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FDA Public Health Notification: Fungal Keratitis Infections Related to Contact Lens Use

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Dear Healthcare Practitioner:

We are updating the Preliminary Public Health Notification of April 10, 2006, with new information on the recent increase in reports of a rare but serious fungal infection of the eye in soft contact lens wearers in the U.S. The infection, a fungal keratitis caused by the *Fusarium* fungus, may cause vision loss requiring corneal transplants.

New Information

On May 15, 2006, **Bausch and Lomb announced its decision to permanently remove all ReNu with MoistureLoc products worldwide. As previously recommended, consumers should stop using ReNu with MoistureLoc immediately.**

On May 19, 2006, the CDC released an MMWR Dispatch updating its on-going multistate investigation into *Fusarium* keratitis occurring in contact lens wearers. This update can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d519a1.htm>. The CDC findings continue to show an increased risk for *Fusarium* keratitis linked to using Bausch and Lomb's ReNu with MoistureLoc in the month prior to the onset of infection

Both the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to investigate reports of fungal keratitis in an effort to determine all contributing factors and/or products that place contact lens wearers at increased risk for *Fusarium* keratitis.

At this time, we do not expect our recommendations to change since Bausch and Lomb has permanently removed all ReNu with MoistureLoc worldwide. However, if we identify additional risk factors, or if we have new recommendations for the clinical community or contact lens wearers, we will provide an update.

Recommendations

For healthcare providers:

- Advise patients to stop using Bausch and Lomb ReNu with MoistureLoc products immediately, discard all remaining MoistureLoc solution and use an alternative cleaning/disinfecting product.
- If a patient presents with a microbial keratitis, consider that a fungal infection may be involved.
- Prior to initiating immediate treatment, an eye care professional should obtain a specimen for laboratory analysis.
- Report cases of fungal keratitis in contact lens wearers to FDA as noted below.

For contact lens wearers:

- Stop using Bausch and Lomb ReNu with MoistureLoc products and discard all remaining MoistureLoc solution including partially used or unopened bottles.
- Consult your eye care professional concerning use of an appropriate alternative cleaning/disinfecting product.
- Consider performing a “rub and rinse” lens cleaning method, rather than a no rub method, regardless of which cleaning/disinfecting solution used, in order to minimize the number of germs and reduce the chances of infection.
- Continue to follow proper lens care practices:
 - Wash hands with soap and water, and dry (lint-free method) before handling lenses.
 - Wear and replace lenses according to the schedule prescribed by the doctor.
 - Follow the specific lens cleaning and storage guidelines from the doctor and the solution manufacturer.
 - Keep the contact lens case clean and replace every 3-6 months.
 - Remove the lenses and consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling

FDA Advice to Patients on this topic can be found at <http://www.fda.gov/cdrh/medicaldevicesafety/atp/041006-keratitis.html>.

Background

In an MMWR Dispatch dated April 10, 2006, CDC stated that it received reports of 109 cases of suspected fungal keratitis in 17 different states. Although the majority of case patients have yet to be interviewed, complete data are available for 30 of them. Twenty-eight of the 30 wore soft contact lenses. Preliminary information obtained by CDC from patient interviews indicates that 26 of these patients remembered which products they used, and that all 26 reported using a Bausch & Lomb ReNu brand contact lens solution in the month prior to the onset of infection. Patients reported using a variety of different ReNu types from multiple different product lots. Five of the patients reported using other solutions in addition to the ReNu product. Nine of the patients reported wearing lenses overnight, a known risk factor for microbial keratitis. Eight required corneal transplantation. Strain typing of the organism is ongoing. This document can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d410a1.htm>.

CDC and FDA are investigating these case reports. Also, investigations by CDC, state and local health departments, FDA, and manufacturers of contact lens solutions are underway to define specific behaviors or products that place contact lens wearers at increased risk for *Fusarium* keratitis.

Clusters of *Fusarium* keratitis were reported among contact lens users in Asia beginning in February 2006. At that time, Bausch & Lomb voluntarily suspended sales of its ReNu multipurpose solutions in Singapore and Hong Kong, pending their investigations, after multiple reports of *Fusarium* keratitis among contact lens users there.

Background on Microbial Keratitis

Microbial keratitis is a severe infection of the cornea. Risk factors for infection include trauma (generally with plant material), chronic ocular surface diseases, immunodeficiency, and rarely, contact lens use. There are an estimated 30 million soft contact lens users in the United States. The annual incidence of microbial keratitis is estimated to be 4-21 per 10,000 soft contact lens users, depending on overnight lens use. Fungal keratitis is a condition more prevalent in warm climates. In the southernmost United States, fungal keratitis comprises up to 35% of microbial keratitis cases compared with 1% in New York. The proportion of fungal keratitis due to *Fusarium* spp. also varies by region, from 25-62% .

Reporting Adverse Events

FDA and CDC are very interested in gathering information related to fungal keratitis in contact lens users. We encourage you to report these infections to FDA. FDA will be sharing reported information with CDC. You can report directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/medwatch/report.htm>.

Please include the following information (if available) on the MedWatch reporting form:

- Contact lens solutions trade names and lot numbers.
- Contact lens type, trade name and mode of wear (extended or daily wear).
- Patient non-compliance with contact lens regimen (e.g., overnight wear in daily wear lenses, not cleaning lenses).
- Results of all cultures taken (e.g., corneal, conjunctival, contact lens, care solutions, lens case).
- Special patient characteristics, including whether the patient was immunocompromised (e.g., used topical or systemic corticosteroids or had diabetes), or had any ocular trauma, surgery, or chronic eye problem.
- Topical ocular medications used to treat the patient (including trade names and lot number if available).

Getting More Information

Additional information regarding the withdrawal of ReNu with MoistureLoc can be obtained from Bausch and Lomb by calling 1-888-666-2258.

If you have questions about this notification, please contact Nancy Pressly, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 240-276-3357 and we will return your call as soon as possible.

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Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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