during the pendency of the OTC drug review, OTC drug products may be permitted to be marketed without the risk of regulatory action provided the following conditions are met:

(1) The product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC drug review on May 11, 1972, a date that was later extended to on or before December 4, 1975. (See 21 CFR 330.13.)

(2) Such product does not constitute a hazard to health.

(3) The product formulation is not regarded to be a prescription drug within the meaning of section 503(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)).

(4) It 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 above 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 NDA.

It should be noted that, in the past, in order for a product to be eligible for the OTC drug review, the product or similarly formulated and labeled products had to be marketed as OTC drugs at the inception of the OTC drug review (May 11, 1972), a date that was later extended to on or before December 4, 1975. In addition, prescription drug products were eligible for the review, but they had to continue to be marketed on a prescription basis while data were being evaluated to ascertain whether the ingredient or combination of ingredients in the product had become generally recognized as safe and effective for OTC use.

The agency emphasizes that this current review is not intended to apply to new chemical entities that have not previously been marketed for OTC use regardless of the claims. Data on such products should be submitted to the agency for evaluation in a new drug application pursuant to 21 CFR part 314. Manufacturers should include any information that would establish that their product is not subject to action under the general regulatory policy described above as part of the data and information submitted in response to this call-for-data. If such information does not exist or is found to be inadequate, such products are at risk of regulatory action being instituted by the agency during the course of this review. To be considered in this review, eight copies of the data and information must be submitted, preferably bound, indexed, and on standard size paper (approximately 8½ by 11 inches). The agency suggests that all submissions be in the format described in 21 CFR 330.10(a)(2).

In accordance with § 330.10(a)(2), all submitted data on eyewash ingredients and claims for first aid relief of acid and alkali burns of the eye(s) will be handled as confidential by the agency. However, all the submitted information will be put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, 30 days after publication of any proposed rules resulting from the review of the submitted material, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the act (21 U.S.C. 331(j)). At the time of publications, requests for confidentiality should be submitted to William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210) (address above).

Data and information should be addressed to the Division of OTC Drug Evaluation (address above). Data submitted after the closing date of June 4, 1990, will not be considered except by petition pursuant to § 10.30 (21 CFR 10.30).

As noted above, some of these products are also labeled for use on the skin. The current call-for-data only applies to use of these products in the eyes. Use of these products on the skin will be addressed at a later date in a different OTC drug rulemaking.

Reference

(1) Comment No. AP, Docket No. 80N-0145, Dockets Management Branch.

Dated: November 23, 1989.

James S. Benson,

Acting Deputy Commissioner of Food and Drugs.

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 540

Control, Custody, Care, Treatment and Instruction of Inmates; Contact With Media; Withdrawal of Proposed Rule

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule; withdrawal.

SUMMARY: By this document the Bureau of Prisons is withdrawing its proposed rule on Contact With the Media which