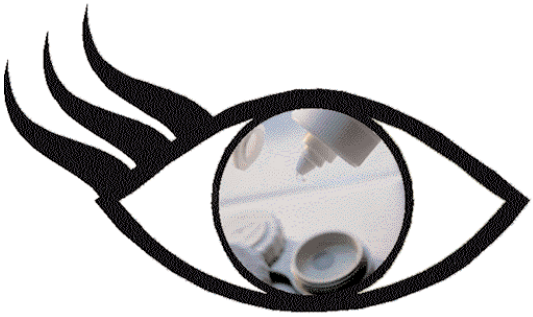
FDA & YOU
News for Health Educators and Students
Issue Number 10 **Spring/Summer 2006**



Contact Lens Solution Linked to Serious Eye Infection

If you wear soft contact lenses, your cleaning solution may be putting you at risk for fungal keratitis, a rare but serious eye infection caused by the *Fusarium* fungus. Bausch and Lomb has announced that it's removing all of its ReNu with MoistureLoc products from store shelves worldwide, and recommends that anyone using these products stop immediately because they have been linked to several cases of fungal keratitis. There are no generic or private labeled brands made using the ReNu with MoistureLoc solution.

What is fungal keratitis?

Fungal keratitis is an inflammation of the cornea, the front part of the eye. It can cause permanent loss of vision, and can appear similar to other eye infections. Any red or painful eye should be examined by your doctor right away.

What are the symptoms?

- Unusual redness
- Eye pain
- Tearing
- Light sensitivity
- Blurry vision
- Discharge
- Swelling

What should I do if I've been using these products?

- Stop using Bausch and Lomb ReNu with MoistureLoc products immediately and throw away all remaining MoistureLoc solution including partially used or unopened bottles.
- Consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling.
- Ask your doctor for help in choosing an alternate cleaning/disinfecting product.
- Follow proper lens care practices.

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In This Issue

Fungal Keratitis *- Continued from page 1*

What lens care practices should I follow?

- Wash your hands with soap and water, and dry them with a lint-free cloth before handling your lenses.
- Wear and replace your lenses according to the schedule prescribed by your doctor.
- Follow the lens cleaning and storage instructions of your doctor and your solution manufacturer.
- Regardless of which cleaning/disinfecting solution you use, consider performing a "rub and rinse" lens cleaning, rather than a no rub cleaning, in order to minimize the number of germs and reduce the chances of infection.
- Keep your contact lens case clean and replace it every 3-6 months.

Have there been reported cases of fungal keratitis?

The Centers for Disease Control and Prevention (CDC) has seen an increasing number of reports of fungal keratitis. In nearly all of the cases patients used a Bausch and Lomb ReNu brand contact lens solution, or a generic product manufactured by the same company.

While *Fusarium* fungus has not been identified in the product or in the manufacturing facility FDA, CDC, state and local health departments, and Bausch and Lomb are continuing to investigate the situation. One focus of the investigations is to see if either certain behaviors of contact lens wearers, or specific contact lens products increase the risk of infection.

Should I report symptoms of fungal keratitis to FDA?

If you've had any symptoms of infection FDA would like to hear from you. You can report directly to MedWatch, the FDA's voluntary reporting program by:

- phone at 1-800-FDA-1088
- FAX at 1-800-FDA-0178
- mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787
- online at http://www.fda.gov/medwatch/report.htm.

Please include information to as many of the following questions on the MedWatch reporting form:

- What brand of contact lens cleaning solution, if any, do you use?
- What is the lot number and expiration date printed on the package?
- What brand/type of contact lenses do you use?
- Do you remove your lenses overnight?
- Do you have any ongoing health concerns (e.g. diabetes)?
- Are you using any medication in the treatment of your eyes?

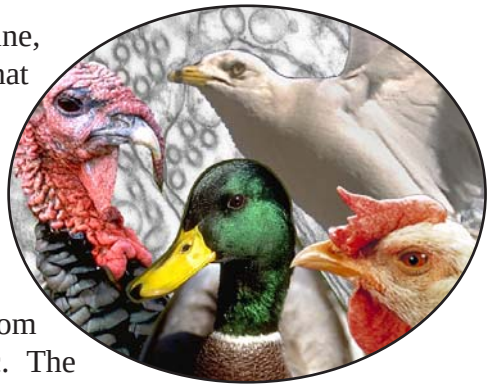
Where can I get more information?

Additional questions regarding the market withdrawal of Bausch and Lomb ReNu with MoistureLoc products should be directed to Bausch and Lomb at 1-888-666-2258.

If you have any concerns about your contact lenses, contact your doctor. You may also contact FDA's Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041. For consumer information, select # 2, or to speak with a Medical Device Specialist, select # 4.

Additional information on this topic for healthcare providers can be found at: http://www.fda.gov/cdrh/safety/041006-keratitis.html.

U.S. Government Continues Developing Response to Avian Flu



Chances are that if you've turned on a TV, read a newspaper or magazine, or walked down the street recently, you've heard of avian flu. Some of what you've heard or read has probably sounded pretty scary and may have left you wondering what avian flu is, and what's being done about it.

Avian flu, also known as "bird flu," is caused by a virus that occurs naturally in wild birds and is usually harmless to people. However, there is concern that a strain of avian flu could potentially change its genetic material (mutate) so that the virus could pass from birds to people, then from person to person, and potentially cause a human flu epidemic or pandemic. The potential for the virus to mutate is a major concern, and one reason why the Federal Government is busy developing a response to this threat.

The virus responsible for the outbreak of avian flu that started in Asia, called H5N1, has shown that it can cause serious illness and death in people. Since 2003, the World Health Organization has reported 207 confirmed cases of human infection. Despite the small proportion of human victims, the risk to human health could increase, especially if the virus becomes highly contagious in people.

Health officials consider the H5N1 flu strain in Asia highly pathogenic in poultry like chickens and ducks, meaning that it usually kills infected poultry. It also efficiently transfers between sick and healthy birds, so it's highly contagious among poultry as well.

The good news is that H5N1 hasn't caused many reported human illnesses, and so far it doesn't appear to have reached the U.S. People who have been stricken with avian flu in Asia are those who had close contact with infected poultry or, in rare cases, with other individuals, usually relatives, who were infected. Although the disease can jump the "species barrier" between poultry and people, at this point it doesn't appear to do so efficiently, and it doesn't appear to spread between people efficiently either. So while the disease is widespread in poultry flocks, it isn't widespread in the human population.

The avian flu first reported in Asia is caused by a Type A virus. Type A viruses include all viruses that can infect poultry, as well as viruses that infect other birds and mammals, including humans. In the event that the avian flu seen in Asia acquires a genetic trait making it more contagious between people -- either by mutating or by taking on genes from another virus -- the world could face a human flu pandemic.

President Bush has responded to a potential pandemic threat by issuing the "National Strategy for Pandemic Influenza." The document outlines the roles and responsibilities of the Federal, State, and local governments, industry, international partners, and individuals in preparing for and responding to a flu pandemic.

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Did You Know?

There is a difference between seasonal flu, avian flu, and pandemic flu.

Seasonal (or common) flu is a respiratory illness that can be transmitted person to person. Most people have some immunity, and a vaccine is available.

Avian (or bird) flu is caused by flu viruses that occur naturally among wild birds. The H5N1 variant reported in Asia is deadly to domestic fowl and can be transmitted from birds to humans. There is no human immunity and no vaccine is available.

Pandemic flu is virulent human flu that causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease can spread easily from person to person. Currently, there is no pandemic flu.

Avian Flu *- Continued from page 3*

In November, Health and Human Services Secretary Michael Leavitt said that the U.S. Department of Health and Human Services (HHS) has developed the HHS Pandemic Influenza Plan. On May 4th, Secretary Leavitt announced the HHS had awarded more than $1 billion in contracts to five companies that develop vaccines. The contracts are intended to put development and production of cell-based technologies for flu vaccines in the U.S. on the fast-track, and create an alternative to producing flu vaccines in eggs.

More information about the White House's response is available at http://www.whitehouse.gov/homeland/pandemic-influenza.html.

More information about the Federal Government's preparations is available at http://www.pandemicflu.gov/.

More information on the ABC TV movie, Fatal Contact: Bird Flu in America is available at http://www.pandemicflu.gov/news/birdfluinamerica.html

Sources: Pandemicflu.gov, FDA Veterinarian Newsletter

FDA ISSUES DRAFT GUIDANCE FOR THE SAFE PRODUCTION OF FRESH-CUT FRUITS AND VEGETABLES

If you like peeled baby carrots and other ready-to-eat vegetables or fruits, you may be interested in FDA's new draft guidance on minimizing microbial (e.g. bacterial) food safety hazards common to fresh-cut food production.

Processing fruits and veggies from the field into fresh-cut produce increases the risk of bacterial contamination and growth by breaking the natural exterior barrier of the produce by peeling, slicing, coring, trimming, or mashing with or without washing or other treatment before being packaged for eating. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melons, sliced pineapple, and sectioned grapefruit.

The draft guidance discusses the production and harvesting of fresh produce and provides recommendations for fresh-cut processing in several areas including personnel health and hygiene, training, building and equipment, sanitation operations, and fresh-cut produce production and processing controls from packaging, to storage and transport.

You can reduce your risk of illness from fresh-cut produce by following safe handling practices such as refrigerating the product after purchase; using only clean hands, utensils or dishes in preparing the product; and discarding the product when the "use by" date has expired.

More information on safe handling practices of produce can be found at http://portal.fightbac.org/pfse/toolsyoucanuse/phec.

Source: FDA Press Release

Did You Know?

Guidances are FDA documents presenting the Agency's current thinking on a particular subject. They are not laws or regulations.

Everyone Has a Role in Minimizing Medication Mix-Ups

Flomax and Volmax, Serzone and Seroquel, iodine and Lodine. All are medications used to treat very different medical conditions, but they all have similar names that can lead to medication mix-ups.

Mixing up a medication can lead to very serious problems for a patient, and it's estimated that these mix-ups contribute to about 10 percent of all reported medication errors. The errors occur at all levels, from prescribing to dispensing, which is why people who receive prescriptions must be vigilant.

The Problems

Medication errors can occur between brand names, generic names, and brand-to-generic names. But sometimes medication errors involve more than just name similarities. Dose designations and other symbols used in medication prescribing also have the potential for causing problems.

Illegible handwriting, unfamiliarity with medication names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list, all contribute to the problem. And, although some medication names and symbols may not necessarily sound or look alike, they could cause mix-ups when prescriptions are handwritten or communicated verbally, according to the United States Pharmacopeia (USP).

The XYZs of Naming a Medication

Names are part of developing a new medication. And coming up with a catchy name that distinguishes one medication from another isn't always easy. For the most part, pharmaceutical companies want a name that will boost sales, while consumers want the name to indicate what the medication does. However, FDA won't allow names that imply medical claims or suggest a use for which a medication isn't approved. Name selection must also take into account concerns for reducing errors and for avoiding trademark infringement.

Because of today's tough trademark requirements, many pharmaceutical companies rely on the growing industry of "naming" consultants for the task. These consultants are charged with creating a unique name that will appeal to both doctors and patients, particularly given the recent surge in direct-to-consumer advertising. No matter how good a name seems, it must be reviewed for potential confusion with other types of medications to decrease the potential for injury in the event of a dispensing error.

Satisfying the FDA

Every medication usually has three names: chemical, generic, and brand, and each is subject to different rules and regulations. The chemical name specifies the chemical structure of the medication. Chemical names are primarily used by researchers.

The FDA requires that either the brand name or generic name appears on the medication's labels and on its product labeling.

The generic name is usually created when a new medication is ready for marketing. It’s selected by the United States Adopted Names (USAN) Council according to principles developed to ensure safety, consistency, and logic. These names are typically used by health care professionals.

Generic names are coined using an established group of letters that represents a specific medication class. For example, the arthritis medications celecoxib, valdecoxib, and rofecoxib are generic names containing the -coxib stem. Each belongs to a class of medications known as the COX-2 inhibitors.

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Medication Mix-Ups *- Continued from page 5*

Names that include such stems, chemistry roots, or any other coded information are easier to remember, and give clues about what a medication is used for. These names, however, typically sound or look so much alike that they contribute to medication errors, especially if the products share common dosage forms and other similarities.

The brand name, also called a trademark, can be created as soon as a generic name is established. Only brand names of products subject to a new medication application or an abbreviated new medication application must first be approved by the FDA.

According to a report in the January-February 2004 issue of the Journal of the American Pharmacists Association, there are more than 9,000 generic medication names and 33,000 trademarked brand names in use in the U.S.

Fixing the Problems

To minimize confusion between medication names that look or sound alike, the FDA reviews about 400 proposed brand names each year; about one-third are rejected. The last time the FDA changed a medication name after it was approved was in 2005, when the diabetes medication Amaryl was being confused with the Alzheimer's medication Reminyl, and one person died. Now the Alzheimer's medicine is called Razadyne.

A number of other efforts are under way to reduce the incidence of medical errors resulting from similar-looking or similar-sounding names. The FDA encourages people to talk with their doctor to ensure they have a complete understanding of the purpose, the possible side effects, and the propoer use of their prescription before leaving the doctor's office. FDA also recommends that people verify the information with their pharmacist before leaving the pharmacy.

Studies by FDA health professionals to simulate the prescription-ordering process are part of every review of proposed brand names. They can help detect any potential sound-alike, look-alike confusion with brand names before a new medication application is approved.

Doctors are encouraged to write prescriptions more clearly, print in block letters rather than writing in cursive, avoid the use of abbreviations, and indicate the reason for the medication. And pharmacists are advised to keep look-alike, sound-alike products separated from one another on pharmacy shelves, avoid stocking multiple product sizes together, and verify unclear information with the doctor before filling a prescription.

FDA encourages consumers and health professionals to report any medication errors to the Agency's MedWatch Adverse Event Reporting System online at http://www.fda.gov/medwatch, by phone at (800) 332-1088, or by fax at (800) 332-0178. Caller identification is kept confidential and is protected from disclosure by the Freedom of Information Act.

Reducing Your Risk of Medication Errors

Here's a list of steps you can take:

- Know the name and strength of prescribed medications before leaving your doctor's office
- Insist your doctor include the purpose of the medication on your prescription
- Ensure that a refill is what it should be
- Tell your doctor of any medical history changes.

For more information visit: http://www.fda.gov/usemedicinesafely

Source: FDA Consumer

The Buzz on West Nile Virus

Her entire lifetime may span only a few weeks, but the female *Culex pipiens* mosquito makes the most of it. Feeding on the blood of humans and animals gives this common carrier of West Nile virus (WNV) the protein she needs to produce several hundred eggs every few days--eggs that evolve into biting adult mosquitoes seeking blood meals of their own. And with each bite, an infected mosquito may transmit WNV.

Most people who become infected with WNV have no symptoms, according to the Centers for Disease Control and Prevention (CDC). About 20 percent develop West Nile fever with its mild, flu-like symptoms: fever, headache, body aches, and sometimes a rash and swollen lymph glands. In a small number of people with symptoms--about 1 in 150--the virus causes life-threatening inflammation of the brain (encephalitis) or inflammation of the membrane surrounding the brain and spinal cord (meningitis).

There is no evidence to suggest that WNV can be spread through casual contact such as touching or kissing a person with the virus or by handling an animal with the virus, says the CDC. But public health officials are concerned that WNV may spread from person to person by other means.

While there is no FDA-approved drug to treat WNV or vaccines to prevent it, recently FDA-approved lab tests help doctors diagnose WNV in people with symptoms of the virus and to screen donors of blood, organs, cells, and tissues.

Did You Know?

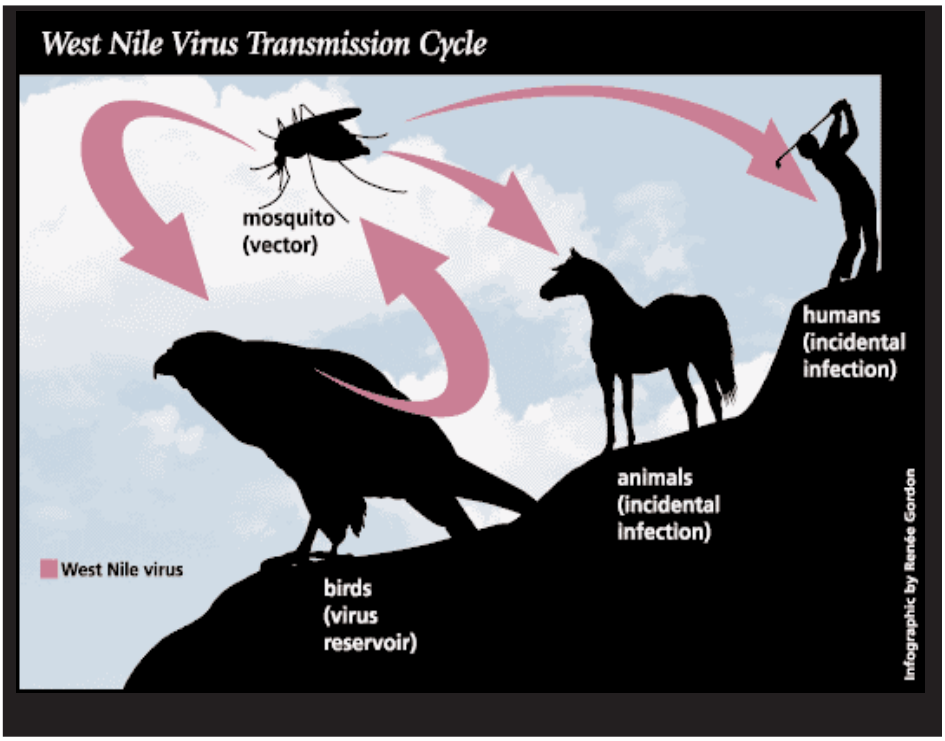
Only female mosquitoes bite and feed on blood; males mosquitoes feed on nectar.

An Insect-Spread Virus

WNV is one of a group of disease-causing viruses called flaviviruses, which are spread by insects, usually mosquitoes. Other flaviviruses include yellow fever, dengue, and St. Louis encephalitis viruses.

WNV primarily circulates between infected birds and mosquitoes that bite them. Only female mosquitoes bite and feed on blood; males feed on nectar. The infected mosquitoes can transmit the virus when they bite other animals or people.

More than 130 species of birds have been reported to be infected with WNV, according to the CDC. The virus also can infect horses and some other animals.



Even in areas where WNV is circulating, not all mosquitoes become infected with it, and human infection doesn't occur in all individuals exposed to mosquitoes. A study done in 1999 among residents at the height of WNV activity in New York City showed that only 2.6 percent had been infected, says the CDC. People who do get West Nile fever typically develop symptoms within three to 14 days after being bitten by an infected mosquito. Symptoms in

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West Nile Virus *- Continued from page 7*

Did You Know?

Unlike other viruses, like HIV and hepatitis B and C which can be lifelong infections, WNV doesn't stay in the blood for a long period of time. Recent studies suggest that most people who are infected develop antibodies that fight against the virus within one to two weeks.

people whose disease is limited to West Nile fever often go away without treatment in three to six days and do not seem to cause any long-term health effects.

Here to Stay

The West Nile virus (WNV), first found in Africa in 1937, was identified in the Western Hemisphere for the first time in 1999 in the New York City area. Since then, it has spread quickly throughout most of the U.S. From January 2003 to the end of October 2003, 44 states and the District of Columbia reported more than 7,700 human cases of WNV infection, resulting in 166 deaths.

There are about 200 different species of mosquitoes in the U.S., and the WNV has been found in 36 of them. No one really knows how it got into this country. It could have been brought in by a migrating bird, an imported bird, a mosquito hitching a ride on a plane or boat, or another host.

No matter the route, scientists believe WNV is here to stay. The only way to truly eliminate the virus in the U.S. is to kill its natural hosts: birds and mosquitoes. Even if this approach were feasible, the virus could potentially re-enter the country by a migrating bird or by other means.

Diagnostic and Blood-Screening Tests

In July 2003, the FDA cleared the first commercially available lab test to help doctors diagnose cases of potentially deadly WNV early on. The test, called the IgM Capture ELISA, detects the levels in the blood of a particular type of antibody to WNV. The test is for use in people who have symptoms of viral encephalitis or meningitis (headache, high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, and paralysis), two life-threatening medical conditions that result from WNV. Results from the IgM Capture ELISA must be confirmed with other lab tests as part of a complete evaluation. Diagnostic testing based on CDC methods, is also available through state health departments.

Another test, the Procleix WNV assay, approved by FDA in December 2005 is used for screening donated blood, organs, cells, and tissues to prevent the spread of WNV through transfusion or transplant. The test works by detecting components of the virus's genetic material, called RNA.

Pathogen inactivation is another promising area of technology under development that is being explored to help make donated blood safe from WNV and other infectious agents. This type of technology uses chemical treatments,

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Protect Yourself from West Nile Virus

If you live in an area where West Nile virus is active, the CDC recommends the following:

- When going outdoors, apply insect repellent containing DEET to bare skin and clothing. Mosquitoes may bite through thin clothing. Products containing 10 percent or less DEET are the most appropriate for children aged 2-12 years. Always follow product instructions when using repellent. (Ultrasonic devices are not effective in preventing mosquito bites.)
- Wear loose-fitting clothing that covers legs and arms while in areas where mosquitoes are likely to be present.
- To the extent possible, avoid outdoor activities between dusk and dawn, when mosquito activity is greatest.
- Ensure that window and door screens are in good repair and that other routes of mosquito access to buildings and living space are blocked.
- Clean out clogged rain gutters to avoid collecting water where mosquitoes can lay eggs.
- At least once or twice a week, empty water from flowerpots, pet food and water dishes, birdbaths, swimming pool covers, and other items that collect water.

West Nile Virus *- Continued from page 8*

often combined with other methods such as ultraviolet energy, to kill the virus in blood. The FDA is evaluating several inactivation methods for their effectiveness and safety.

Prevention and Treatment

The only way to control the spread of WNV is by controlling mosquitoes that carry the virus and taking precautions to avoid getting bitten. But medical researchers are also working on drugs to treat WNV and a vaccine to prevent it.

More than 550 drugs have been screened to treat the disease, and about 3 percent have shown potential for additional testing in animals, according to the National Institute of Allergy and Infectious Diseases (NIAID).

NIAID is supporting the development of several vaccine approaches, including a live vaccine made by mixing WNV with the yellow fever vaccine. Scientists are exploring additional approaches to developing effective WNV vaccines and the FDA is committed to helping to get these products developed and evaluated as quickly as possible.

Protect Your Pet Against West Nile Virus

People aren't the only ones who can get West Nile virus (WNV). The virus is a threat to some animals, especially wild birds and horses. About 40 percent of horses that developed encephalitis (brain inflammation) from WNV died during the 1999 outbreak that originated in the New York City area. A USDA-licensed horse vaccine for WNV is now available through veterinarians.

WNV has been shown to infect dogs, cats, bats, chipmunks, skunks, squirrels, and domestic birds and rabbits. The virus has rarely caused illness in these animals.

You should NOT use human repellents that contain DEET on your pets or other animals. Some animals are more sensitive than people to direct application of DEET products, making their use potentially harmful. Check with your veterinarian for the appropriate products to protect your pet. Also contact your veterinarian if your pet shows signs of WNV infection, such as fever, depression, lack of coordination, muscle weakness or spasms, or seizures or paralysis.

Adapted from the American Veterinary Medical Association and the ASPCA Animal Poison Control Center. For more detailed information, visit http://www.avma.org or http://www.apcc.aspca.org.

Keeping the Risk in Perspective

The risk of getting WNV through blood and tissue products appear to be rare. For people who need a transfusion or transplant, current knowledge suggests that the potential benefits outweigh the risks, including the risk of West Nile virus infection.

According to the CDC, out of more than 4 million blood transfusions performed each year only a few dozen cases of possible WNV transmission are under investigation. Bites from mosquitoes carrying WNV remain the most common means of transmission.

More Information on WNV

FDA's WNV Web site:
http://www.fda.gov/oc/opacom/hottopics/westnile.html

CDC's WNV Web site:
http://www.cdc.gov/ncidod/dvbid/westnile/

CDC's WNV Brochure:
http://www.cdc.gov/ncidod/dvbid/westnile/brochure.htm

Or, call the CDC hotline:

English 1-888-246-2675

Español 1-888-246-2857

TTY 1-866-874-2646

For information on WNV in your area, visit
http://www.cdc.gov/ncidod/dvbid/westnile/city_states.htm

Source: FDA Consumer

Calendar of National Health Events

June	July	August
Fireworks Safety Month **Prevent Blindness America** 500 East Remington Road Schaumburg, IL 60173 (800) 331-2020 info@preventblindness.org www.preventblindness.org Materials available Contact: PBA Consumer and Patient Hotline	**UV Safety Month** **American Academy of Ophthalmology** P.O. Box 7424 San Francisco, CA 94120-7424 (415) 447-0213 (415) 561-8533 Fax eyemd@aao.org www.aao.org Materials available Contact: Georgia Alward	**National Immunization Awareness Month** **National Partnership for Immunization** 121 North Washington Street, Suite 300 Alexandria, VA 22314 (703) 836-6110 npi@hmhb.org www.partnersforimmunization.org Materials available Contact: NIAM Resource Center

Learn About it Online: Contact Lenses

Contact lenses are the first choice for many people with vision impairments, such as myopia (nearsightedness) and astigmatism, because of the flexibility and convenience they offer. With the variety of lens types available, almost any one who needs to can wear them.

The new FDA contact lens page provides one-stop access to the latest information about contact lenses.

Visit

http://www.fda.gov/cdrh/contactlenses

to learn more

Summer is Coming!

Learn how to protect yourself from the hazards of tanning. *FDA & YOU's* 2005 Special Summer Issue includes information on UV radiation, sunburn, long-term skin damage, skin cancer, sunscreen and artificial tanning.

The Truth About Tanning: What You Need to Know to Protect Your Skin

http://www.fda.gov/cdrh/fdaandyou/issue07.html

About *FDA & You*

FDA & You is an FDA publication to inform and encourage health educators and students to learn about the latest FDA medical device and health news.

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