DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

Summary of the Ophthalmic Devices Panel Meeting
May 13, 2014

Introduction:

The Ophthalmic Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on May 13, 2014 to discuss and make recommendations regarding the guidance documents for contact lenses and contact lens care products. The discussions included topics such as a grouping system for silicone hydrogel contact lenses, microbiological and chemical pre-clinical testing, revision of pre-clinical test requirements to address patient non-compliance, potential modification of rigid gas permeable lens care regimens to remove use of water, and labeling for these devices.

Presentations:

The FDA presented on the demographics and patient noncompliance of contact lens users; interactions of contact lens materials with multipurpose care product solutions; a grouping system for silicone hydrogel contact lenses, a potential screening method to assess preservative uptake and lens solution incompatibilities of contact lenses; variables that may impact care product disinfection efficacy from a microbiological perspective and the impact of using tap water as a rinsing agent in the care of Rigid Gas Permeable (RGP) lenses.

The guest speaker, from the U.S. Centers for Disease Control and Prevention presented a summary of their *Acanthamoeba* keratitis investigations from 1985 – 2011 in addition to their Healthy Contact Lenses Program.

Open Public Hearing:

There were two open public hearing speakers that presented and provided comments and one written statement that was read.

FDA Questions and Panel Discussion:

The panel discussed and provided input to the following questions:

1. Do you believe that FDA's proposed grouping scheme for silicone hydrogel lenses is adequate to mitigate concerns regarding dimensional tolerance and compatibility? If not, what recommendations for modifications would you make?

2. Do you believe that the proposed clinical test matrix for silicone hydrogel lenses is sufficient to address clinical performance issues? If not, what additional testing would you recommend?

3. As a modification to our care product guidance, new care product solutions will be screened for lens preservative uptake incompatibilities using representative lenses per FDA's contact lens grouping system. We propose that the preservative concentration of the solution in the lens case should remain within the manufacturer's specifications after the recommended lens soak time. Incompatible lenses will be listed in the labeling. Please discuss the following:

    a. Should our acceptance criterion account for patient non-compliance (e.g., longer soak times than recommended, solution reuse)?

    b. How should the incompatible lenses be listed in the labeling (e.g., bold text, a unified table)?

    c. Other recommendations?

4. Current microbiological test methods (e.g., ISO 14729) do not take into account "real-world" solution testing parameters in which the lens stored in a case is considered. Please discuss whether you believe the following factors should be incorporated into current preclinical testing:

    a. Soil

    b. Longer soak times

    c. Lens uptake

    d. Any other factors

5. Some RGP lens regimens still recommend the use of water. What alternatives would you recommend to replace water (e.g., preserved saline, unpreserved saline etc.)?

Contact:
Natasha Facey, Designated Federal Officer
301-796-5290, Natasha.Facey@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 1 800-231-8973 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