

MEMORANDUM OF TELEPHONE CONVERSATION

Date: April 2, 2004

BETWEEN: Janice Comer Bradley, CSP
Technical Director
International Safety Equipment Association
703-525-1695

and Michael T. Benson
Regulatory Review Pharmacist (HFD-560)

Subject: Proposed Amendment of OTC Ophthalmic Drug Products Monograph to
Include OTC Emergency First Aid Eyewash Drug Products

BACKGROUND:

The subject document was published in the FEDERAL REGISTER of 2/19/03 (68 FR 7951), and provided in proposed § 349.82(d)(3) that directions for products using a concentrate with potable water shall state that the concentrate should be added to potable water to have a fully constituted solution. One comment from the American Academy of Ophthalmology disagreed with adding a sterile concentrate product to a potable water system for emergency first aid ophthalmic treatment because the prepared solution would not be sterile and may introduce ocular risks without benefit over the original potable water. Risks cited were: (1) variability of bacterial load in potable water, making it impossible without prior microbial assessment to determine the proper amount of additive needed to make a given amount of potable water sterile, (2) while it's possible to add enough antimicrobial additive to kill all microorganisms in potable water, the resulting solution would irritate the eye, and the production of endotoxin caused by killing the organisms can result in additional ocular harm, (3) harmful bacteria, endotoxins, or chemical reagents can be just as harmful when introduced into the eye as part of a treatment as when introduced by an initial insult, and (4) the introduction of non-sterile particles or water may lead to secondary ocular infections where the eyes' defense mechanisms are impaired in the cases of ocular injury or ocular disease.

I called Ms. Bradley, and asked her whether she saw the proposed amendment and the comment. She answered that she saw the proposal, but not the comment. I telefaxed the comment to her at 703-528-2148, asked her to assess it, and if she disagreed with its substance or any part, I asked her to submit a comment with reasons within 30 days of our conversation to the Division of Dockets Management at the same address written in the comment. I also asked her to send a desk copy to me. She said that she read part of the comment after receiving my fax, disagreed with its substance up to the point where she read, and could eventually telefax a response to me. I told her that a fax was fine and our conversation concluded cordially.


Michael T. Benson

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