

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0628]

Microbiological Testing for Contact Lens Care Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “Microbiological Testing for Contact Lens Care Products.” FDA is co-sponsoring the public workshop with the American Academy of Ophthalmology, the American Academy of Optometry, the American Optometric Association, and the Contact Lens Association of Ophthalmologists. The purpose of the public workshop is to discuss test method parameters for evaluating the activity of contact lens care products against *Acanthamoeba* and to discuss elements of microbiological test methods that simulate “real world” consumer use conditions.

Date and Time: The public workshop will be held on January 22 and 23, 2009, from 8 a.m. to 5 p.m. Participants are encouraged to arrive by 7:30 a.m. to allow enough time for parking and security screening. Security Screening will begin at 7 a.m.

Location: The public workshop will be held at the Food and Drug Administration, White Oak Conference Center, 10903 New Hampshire Ave., Bldg. 2 (Central Shared Use Building), Silver Spring, MD. Attendees should follow the directions provided in the *Registration Information* section of this document.

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Agenda: The purpose of the conference is to discuss test methods for evaluating the anti-microbial activity of contact lens care products.

On January 22, 2008, we hope to reach consensus on critical test method parameters for evaluating the activity of contact lens care products against *Acanthamoeba*. These parameters include organism species and strain, trophozoite culture and cyst production, microbial challenge level, and assay method for survivors.

On January 23, 2008, we hope to present and discuss critical elements for new or modified disinfection efficacy test methods that simulate “real world” consumer use conditions. These elements include contact lens and lens case uptake of preservative and other solution ingredients, solution evaporation, minimal consumer compliance, biofilm formation and clinical isolates as challenge organisms.

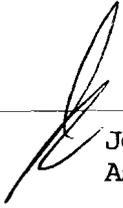
Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted on the Internet at *www.jcahpo.org/clmw*.

Registration Information: Registration must be completed online at *www.jcahpo.org/clmw*. Please pre-register no later than January 8, 2009 (see instructions in this paragraph). There will be no onsite registration. Non-U.S.

citizens are subject to additional security screening and should pre-register at least 3 weeks in advance. There is a registration fee of \$250 for this workshop. Early registration is recommended because seating is limited.

If you need special accommodations due to a disability, please contact Ms. Janice Prestwood at 800-284-3937, ext. 229 (toll free), 651-731-7229 (direct) or 651-731-0410 (fax) at least 7 days before the public workshop. Lodging, travel, and security clearance information are also available from the registration Web site. Persons without Internet access may contact Ms. Janice Prestwood for help in completing the registration form.

Dated: 12/9/08
December 9, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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