

# 24 Hour Summary of the Ophthalmic Medical Devices and Risk Communications Joint Panel Meeting

---

March 17, 2017

## **Introduction:**

The Ophthalmic Medical Devices Panel of the Medical Devices Advisory Committee and Risk Communications Advisory committee to the Food and Drug Administration met on March 17 2017 to discuss and make recommendations regarding the potential risks of misuse of peroxide-based contact lens products

## **Panel Deliberations/FDA Questions:**

### **Panel Question 1:**

1. Panel Question 1: Please discuss the currently used labeling for peroxide based contact lens care products with respect to the adequacy of specific warnings and clarity of instructions for use. Does the panel have any recommendations for modifying this labeling? During your deliberations, please address the following examples of the current labeling and instructions for use specific to the issues of misuse in your discussion:
  - a) The phrase “NO RUB” has been removed so that it would not be confused with other products portraying the “No Rub” label
  - b) The addition of a red cap and a red tip to identify it as different from other care products. Carton and Bottle both state the following in enhanced text and red boxes to alert the user:
    - Use only the lens case provided
    - Only use the special case for disinfection and neutralization.
    - DO NOT use flat lens case.
    - Hydrogen Peroxide (Brand X) only works with the special lens case provided.
  - c) IMPORTANT: Failure to follow directions for use will result in burning and stinging

Panel Discussion: Members of the panel supported a need for consistency as well as simplicity on the box and bottle in regards to warning labels and instruction for use. Panelists looked at the Coopervision and Alcon labeling examples. SGEs supported the design, but there is room for improvement. One panelist stated that the clear red label stating “Do Not Remove,” is an

example of clear action and reasoning that consumers would easily understand. Many panelists found the writing on the labeling too busy and font too small, many panelists preferred a large icon, which was previously presented to the panelists (an image of bottle squirting in the eye crossed out) on the box and bottle. The panelists general consensus was a need for simplicity, clear messaging, easy to recognize, and standardization, in addition to the red tip and red cap already on Hydrogen Peroxide solutions. Other ideas that were discussed were, including a big “STOP” sign on the top of the bottle, involve social media connections to manufacturers and FDA to increase awareness, different tactile or feel of the bottle, using huge warning signs/icons on the opening flap of the box, using iphone or smart phone to scan box/product code to inform/educate consumers.

### **Panel Question 2:**

2. What strategies should be considered to reduce the risks of mistaken purchases of peroxide based contact lens care products? Please include the following propositions in your discussions and recommendations including potential benefits/additional risks these strategies may impose:
  - a) Redesigning the carton label (color, font sizes, etc.) so that it is distinctly different than other contact lens care products
  - b) Placement of hydrogen peroxide care products separate from other contact lens care products
  - c) For sale only at offices of contact lens practitioners (optometrists, ophthalmologists)
  - d) Other strategies

Many SGEs referred to Dr. Fairbank’s presentation in which he presented on how design change in different industries solved problems and can substantially reduce human error. Almost all panelists did agree with 2.a), the redesign of the carton label i.e. color, font size, so it’s different than other contact lens products. A few SGEs gave prescription drug examples, in which the difference of color of a bottle would alleviate the confusion of another prescription medication to patients. Almost all panelists believed that 2. b), the placement of Hydrogen Peroxide care products separate from other contact lens products would not be practical and 2. c) would reduce patient accessibility. A few SGEs did not agree with any of the suggestions above, and focused on other strategies such as patient knowledge and multiple communication strategies in delivering information to patients and consumers. Our pharmacist SGE did not support pharmacist dispensation of Hydrogen Peroxide because of limited accessibility, most panelists did agree with Hydrogen Peroxide statement more prominent on the box and label, along with a red label warning sign.

### **Panel Question 3:**

3. Panel Question 3: What are the panel’s recommendations for reducing the risks of misuse of peroxide based contact lens care products once purchased? Please consider the following in your discussions:

- a) Redesigning the bottle size, shape and color to alert the consumer that it is not the same as saline or other contact lens products
- b) Redesigning the case and bottle to be functionally dependent (the peroxide cannot be released unless directly and physically connected to the special neutralization case)

Most panelists agreed with 3.b), redesigning the case and bottle to be functionally dependent. Many agreed and supported Dr. Fairbank's presentation in which he focused on design to influence human error. Another suggestion was creating a bigger hole, or unique stout in the Hydrogen Peroxide Solution bottles that differentiate from other Contact Solutions. Other examples included using a device which attaches the case and bottle, adopting the "mouthwash" idea in which the solution is filled at the top by squeezing the bottle, and using engineering students to redesign the bottle that would be suitable for use and solve the problem of adverse events. The panelists' general consensus was redesigning the case and bottle would be a good idea. The industry representative mentioned that the industry is open to ideas that would be cost effective, and increase compliance without decreasing the efficacy of the product.

#### **Panel Question 4:**

4. What are the panel's recommendations for how we can better engage contact lens consumers, advocacy groups, professional organizations, and industry to promote improved compliance with instructions for use for contact lens care regimens?

The consumer representative stated that industry and FDA should work with retailers. Many retailers are manufacturers of Hydrogen Peroxide solutions, as well as working with optometrists for the education and communication. The patient representative urged the panel to focus on awareness and mentioned that October is Contact Lens Safety Awareness Month, and that would be a good time to bring awareness through literature and other communication avenues to patients and consumers. Panelists discussed the number of adverse events and consumers experiencing burning or irritation by accidentally using Hydrogen Peroxide Solution is far more than the number of cases reported by FDA. The panelists agreed that it is a big problem when most of the adverse events are unreported. Panelists urged advocacy groups to be involved with patients and consumers to keep a database for a more accurate reporting system. The panelists general consensus agreed that changing consumer behavior is difficult, but efforts should be in education/communication and awareness via many different outlets (optometrists, social media, FDA website, retailers), as well as improving the labeling/design of the bottle to improve adherence and reduce human error.

**Contact: Aden Asefa, Designated Federal Officer –(replace with your info)  
(301) 796- 0400 aden.asefa@fda.hhs.gov**

Transcripts may be purchased from: (written requests only)  
Free State Reporting, Inc. 1378  
Cape St. Claire Road Annapolis, MD 21409  
410-974-0947 or 800-231-8973 Ext. 103  
410-974-0297 fax

Or  
Food and Drug Administration  
Freedom of Information Staff (FOI)  
5600 Fishers Lane, HFI-35  
Rockville, MD 20851  
(301) 827-6500 (voice), (301) 443-1726