FDA & YOU

News for Health Educators and Students

Issue Number 13 **Spring 2007**

FDA Warns Against Buying Accutane and Its Generics Online

FDA has launched a special website to warn consumers about the dangers of buying isotretinoin products, like Accutane, online. Isotretinoin is a drug approved for the treatment of severe forms of acne that don't respond to antibiotics, and it should only be used under the close supervision of a health care professional. Isotretinoin can cause severe side effects, including birth defects. Serious mental health problems have also been reported with isotretinoin use.

When you buy drugs over the Internet, especially from sites that don't require a prescription, you may get counterfeit products, products with dangerous ingredients, products that don't work, and products that weren't labeled or shipped correctly.

The new Accutane website provides links to helpful information, including ways to check that drugs purchased online come from legitimate pharmacies.

VISIT

www.fda.gov/buyonline/accutane

Study Up on Summer Safety

Now that the school year is almost over, it's a great time to bone-up on your summer safety skills! Learn how to protect yourself from the hazards of summer with these past articles from the *FDA & YOU* archives:

Allergies: www.fda.gov/cdrh/fdaandyou/issue06.html#3

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

Summer Safety: www.fda.gov/cdrh/fdaandyou/issue06.html#5

West Nile Virus: www.fda.gov/cdrh/fdaandyou/issue10.html#5

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Artificial Sweeteners: No Calories... Sweet!

In the battle against bulge, artificial sweeteners can help add flavor to a calorie-conscious diet. According to the American Dietetic Association (ADA), they can also cut down on calories and control weight, help to manage chronic conditions such as diabetes, and potentially prevent dental cavities.

FDA regulates artificial sweeteners as food additives, which must be approved as safe before they can be marketed. To date, five artificial sweeteners are approved by the FDA:

- Aspartame
- Saccharin
- Acesulfame-K
- Neotame
- Sucralose

The FDA's Office of Food Additive Safety in the FDA's Center for Food Safety and Applied Nutrition (CFSAN) conducts various types of safety studies and evaluates a sweetener's composition, properties, and how much of the substance is likely to be consumed.

For each of the approved sweeteners, the typical amount used by U.S. consumers is well within designated "acceptable daily intake (ADI)" levels, or levels that can be consumed safely every day over a lifetime. Here's a detailed look at each of the sweeteners.

Aspartame

Aspartame is 200 times sweeter than sugar. It has a caloric value similar to sugar, but the amounts used are small enough to consider aspartame essentially free of calories. Brand names include NutraSweet and Equal. Aspartame was first approved by the FDA in 1981 as a tabletop sweetener, and for use in gum, breakfast cereal, and other dry products. FDA expanded the use of aspartame to use in sodas in 1983 and then to use as a general-purpose sweetener in all foods and drinks in 1996.

Before approval, the FDA reviewed numerous studies showing that aspartame did not cause cancer or other adverse effects in lab animals. FDA's review included three studies in which rats were fed aspartame in proportions more than 100 times higher than humans would likely consume.

In the mid-1990s, a researcher raised concerns that a rise in brain cancer incidence in the United States was linked to aspartame use. According to FDA experts, there is no scientific evidence supporting a link between aspartame and any type of cancer. The National Toxicology Program, part of the U.S. Department of Health and Human Services, conducted aspartame studies in mice and found no cancer link.

In 2005, the European Ramazzini Foundation (ERF) published new findings of a long-term feeding study on aspartame in rats. ERF scientists concluded that aspartame causes leukemia and lymphoma and that current uses of aspartame should be reevaluated. After reviewing the study data, however, the European Food Safety Authority (EFSA) released a statement in May 2006 that said the ERF's conclusion was not supported by the data. After learning of the ERF study results, the FDA/CFSAN requested the study. CFSAN reported that at this time, their position that aspartame is safe is based on the large body of information previously reviewed. Their conclusions are based on a detailed review of more than 100 toxicological and clinical studies on safety.

After it is swallowed, aspartame is converted in the body to methanol and two amino acids--aspartic acid and phenylalanine. These substances are produced in much greater amounts by other common foods.

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Artificial Sweeteners *- Continued from page 3*

Because of the phenylalanine component, aspartame does carry a risk for people with the rare genetic disorder phenylketonuria. (Phenylketonuria (PKU) is a rare genetic disorder in which an amino acid is not properly metabolized and can cause severe mental retardation if not treated.) People who have this disorder should avoid or restrict aspartame use because of their body's difficulty in metabolizing phenylalanine. Its use can cause phenylalanine to build up in the blood at higher levels than normal. The aspartame regulation requires that a statement be placed on the label of all products containing aspartame specifically to alert people with PKU of the presence of phenylalanine.

Saccharin

Saccharin is 200 to 700 times sweeter than sugar and has no calories. Brand names include Sweet'N Low, Sweet Twin, and Necta Sweet. Saccharin is used in tabletop sweeteners, baked goods, soft drinks, jams, and chewing gum.

Saccharin was discovered in 1879 and was considered Generally Recognized As Safe (GRAS) until 1972, when its safety was questioned, and it was removed from the GRAS list by the FDA. By definition in the law, a GRAS substance has a long history of safe use in foods, or is determined to be safe based on proven science. But if new evidence suggests that a GRAS substance may no longer be safe, the FDA can prohibit its use or require further safety studies.

In 1977, the FDA proposed a ban on saccharin because of concerns about rats that developed bladder cancer after receiving high doses of saccharin. In response, Congress passed the Saccharin Study and Labeling Act. This legislation put a moratorium on the ban while more safety studies were under way. Also, foods containing saccharin were required to carry a label warning that the sweetener could be a health hazard and that it was found to cause cancer in laboratory animals. Saccharin has been the subject of more than 30 studies in humans.

According to the National Cancer Institute, further studies showed that saccharin did not cause cancer in humans, and that the bladder tumors in rats were related to a mechanism that is not relevant for humans.

In 2000, the National Toxicology Program determined that saccharin should no longer be listed as a potential cancer-causing agent. Federal legislation followed in 2001, removing the requirement for the saccharin warning label.

Acesulfame-K (potassium)

Acesulfame-K is 200 times sweeter than sugar, with zero calories. Brand names include Sunett and Sweet One. Acesulfame-K was first approved by the FDA in 1988 for specific uses, including as a tabletop sweetener. The FDA approved the sweetener in 1998 for use in beverages. In December 2003, it was approved for general use in foods, but not in meat or poultry. Acesulfame-K can be found in baked goods, frozen desserts, candies, beverages, cough drops, and breath mints.

The FDA and the Food and Agriculture Organization/World Health Organization

Sweetener or Sugar? A Quick Look

Sweetener	Comparison to Sugar	Brand Name	Calories
Aspartame	200 times sweeter	NutraSweet Equal	Nearly 0
Saccharin	200-700 times sweeter	Sweet;N Low Sweet Twin Necta Sweet	0
Acesulfame-K	200 times sweeter	Sunett Sweet One	0
Neotame	7,000 to 13,000 times sweeter	Neotame	0
Sucralose	600 times sweeter	Splenda	0

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Artificial Sweeteners *- Continued from page 3*

(FAO/WHO) Joint Expert Committee on Food Additives have evaluated the sweetener's safety. More than 90 studies support the safety of acesulfame-K.

Neotame

Neotame is 7,000 to 13,000 times sweeter than sugar, depending on how it is used in food. It has no calories. The FDA approved neotame in 2002 as a general-purpose sweetener in a wide variety of food products other than meat or poultry. It has been approved for use in baked goods, soft drinks, chewing gum, frosting, frozen desserts, jams, jellies, gelatins, puddings, processed fruit and fruit juices, toppings, and syrups.

FDA reports that neotame is structurally similar to aspartame. However, the potential release of phenylalanine from neotame is so limited that a warning for patients with PKU is not necessary.

The FDA reviewed data from more than 100 animal and human studies on neotame. These studies evaluated cancer-causing, reproductive, and neurological effects. Based on a thorough evaluation of the data, CFSAN concluded that there are no adverse effects when neotame is ingested at levels that are used in foods.

Sucralose

Sucralose is 600 times sweeter than sugar on average and has no calories. Although sucralose is made from table sugar, it adds no calories because it is not digested in the body. Sucralose is sold under the brand name Splenda. After reviewing more than 110 animal and human studies, the FDA approved sucralose in 1998 for use in 15 food categories, including as a tabletop sweetener and for use in products such as beverages, chewing gum, frozen desserts, fruit juices, and gelatins. In 1999, the FDA allowed sucralose as a general-purpose sweetener in all foods.

Source: FDA Consumer July/August 2006

Purchasing Pet Drugs Online: Buyer Beware

If you're a pet owner who shops online for your pet's medication – be cautious. Some Internet sites attract buyers with message like "Discount pet drugs—no prescription required." This may sound appealing, but FDA wants consumers to know buying drugs online can be risky.

Some Internet sites that sell veterinary drugs represent legitimate, reputable pharmacies. But others are fronts for unscrupulous businesses operating in violation of the law.

If you purchase veterinary drugs online your run the risk of the drug

- not being FDA-approved
- being a counterfeit pet product
- being expired

Some internet companies

- make fraudulent claims
- dispense prescription drugs without a prescription

Pet owners who purchase veterinary drugs from these companies may think they are saving money, but in reality they may be short-changing their pet's health and putting its life at risk. Also, if you purchase preventives on the Internet without having your pet seen by your veterinarian, nobody stands behind them—the veterinarian doesn't, the manufacturer doesn't.

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Buying Pet Drugs Online *- Continued from page 4*

Look for Red Flags

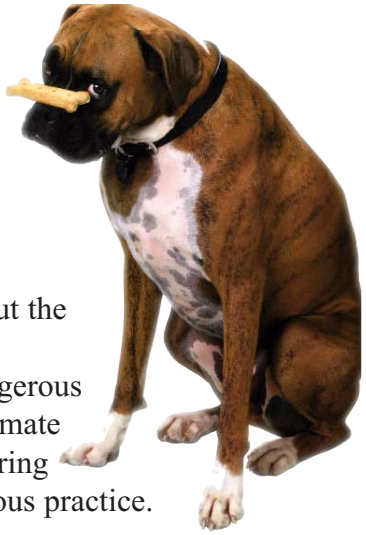
The only sure way to keep your pet safe is to have a veterinarian physically examine it. Only then can the doctor diagnosis and decide the proper therapy. Prescribing medications sight unseen and without follow-up monitoring is not a valid veterinarian-client-patient relationship. Be leery of sites that

- dispense veterinary drugs without requiring a prescription
- claim a staff veterinarian will "evaluate" your pet and then prescribe drugs

Licensed Internet Pharmacies

FDA recommends consumers make sure an Internet site is a state-licensed pharmacy within the United States before buying online. Consumers should check with their state board of pharmacy or the National Association of Boards of Pharmacy (NABP) to see whether an online pharmacy has a valid pharmacy license and meets state quality standards.

Some veterinary hospitals have valid relationships with state-licensed Internet pharmacies known as outsourced prescription management services. These pharmacies usually stock more medications than the veterinary hospital is able to, and they work directly with the veterinarian, require a prescription be written by the veterinarian, and are supportive of the veterinarian-client-patient relationship.



NSAIDs and Heartworm Preventives

The FDA's Center for Veterinary Medicine (CVM) is especially concerned about the online purchase of two commonly prescribed veterinary drugs—nonsteroidal anti-inflammatory drugs (NSAIDs) and heartworm preventives. Both drugs can be dangerous if there is no professional involvement. It's not a concern if the owner uses a legitimate online pharmacy and mails in a prescription from their veterinarian, who is monitoring the animal. But if there is no veterinarian–client–patient relationship, it's a dangerous practice.

NSAIDs

NSAIDs are often prescribed for pain relief in dogs with degenerative joint disease (osteoarthritis) or with pain after surgery. It is recommend that

- your dogs undergo blood testing and a thorough physical examination before starting NSAIDs
- your dog be monitored during NSAID therapy
- you read the NSAIDs Client Information Sheet that explains important safety information to the dog owner

Heartworm Preventives

Heartworm disease is a potentially fatal condition transmitted by the bite of a mosquito that is carrying the larvae (infective stage) of the heartworm parasite. It only takes one infected mosquito to transmit heartworm disease. The larvae enter the bite wound and migrate through the tissue of the animal, where they grow into adult worms that live in the arteries of the lungs and in the right side of the heart. Dogs, cats, ferrets, and some other mammals can get heartworm.

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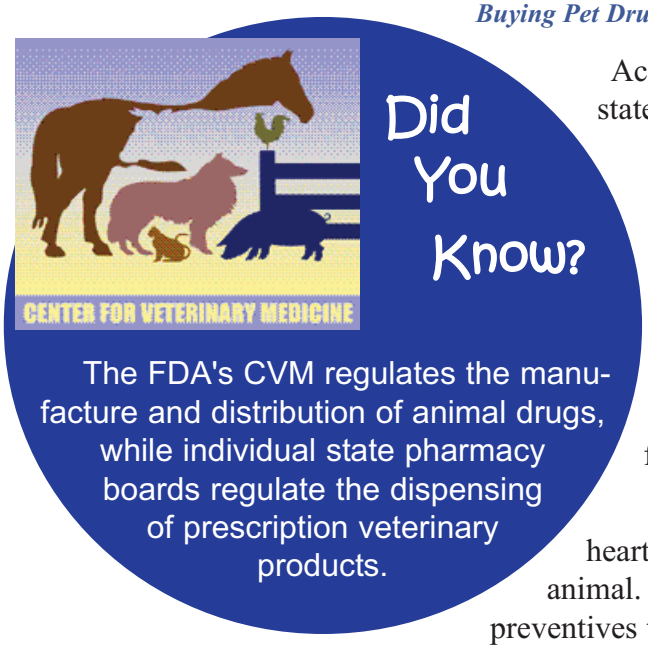
Buying Pet Drugs Online *- Continued from page 5*



According to the American Heartworm Society (AHS) all 50 states have reported heartworm disease. The AHS recommends

- using heartworm medication for dogs year-round
- getting dogs tested yearly to make sure they're not infected

Testing is important even in dogs regularly treated with heartworm preventive products due to the occasional reports of product ineffectiveness. If the animal is infected, a yearly test can ensure an early diagnosis and maximum benefit from treatment.

An Internet pharmacy veterinarian cannot perform the heartworm test because it requires drawing blood from the animal. If the test isn't done, a pet owner could be giving heartworm preventives to a dog that has heartworms, leading to severe reactions.

FDA Approves Two New Animal Drugs

This year FDA announced the approval of two new animal drugs, Slentrol (dirlotapide), a prescription drug for the management of obesity in dogs and two formulations of Cerenia (maropitant citrate), a new class of drug that is effective against certain causes of vomiting in dogs.

Slentrol

Slentrol reduces appetite and fat absorption to produce weight loss. A veterinarian will determine whether the dog should be treated, based on the dog's weight and general health.

This is a welcome addition to animal therapies, because dog obesity appears to be increasing. Veterinarians are well aware that overweight pets are at a higher risk of developing various health problems, from cardiovascular conditions to diabetes to joint problems.

Read FDA's Press Release at: www.fda.gov/bbs/topics/NEWS/2007/NEW01542.html

Cerenia

Cerenia is the first product approved for the prevention of vomiting due to motion sickness and the prevention and treatment of acute vomiting in dogs. Both products are available only by order of a veterinarian.

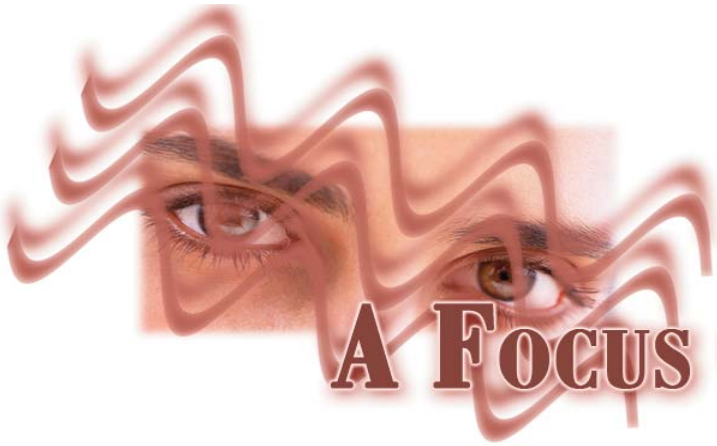
This approval is good news for many dog owners whose dogs suffer from motion sickness and for whom even a small journey can trigger vomiting. But it is even more important for cases in which vomiting -- whatever its cause -- can be a serious health hazard.

Read FDA's Press Release at: www.fda.gov/bbs/topics/NEWS/2007/NEW01573.html

For More Information

- "Pain Drugs for Dogs: Be an Informed Pet Owner" (www.fda.gov/fdac/features/2006/506_nsaid.html) FDA Consumer magazine
- Medicines and Medical Products Online (www.fda.gov/buyonline)

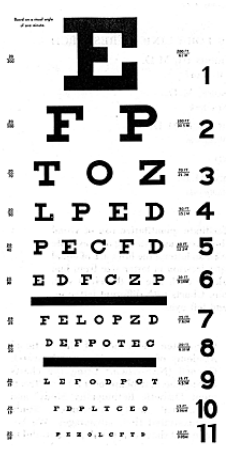
Source: Purchasing Pet Drugs Online www.fda.gov/fdac/features/2006/606_pets.html



A Focus On Vision

Eye problems tend to get overlooked in a crowd of broader health issues such as heart disease and cancer. For this reason, the vision health care community has been working to emphasize the importance of proper eye care.

The focus has been on increasing the number of people who receive regular vision checks, and addressing diseases, injuries and, the defects and refractive errors--most often responsible for impairing vision. As a result, vision goals have been added recently to a set of national health objectives, called Healthy People 2010, which are aimed at preventing disease and promoting health.



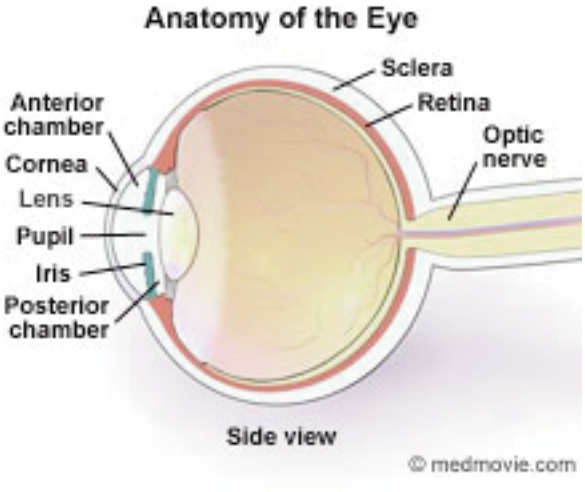
Vision Testing

The "Snellen Eye Chart," a series of letters arranged in lines, is the standard for measuring how well each eye sees. People view the chart at a distance of 20 feet. One eye is covered while the other is tested.

Having 20/20 vision means seeing the 20 foot letter at 20 feet. 20/20 is considered to be normal vision. Having 20/40 vision means seeing the 40 foot letters (the larger ones) at 20 feet. Someone able to read additional lines smaller than the line representing normal vision has 20/15, or even 20/10, vision. A person who has worse-than-normal vision and can only read letters larger than the 20/20 line has 20/40 vision, or higher. As a result, a person who has 20/40 vision can see at 20 feet what the person with normal vision sees at 40 feet. And so on.

How We See

The eye does not actually "see" objects. Instead, it sees the light that objects reflect. To see clearly, light striking the eye must be bent or "refracted" through the cornea--the clear window at the front of the eye that provides most of the focusing power. Light travels through the lens, where it is fine-tuned to focus properly on the nerve layer that lines the back of the eye, the retina, and is then sent to the brain through the optic nerve. The retina acts like the film in a camera, and clear vision is achieved only if light from an object is precisely focused on it. If not, the image you see is blurred. This problem is called a refractive error.



Refractive Errors

Refractive errors usually occur in otherwise healthy eyes, and are caused mostly by an imperfectly shaped eyeball, cornea, or lens, according to the National Eye Institute (NEI). Nearsightedness (myopia) and

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farsightedness (hyperopia) are the most common refractive errors. People with myopia see near objects clearly, while distant ones are blurred. People with hyperopia experience just the opposite--they see distant objects clearly, while near ones are blurred. Uneven focus or distorted vision (astigmatism) and aging eye that can't focus close up (presbyopia) are other common refractive errors.

The magnitude of refractive error is measured in units called diopters. Each diopter of refractive error affects a person's ability to read smaller lines of an eye chart.

Why refractive errors develop is not known. The NEI says that most infants have some degree of hyperopia, but that vision becomes more normal with age, usually leveling off by age 6. However, some children remain farsighted, or become so later in life. While some children may be nearsighted early in life, most myopia occurs later during adolescence. Refractive error can continue to change over a person's lifetime. According to the NEI, 60 percent of Americans have refractive errors that need correcting for sharper vision.

Glasses, contact lenses, and various eye surgeries and procedures are aimed at reducing refractive errors by focusing light rays properly on the retina. The past 20 years have seen many innovations in vision correction methods, including implantable intraocular lenses and different types of lasers used to reshape parts of the eye, which are regulated as medical devices by the Food and Drug Administration.

It's important to

- learn as much as possible about the differences between the available corrective lenses, new and older surgeries, and any other vision correction procedures.
- know what factors make some a good candidate for certain procedures but a poor candidate for others.
- weigh the benefits and risks of each vision correction option, and to have realistic expectations.

Corrective Eyewear

The National Eye Institute (NEI) estimates that more than 150 million Americans spend over $15 billion each year on corrective eyewear to compensate for refractive errors. Discussing the latest alternatives to corrective eyewear with an eye care practitioner will help ensure that any risks are minimized.

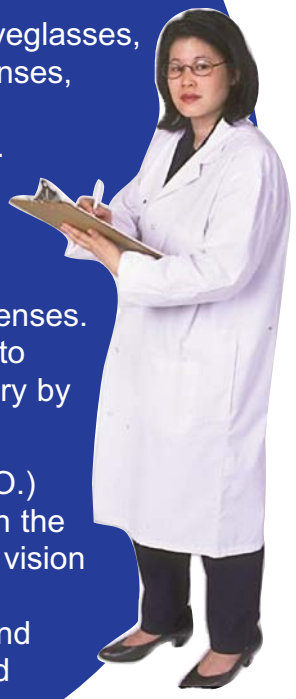
All contact lenses are regulated by the FDA as medical devices. By law, people need a prescription to buy them, even for "plano" lenses (sometimes called decorative or noncorrective lenses) worn only to change the appearance of the eye.

In addition, because people have many choices in how, where, and from whom to buy contact lenses, the Federal Trade Commission (FTC) enforces the Contact Lens and Eyeglass Rules, which help increase the ability to shop around. In this way, the FTC works to prevent fraudulent, deceptive, and unfair business practices regarding contact lenses.

Did You Know

Eye care professionals have different educations, and the services they can provide are determined by varying regulations:

- **Opticians** grind and dispense eyeglasses, and in some states, fit contact lenses, following prescriptions written by optometrists or ophthalmologists.
- **Optometrists** (O.D.) examine eyes, diagnose and treat vision problems and abnormalities, and prescribe eyeglasses and contact lenses. The medications they are licensed to prescribe to treat eye conditions vary by state.
- **Ophthalmologists** (M.D. or D.O.) are physicians who specialize in the diagnosis of eye diseases and vision problems and their treatment with medication, surgery and prescription glasses and contacts.



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Contact lens quality continues to improve. Advances in materials have made several types of precision contact lenses available for more people. While different types of plastics offer options for replacement and wear schedules, contact lenses are divided into two main groups: soft and rigid gas-permeable (RGP), also called hard contact lenses. From there, the lenses are broken down based on what they're made of, how often they need replacing, and whether they can be worn overnight.

RGP lenses give clearer, crisper vision for some people. They tend to be less expensive over the life of the lens, but the initial cost often is higher. RGPs last for several years, while soft contacts, depending on the type, are meant to be replaced after short periods. In addition, RGP lenses can be marked to show which lens is for which eye, and they're less likely to tear or rip, making them easier to handle. It may take several weeks, however, to get accustomed to wearing rigid lenses, compared with several days for soft lenses.

Daily-wear soft contacts contain from 25 percent to 79 percent water, are easy to adjust to, and are initially more comfortable than RGPs, due to their ability to conform to the eye and absorb water. Soft lenses aren't as likely to pop out or capture foreign material, such as dust, as hard lenses. There are a variety of soft lens materials available for some people with very sensitive eyes.

The development of hyper-oxygen-transmissible lens materials, for both rigid and soft lenses, has created a new generation of extended-wear contacts that are intended to decrease the incidence of, and the risks for, lens-related eye infections. Silicone hydrogel contact lenses, which, according to the NEI, allow physiological levels of oxygen to reach the ocular surface, have improved the safety of extended- or continuous-wear contacts. Extended-wear lenses are available for overnight, and extended-wear disposables are soft lenses worn from one to six days and then discarded.

In October 2001, the FDA approved a new type of soft contact lens, safe enough to wear continuously for up to 30 nights. These lenses allow six times more oxygen to reach the eye than previously approved lenses. All extended-wear contact lenses, however, carry a greater risk of serious eye infections than lenses that are removed before bedtime.

The replacement schedule of contact lenses refers to the length they can safely be worn. RGPs generally are replaced every couple of years because they are made of a durable material, although a prescription change would mean new lenses. Soft contacts have a wider variety of replacement schedules.

Some soft and hard contact lenses have special features including bifocals, colored contacts, plano lenses, torics for astigmatism, and UV-blocking contacts.

The rule of thumb for contact lens wearers, is to practice good hygiene and follow manufacturers' instructions for proper use, cleaning, and storage of the lenses. Report any signs of infection to your doctor. And follow your doctor’s instructions for contact lens wear times. Be sure to ask for written instructions and follow them carefully. Patient package inserts usually accompany contact lenses. If the package insert is missing, you should ask your doctor for a copy.

The most serious safety concerns with any contact lens deal with overnight use, or extended wear. Rigid or soft, wearing these types of contact lenses overnight or for too many hours at a time, increases the risk of corneal ulcers--infection of the cornea that can lead to blindness. Symptoms include vision changes, eye redness, eye discomfort, and excessive tearing. Keeping lenses clean, replacing them often, and wearing them as prescribed by your doctor can help minimize the risks of wearing contacts.

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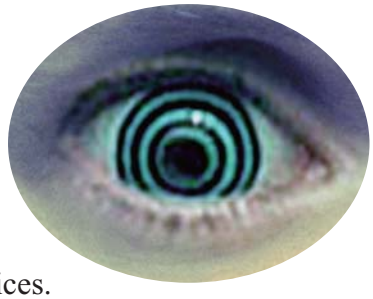
Orthokeratology (Ortho-K) is a nonsurgical procedure that uses RGP contact lenses to change the curvature of the cornea to improve its ability to refract light and successfully focus on objects.

The Ortho-K system was initially approved for daily wear. But in 2002, the FDA approved the lenses for overnight use. A person takes them out in the morning to enjoy the day free of contacts. This method, however, does not produce a permanent result, and a doctor must be certified to fit Ortho-K lenses.

Decorative Contact Lenses--Wearer Beware



Plano lenses, also known as zero-powered, decorative, or noncorrective lenses, were at one time considered cosmetic products. Their purpose is to temporarily change, for example, a brown-eyed person's eye color to blue, or to make a person's eyes look "weird" by portraying Halloween themes or the logos of a favorite sport team. But because these lenses carry the same infection risks to the eye as corrective contact lenses, in 2005, they were defined by law as medical devices.

As with other contact lenses sold by prescription, eye care providers are needed to fit decorative lenses, because of the potential for eye problems, such as pink eye (conjunctivitis) and corneal ulcers. FDA has informed health care professionals of the risk of blindness and other eye injuries if non-corrective, decorative, or cosmetic lenses are distributed without an eye care professional's involvement.

FDA further advises people never to buy decorative lenses at any store that doesn't ask for a valid prescription from an eye care professional. FDA has never cleared an over-the-counter decorative lens. Such sales are illegal in the United States, and for good reason: wearing contact lenses that don't fit properly is dangerous and can cause serious vision problems, abrasions, and infections.

TYPES OF CONTACT LENSES

Types of Lenses	Advantages	Disadvantages
Rigid gas-permeable (RGP) Made of slightly flexible plastics that allow oxygen to pass through to the eyes.	Excellent vision; short adaptation period; comfortable to wear; corrects most vision problems; easy to put on and to care for; durable with a relatively long life; available in tints (for handling purposes) and bifocals.	Require consistent wear to maintain adaptation; can slip off center of eye more easily than other types; debris can easily get under the lenses; require office visits for follow-up care.
Daily-wear soft Made of soft, flexible plastics that allow oxygen to pass through to the eyes.	Very short adaptation period; initially more comfortable and more difficult to dislodge than RGP lenses; available in tints and bifocals; great for active lifestyles.	Do not correct all vision problems; vision may not be as sharp as with RGP lenses; require regular office visits for follow-up care; lenses soil easily and must be replaced periodically.
Extended-wear Available for overnight wear in soft or RGP lenses.	Can usually be worn up to seven days without removal by suitable individuals..	Do not correct all vision problems; require regular office visits for follow-up care; increase risk of complication; require regular monitoring and professional care.
Extended-wear disposable Soft and worn for an extended period of time, from one to six days, and then discarded.	Require little maintenance if disposed of when removed from the eye according to wearing instructions; available in tints and bifocals; spare lenses available	Vision may not be as sharp as with RGP lenses; do not correct all vision problems. Same risks as extended wear lenses.
Planned replacement Soft, made for daily or extended wear, and are replaced on a planned schedule, most often either every two weeks or months.	Require simplified cleaning and disinfection; good for eye health; available in most prescriptions.	Vision may not be as sharp as with RGP lenses; do not correct all vision problems. Same risks as extended wear lenses.

Source: American Optometric Association

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Corrective Surgeries

Refractive surgery includes several surgical procedures designed to help reduce the need for glasses or contact lenses. These procedures correct refractive errors by changing the focus of the eye. Common procedures such as photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) do this by reshaping the curve of the cornea to move the point at which light is focused onto the retina.

Various procedures with different capabilities are available. There are now four categories of refractive surgery procedures: excimer laser, implant, thermal, and other refractive procedures.

In PRK, an excimer laser capable of removing precise amounts of tissue with micron accuracy is used to reshape the central cornea--to flatten it to correct myopia, or to steepen it to correct hyperopia. PRK can also be used to correct astigmatism. The layer of cells covering the cornea, the epithelium, is removed, and the laser sculpts the cornea to correct the refractive error. A bandage contact lens is placed over the eye after the procedure to speed the epithelial healing process.

PRK gained popularity in the mid-1990s, but also was met with limitations. It worked best in patients with low-to-moderate myopia, because with higher levels, there was a risk of corneal haze. The procedure also was associated with some physical discomfort after surgery, since the cornea needed several days to heal. In some cases, it could take several months to reach the best level of vision.

By far the most popular vision correction procedure has been LASIK. Surgeons use a surgical knife, called a microkeratome, to create a hinged flap on the surface, fold it over to sculpt the underlying cornea into a new shape, and fold it back onto the cornea.

The advantages of LASIK include a quicker visual rehabilitation, reduced pain and discomfort, and the surgeon's ability to treat higher levels of refractive error without the limitations associated with PRK.

Doctors say that one of the keys to a successful LASIK procedure is the measurement an ophthalmologist takes to determine refractive error. Small imperfections in the eye may cause some light to travel through the eye at different angles, making light strike the retina in different places. Collectively, these imperfections are called optical aberrations.

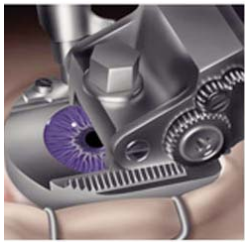
Traditional laser technology allows for correction of the refractive errors myopia, hyperopia, and astigmatism, also

LASIK
STEP-BY-STEP

Step 1: Anesthetic eye drops are applied to numb the eye for surgery, and the surgeon marks the cornea with water-soluble ink to guide replacement of the flap.

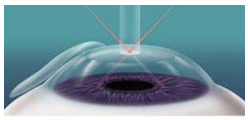
Step 2: The surgeon applies a suction ring designed to hold the eye steady and checks the pressure of the eye.

Step 3: The surgeon raises a thin layer of the cornea, or corneal flap, with the microkeratome to expose the portion beneath. This part of the procedure is called keratectomy.



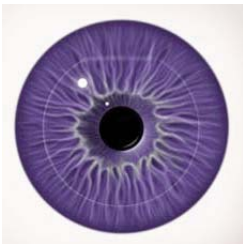
Step 4: The flap - the outer-most 20 percent of the thickness of the cornea - is lifted and reflected to the side.

Step 5: The surgeon tests for laser alignment and walks the patient through the fixation process.



Step 6: The computer-controlled excimer laser removes the tissue under the flap and reshapes the cornea of the affected eye. In less than 60 seconds, ultraviolet light and high-energy pulses from the excimer laser reshape the internal cornea (the stroma) with accuracy up to 0.25 microns, or 1/4000 of a millimeter.

Step 7: Then, the surgeon lays the flap back into its original position and observes the eye for three to five minutes to ensure bonding. Because the cornea bonds quickly, healing is rapid, and the eye does not require stitches.



Credit: www.eyesurgeryeducation.com

Continued on page 12

Vision *- Continued from page 11*

known as "lower order" aberrations. A new excimer laser procedure, called wavefront-guided LASIK, treats lower order and "higher order" aberrations, which are subtle focusing imperfections in an eye's optical system that can result in less-than-optimal clarity.

Wavefront, or custom LASIK, uses a measuring device to create a "map" of how a person's eye focuses light to precisely assess the unique irregularities and variations of the eye. These variations, experts claim, can be as unique as a person's fingerprints.

The wavefront map is very detailed: Instead of simply creating a general description of the eye's focusing power, for example, nearsightedness, farsightedness, or astigmatism, it records every subtle distortion in the pathway of light moving through the eye.

Laser Epithelial Keratomileusis, or LASEK, corrects myopia, hyperopia, and astigmatism. The epithelium, or outer surface of the cornea, is loosened with alcohol, not with the microkeratome used in LASIK. It is then peeled back to expose the cornea. The same excimer laser used in LASIK is applied to the cornea, but only to the surface. The epithelium is placed back into position, and a bandage contact lens is placed on the eye to promote healing. Like LASIK, the recovery time is rapid. Discomfort is somewhat increased, compared with LASIK.

While the FDA regulates excimer lasers, the agency doesn't have the authority to regulate a doctor's practice of medicine or the off-label use of medical products. Therefore, the FDA does not tell doctors what to do when running their businesses or what they can or cannot tell their patients. Consequently, people considering laser surgery should ask questions and fully understand any procedure they might be considering.

The idea of a person walking into a doctor's office and an hour later walking out with perfect vision is a very attractive one, but the reality is that these are surgical procedures with potential complications, and perfect results are not guaranteed, experts say. Refractive surgeries are elective procedures, some of which can't be undone.

Remember that you can change glasses or contacts, but not implants or surgery. Be sure to consult with a refractive surgeon to determine your eligibility for surgery. Surgical procedures are not without some risk, and that the long-term effects of many procedures are still unknown.

According to the American Academy of Ophthalmology (AAO), more than 90 percent of people who have refractive surgery for myopia and astigmatism end up with 20/40 vision or better without glasses, a correction sufficient enough to allow them to drive legally without glasses. Sixty percent to 70 percent of patients achieve 20/20 vision or better.

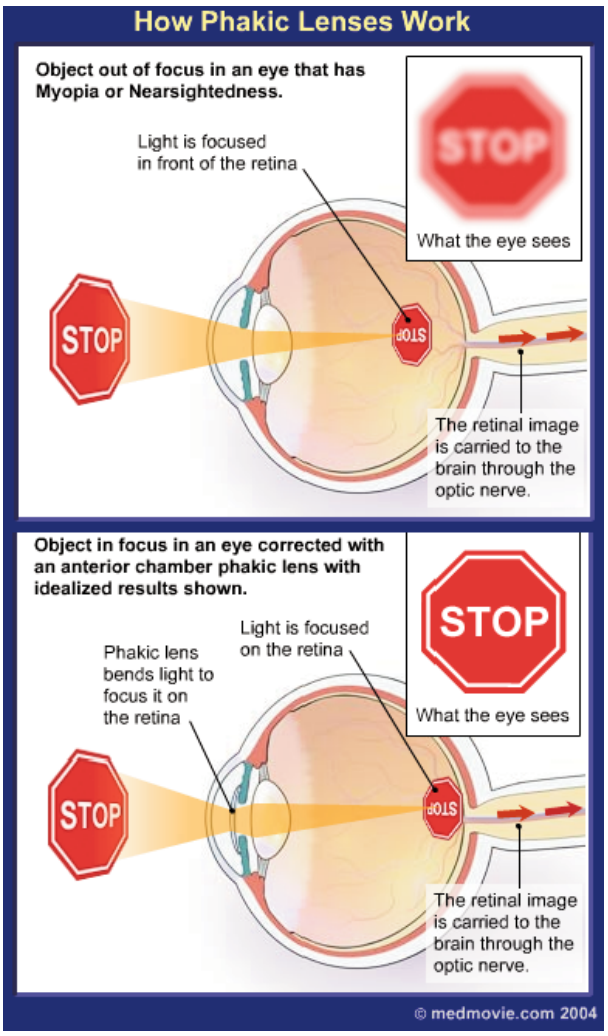
Implant Procedures

Corrective artificial lens implants give people who don't want to bother with eyeglasses or manual insertion of contact lenses another option to consider.

Intrastromal corneal ring segments are semicircular pieces of plastic that are implanted within the cornea to treat mild forms of myopia. They also are sometimes used for other conditions affecting the cornea. The inserts are designed to change the shape of the cornea by adjusting the focusing power of the eyes so that light is focused onto the retina. A small incision is made near the upper edge of the cornea, in which the ring segments are inserted. The incision is closed with two small sutures that are usually removed two to four weeks after surgery.

Continued on page 13

Medicines in My Home *- Continued from page 3*



While tissue removed during laser eye surgeries cannot be replaced, the intrastromal corneal ring segments are removable.

Phakic Intraocular Lenses (phakic IOLs) are new devices made of plastic or silicone, approved by the FDA for correcting nearsightedness. These thin lenses are implanted into the eye to help reduce the need for glasses or contact lenses. A small incision is made in the front of the eye, in which the phakic lens is inserted. Phakic refers to the lens being implanted into the eye without removing the eye's natural lens. Since phakic IOLs involve entering the eye, unlike LASIK and PRK, the risk of complications is higher.

Phakic lenses are intended to be permanent. If a cataract develops, however, the natural and phakic lenses would be removed and replaced with artificial lenses. There's no guarantee that the eye will return to its previous level of vision. While phakic lenses are a good alternative for people who are very myopic and can't be corrected with LASIK, there's no guarantee that you will always be able to go without glasses.

Thermal Procedures

Conductive keratoplasty (CK) uses radio frequency energy, instead of a laser, to bend the cornea. CK corrects for hyperopia. CK does not involve making an incision, but instead, a tiny probe releases controlled amounts of very low heat from radio frequency energy, causing the outside area of the cornea to tighten like a belt, making the central cornea steeper. CK causes little or no discomfort or irritation, and vision improvement is almost instantaneous. Unlike other types of refractive surgery, such as LASIK, correction from CK may be temporary and re-treatment may be necessary.

CK is also approved for monovision, known as "blended vision". By overcorrecting the cornea, CK causes the eye to become nearsighted. CK achieves its correction of presbyopia by inducing monovision with one nearsighted eye.

Monovision is a corrective technique used to treat people with presbyopia. The intent is for the person to use one eye for distance viewing and one eye for near viewing. Having each eye configured for different focusing distances can reduce or eliminate the need for eyeglasses or contact lenses.

The practice was first applied to contact lenses, and more recently to CK. In CK, the technique treats one eye to focus at close proximity, while the other eye is left untreated or, if needed, treated to be able to focus at a distance. This method may be difficult to adjust to at first but, according to the International Society of Refractive Surgery, about six to eight weeks after the monovision procedure, most people's brains are able to adjust to the different focusing ability of the eyes.

The FDA recommends that anyone considering monovision try the contact lens procedure first, as a trial run, before having the surgery, which is permanent. Also, it's important to check state drivers' license requirements with monovision.

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Vision *- Continued from page 13*

Other Refractive Surgery Procedures

Accommodative and multifocal IOLs are used to treat nearsightedness, farsightedness, and the inability to focus up close because of age. These artificial lenses are surgically implanted in the eye. Unlike the phakic IOLs, which are implanted in front of the eye's natural lens, accommodative and multifocal IOLs actually replace the eye's natural lens once a cataract has developed. These lenses enable the eye to regain its focusing and refractive ability.

Eyeglasses--The Reliable Standby

Glasses correct refractive errors by adding or subtracting focusing power to the eye. The power needed to focus images directly on the retina is measured in diopters. This measurement is also your eyeglass prescription.

Like contact lenses, glasses come in all shapes and sizes, offering an array of choices for both function and fashion. Eyeglass frames, for example, are more durable and tout materials such as titanium and new "memory metals." Manufacturers are making lenses that are thinner, stronger, and lighter. And lens options include antireflective coating, light-changing tints, line-free (progressive) bifocal, and polycarbonate--the most impact-resistant lens material available.

Regular eye exams are important because they can detect early signs of disease and refractive error long before either leads to vision impairment. Doctors recommend that everyone have an eye exam shortly after birth, and at least every few years until age 40. After that, the eyes should be routinely checked every two or three years. People with diseases such as diabetes and hypertension should have their eyes checked more frequently.

For More Information

Food and Drug Administration
- www.fda.gov/cdrh/contactlenses/
- www.fda.gov/cdrh/lasik/
- www.fda.gov/cdrh/phakic/

National Eye Institute
- www.nei.nih.gov

American Academy of Ophthalmology
- www.aao.org

American Optometric Association
- www.aoanet.org

Federal Trade Commission
- www.ftc.gov

Association of Regulatory Boards of Optometry
- www.arbo.org

Source: Vision Problems and Care (FDA Consumer: Jul.-Aug. 06) www.fda.gov/fdac/features/2006/406_vision.html

Medical Device Recall – HoMedics® Thera-P® Heating Pads

HoMedics Inc. is voluntarily recalling several models of heating pads. Some heating pads may contain a loose connection which may cause the unit to short circuit. This problem may pose a risk of burn injuries or fire as well as damage to the heating pad itself or to materials (like bedding and furniture) which may be in contact with the pad.

Consumers should discontinue the use of these heating pads immediately and return them to the place of purchase for a full refund.

For more information on the recall go to www.fda.gov/cdrh/recalls/recall-020907.html or read the company's press release at www.homedics.com/MediaCenter/PressRelease.aspx?id=90&cat=prp

Tattoos: Making a Mark

Tattoos have come a long way since the days when sailors had "Mom" imprinted within a heart on their arms as an unofficial rite of passage. A quick scan of any public place reveals that tattoos are now very popular even outside the sea-faring professions.

The practice of decorating human skin with ink goes back thousands of years. The oldest example of tattooing was found in 1991 on a mummified Neolithic man discovered by hikers in a melting glacier in the Austrian Alps. The man, dubbed "Oetzi" for the valley in which he was found, lived more than 5,000 years ago and had several dozen tattoos on his body.

Many people choose to undergo tattooing in its various forms. For some, it's an aesthetic choice or an initiation rite. Some choose permanent make-up as a time saver or because they have physical difficulty applying regular, temporary make-up. For others, tattooing is part of reconstructive surgery, particularly of the face or breast, to simulate natural pigmentation. People who have lost their eyebrows due to alopecia (a form of hair loss) may choose to have "eyebrows" tattooed on, while people with vitiligo (a lack of pigmentation in the skin) may try tattooing to help camouflage the condition.

Over the years, tattoos have been used for many purposes, including medical, cosmetic, and animal tattooing. But how are tattoos regulated? While state and local authorities oversee the practice of tattooing, inks and ink pigments used in tattoos are subject to FDA regulation as cosmetics and color additives.

Types of Tattoos

There are many different kinds of tattoos. Some examples include:

- **Permanent tattoos -** Considered the traditional tattoo, one or more needles attached to tubes of ink are used to inject colored ink deep below the skin's surface.
- **Permanent make-up -** Permanent tattoos that also use a needle to inject colored ink into the skin and mimic temporary cosmetic products such as eyebrow pencil, lip liner, eyeliner or blush.
- **Henna (mehndi) tattoos -** A natural plant dye called henna or mehndi is used to stain the skin for 2 to 3 weeks without using needles. The use of henna in tattoos is illegal because henna is only approved for use as a hair dye and it should not be put on the skin.
- **"Sticker" type temporary tattoos -** The tattoo design is printed on a piece of coated paper and applied to the skin with water. Temporary tattoos last only a few days. "Sticker" tattoos from countries other than the U.S. should not be used because the colors may not be FDA-approved, and could cause allergic reactions or worse.

Did You Know?

FDA's website on tattoos has a good overview of all types of tattoos (www.fda.gov/oc/opacom/hottopics/tattoos.html) and possible risks from having one applied. The site also has a section on novelty makeup, and answers questions about the possibility of getting hepatitis C or HIV from a tattoo.

Continued on page 16

Tattos - Continued from page 3

What are the risks?

Remember ...

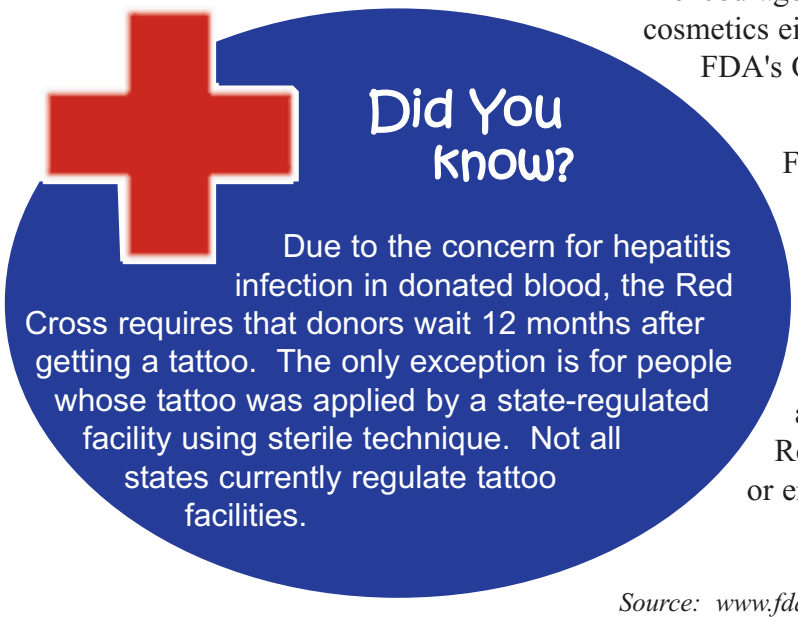
Think very carefully before getting a tattoo. Most tattoos are permanent and some cannot be removed by any method. Removing tattoos and permanent make-up can be difficult, painful, and can cost a lot of money. It often requires surgery and can result in scarring.

- **Infection -** Dirty needles can pass infections like hepatitis and HIV, from one person to another. If you are getting any type of permanent tattoo, make sure the needles that will be used are clean and germ-free.
- **Allergies -** You might be allergic to the ink pigment, diluent, or something else used in your tattoo. While allergic reactions are rare, they can cause serious problems because the pigments used in tattooing can be difficult, or impossible, to remove. Occasionally, people may develop an allergic reaction to tattoos they have had for years. FDA has also received reports of allergic reactions to products applied to the skin that contain henna.
- **Scarring -** Unwanted scar tissue may form when getting or removing a tattoo. If you are prone to developing keloids -- scars that grow beyond normal boundaries -- you are at risk of keloid formation from a tattoo. Keloids may form any time you injure or traumatize your skin.
- **Granulomas -** These are small knots or bumps that may form around material that the body perceives as foreign, such as particles of tattoo pigment.
- **MRI complications -** People may have swelling or burning in the tattoo when they have magnetic resonance imaging (MRI). This happens rarely and does not last very long.
- **Buyers' Remorse -** You may not like your tattoo even if it was done well. Not liking the tattoo is the most common reason people give for having one removed.
- **Cost of Removal -** If you decide you want to get rid of a tattoo, it usually takes many treatments and costs a lot of money. Common methods of removal include surgical excision with a scalpel (large areas may require skin grafts), dermabrasion, and laser removal.

How do I report an adverse reaction to a tattoo or other cosmetic?

FDA encourages consumers to report any adverse reactions to cosmetics either to their nearest FDA district office or to FDA's Office of Cosmetics and Colors. Here's how:

- You can find the contact information for your FDA district office on FDA's Web site. These phone numbers also are included in the U.S. Government listings in the Blue Pages of the phone book under United States Government/Health and Human Services.
- To contact FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS), call (301) 436-2405 or email CAERS@cfsan.fda.gov.



Source: www.fda.gov/oc/opacom/hottopics/tattoos.html

BACTERIA-EATING VIRUS APPROVED AS FOOD ADDITIVE

Not all viruses harm people. FDA has approved a mixture of viruses as a food additive to protect people. The additive can be used when processing foods, and for spraying onto ready-to-eat meat and poultry products to protect consumers from the potentially life-threatening bacterium *Listeria monocytogenes* (*L. monocytogenes*).

The viruses used in the additive are known as bacteriophages. Bacteriophage means "bacteria eater." A bacteriophage, also called a phage (pronounced fayj), is any virus that infects bacteria.

Eating food contaminated with the bacterium *L. monocytogenes* can cause listeriosis. Listeriosis is an infectious disease that is rarely serious in healthy adults and children, but can be severe and even deadly in pregnant women, newborns, older people, and people with weakened immune systems. According to the CDC, about 2,500 people become ill with listeriosis each year in the United States. Of these, about 500 die.

Cooking can kill L. monocytogenes, but many ready-to-eat foods, such as hot dogs, sausages, luncheon meats, and other deli-style meats and poultry, may become contaminated at the processing plant after cooking and before packaging. Unlike fresh meat and poultry, the ready-to-eat products can be consumed without reheating, so the L. monocytogenes survive and are eaten. *L. monocytogenescan* bacteria can continue to thrive and multiply in the refrigerator.

<u>How Bacteriophages Work</u>

Bacteriophages are found in the environment. We're routinely exposed to bacteriophages found in soil and water, and they are part of the microbial population in the human gut and oral cavity.

Bacteriophages infect only bacteria. They don't infect plants, people, or other mammals. Thousands of varieties of phages exist, and each one infects only one type or a few types of bacteria. The particular phages approved as a food additive are very specific to Listeria and only thrive if *Listeria* is present.

The type of phage that was approved is lytic, which means that the phage destroys its host during its life cycle without integrating into the host's genetic makeup. This type of phage works by attaching itself to a bacterium and injecting its genetic material into the cell. The phage takes over the metabolic machinery of the bacterium, forcing it to produce hundreds of new phages and causing the bacterial cell walls to break open. This process kills the bacterium and releases many new phages, which seek out other bacteria to invade and repeat the cycle.

The process continues until all host bacteria have been destroyed, then the bacteriophages cease replicating. They need a host to multiply and will gradually become inactive when they lose the host.

This approval marks the first time that the FDA has regulated the use of a phage preparation as a food additive. Phages are currently approved in the United States for pesticide applications, such as spraying on crops.

Scientists continue to be interested in other uses for phages, such as to prevent food products from contamination with other types of harmful bacteria and to act as possible treatments for bacterial infections in people.

<u>For More Information</u>

FDA Bacteriophage Questions and Answers www.cfsan.fda.gov/~dms/opabacqa.html

Source: www.fda.gov/fdac/features/2007/107_virus.html

What's the difference between viruses and bacteria?

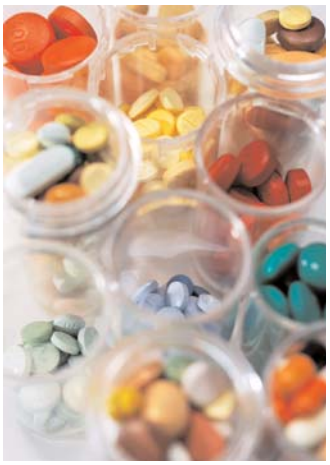
Viruses are the smallest and simplest known life form. They are 10 to 100 times smaller than bacteria. The biggest difference between viruses and bacteria is that viruses must have a living host - like a plant or animal - to multiply, while most bacteria can grow on non-living surfaces.

Unlike bacteria, which attack the body like soldiers mounting a pitched battle, viruses are guerilla fighters. They don't attack so much as infiltrate. They literally invade human cells and turn the cell's genetic material from its normal function to producing the virus itself.

In addition, bacteria carry all the machinery needed for their growth and multiplication, while viruses carry mainly information - for example, DNA or RNA, packaged in a protein and/or membranous coat. Viruses harness the host cell's machinery to reproduce. In a sense, viruses are not truly "living," but are essentially information (DNA or RNA) that float around until they encounter a suitable living host.

Source: What's the Difference Between Viruses and Bacteria? www.cfsan.fda.gov/~dms/qa-fdb38.html

Information for Parents and Teens on the Abuse of Over-the-counter and Prescription Medicines



Abusing over-the-counter and prescription medicine can be as harmful to teens as using illicit drugs. Thirteen organizations and federal agencies have joined together to alert parents and teens to the dangers. **Parents: The Antidrug** at www.theantidrug.com, has tips for parents on how to recognize the signs and symptoms of medicine abuse and how to talk to their teens about it. For more information, visit the website or call toll-free: 1-800-788-2800.

On TV this Spring!

FDA has partnered with the Consumer Health Education Center, NY Poison Control Center, and NY Maternal Infant Health Network of the Capital Region, to create an informative video for parents on how to safely give an over-the-counter medicine to their young children.

The six-minute video will air on the Today's Health television show across the country on major network stations, the Health Channel on the Dish Network, and the GE Hospital Network, beginning in mid-May and running through June.

Learn About It Online: FDA's Consumer Website

FDA's Consumer website is a one-stop shop for all of FDA's most current consumer information. You'll find links to all of FDA's consumer-friendly websites with information on everything from heart health and weight management to cell phones and LASIK surgery.

The page is broken down by topic and audience, and includes links to:

- All FDA e-newsletters and subscription pages
- A database of FDA consumer publications
- Interactive tools, such as the "Make Your Calories Count" food label and weight management module
- Consumer guides such as "Buying Medicines Online"
- Information about FDA and how FDA regulates many of the products you use everyday

VISIT
www.fda.gov/consumer
to learn more

Calendar of National Health Events

May	June	July
1 - 31 **Mental Health Month** National Mental Health Association and National Council for Community Behavioral Healthcare 2001 North Beauregard Street, 12th Floor Alexandria, VA 22311 (800) 969-6642 www.nmha.org	**27** **National HIV Testing Day** National Association of People with AIDS 1413 K Street, NW, Suite 700 Washington, DC 20005 (800) 458-5231 (202) 898-0414 nhtd@napwa.org www.napwa.org	**1 - 31** **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

Other health events that may be of interest to teens are listed on our website at www.fda.gov/cdrh/fdaandyou/calendar.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. The information published herein was current as of the date of publication.**

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