

MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

Issue 2

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FDA Centennial:

Celebrating 100 years of Protecting and Promoting Public Health

The U.S. Food and Drug Administration's (FDA) history began in 1906 when President Teddy Roosevelt signed the Federal Food and Drugs Act. Though the names and faces have changed over the past century, the mission of FDA has remained the same: to protect and promote the public health.

FDA is the oldest federal agency dedicated to consumer protection and is a scientific, regulatory, and public health agency that oversees products accounting for 25 cents of every dollar spent by Americans. Almost any food, cosmetic, drug, radiation product, medical device or biologic product in use you can think of is regulated by the FDA. Scientists and medical professionals within FDA's five Centers work to ensure products you use, such as medicines, pacemakers, vaccines and dietary supplements, are safe and effective.

For more information, visit the FDA Centennial Website at <http://www.fda.gov/centennial>.

New Wheelchair Keeps People on the Move

Imagine losing use of your legs and still being able to function at an eye-level height and climb stairs. It is possible with a new motorized wheelchair that knows how to keep its balance.

The INDEPENDENCE iBOT 4000 Mobility System is a battery-powered wheelchair that enables people with mobility impairments to go up and down stairs, reach high shelves, climb curbs, travel over a wide variety of terrain, negotiate uneven or

inclined surfaces, and hold eye-level conversations with others who are standing. The Food and Drug Administration (FDA) approved the iBOT 4000 in March 2005. It uses the same technology as the previously approved iBOT 3000.

FDA expedited review of the original iBOT 3000 because it represented a breakthrough technology with the potential to benefit people with disabilities. "Its approval is emblematic of FDA's commitment to help innovative medical technologies reach patients promptly," said the Acting FDA Commissioner at the time of the original approval. According to the FDA, which approved the device in August 2003, an estimated two million Americans use wheelchairs.

Powered by rechargeable batteries that can operate up to a full day on a single charge, the wheelchair uses a system that connects computers, software, gyroscopes, motors, and electronics to automatically adjust itself according to the user's center of gravity to maintain balance and stability.



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To select the mode of operation, the user pushes a toggle switch to command one of five modes: standard, four-wheel drive, balance, stair climbing, or remote function. A joystick controls the speed and direction of travel. The iBOT can be easily commanded to convert from a standard wheelchair, with four wheels in contact with the ground, to an elevated wheelchair balanced on only two wheels. Operating the device in balance function allows the user to reach high objects or to move around while seated at an elevated eye-level height. When the user commands the system to operate in balance function, the front pair of wheels rotates above the back wheels. This elevates the user to an eye-level seated position and allows the user to move around at this height while the system continues to balance on its two back wheels. In both standard function and balance function, the user can travel over obstacles up to one inch in height and can drive on slopes up to five degrees (such as typical building entrance ramps and sidewalk curb cuts).

Four-wheel drive enables the user to go over rough terrain, travel over gravel or sand, go up steeper 10-degree slopes, and climb five-inch curbs. Because of its unique balancing mechanism, the wheelchair remains stable and the seat stays nearly level during all these movements. For use on stairs, there are two sets of drive wheels that rotate up and over each other to climb up or down, one step at a time. When operating on stairs, the user leans forward or backward, directing the chair to go up or down. For remote operation of the unoccupied wheelchair, the user or an assistant can remove the joystick control from its mount and maneuver the chair from up to four feet away. This is useful for driving into a vehicle for transport, for positioning the chair for transfers, and for parking after transferring out of the chair.

The iBOT is not for everyone, however. The chair is available only with a doctor's prescription, and people must have use of at least one arm to operate it. The chair also must be adjusted to the patient's weight, which is limited to no more than 250 pounds, and users must undergo special training. Using the wheelchair requires some physical effort, and users must have the skills and judgment to constantly assess the environment and choose between different travel routes and device functions. Although the price of the iBOT is \$26,100, people who buy the device may escape the costs of typical modifications, such as ramps and elevators, needed for home use of a conventional wheelchair.

Modes of Operation - iBOT 4000 Mobility System				
Mode	How it works	Features	Can be used on	Speed and range
Standard	Similar to conventional powered wheelchair; casters contact ground	Provides good turning performance and mobility on firm, level surfaces	Inclines up to five degrees; negotiates obstacles up to one inch	Maximum speed: 6.8 mph; Range: 12.4 miles
4-Wheel Drive	Four drive wheels contact ground; casters are elevated	Provides good performance and mobility on soft or loose terrain	Inclines up to 10 degrees; negotiates obstacles up to five inches	Maximum speed: 4.9 mph; Range: 13.7 miles
Balance	One pair of drive wheels makes contact with ground	Provides mobility at elevated height; mode can be turned on/off by clinician	Inclines up to five degrees; negotiates obstacles up to one inch	Maximum speed: 3.2 mph; Range: 15.5 miles
Stair Climbing	Drive wheels rotate up and over each other; Available settings: assist or solo	Use solo with one or two stair rails, or assisted if user does not have needed upper body strength; mode can be turned on/off by clinician	Tread depth: 10 to 17 inches; Riser height: five to eight inches	
Remote	Operated with joystick, which can be removed from its mount on the armrest	Useful for maneuvering the device when not seated in it	Inclines up to 20 degrees; obstacles up to one inch	Maximum speed: 0.5 mph

Investigation of Serious Eye Infections Associated With Soft Contact Lens Use and Contact Lens Solution

Consumers Are Advised to Follow Good Hygiene Practices and Manufacturer's Instructions to Prevent Infection

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are alerting health care professionals and their patients who wear soft contact lenses to an increasing number of reports in the United States of a rare but serious fungal infection in the eye that can cause permanent loss of sight. Some patients have reported a significant loss of vision, resulting in the need for a corneal transplant. For more information, please visit: <http://www.fda.gov/cdrh/medicaldevicesafety/atp/041006-keratitis.html> and <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01354.html>.



Shingles: An Unwelcome Encore

Shingles is caused by the same virus that causes the childhood disease chickenpox. Shingles (also called herpes zoster) most commonly occurs in older adults. Treatment was once limited to wet compresses and aspirin. Today's treatments provide a variety of ways to shorten the duration of a shingles outbreak and to control the associated pain. Sometimes, however, shingles leads to a chronic painful condition called post-herpetic neuralgia (PHN) that can be difficult to treat and can last from months to years.

Initial Symptoms

After an occurrence of chickenpox, the virus retreats to nerve cells in the body, where it may lie dormant for decades. But under certain conditions, usually related to aging or disease, the virus can reactivate and begin to reproduce. Once activated, the virus travels along the path of a nerve to the skin's surface, where it causes shingles.

Shingles' symptoms may be vague and nonspecific at first. People with shingles may experience numbness, tingling, itching, burning sensation or pain before the classic rash appears. In the pre-eruption stage, diagnosis may be difficult, and the pain can be so severe that it may be mistaken for pleurisy, kidney stones, gallstones, appendicitis, or even a heart attack, depending on the location of the affected nerve.

The Outbreak

Pain may come first, but when the migrating virus finally reaches the skin--usually the second to the fifth day after the first symptoms--a painful, red rash appears that resembles chickenpox. The rash tells it all.

Doctors can distinguish shingles from chickenpox (or dermatitis or poison ivy) by the way the spots are distributed. Since shingles occurs in an area of the skin that is supplied by sensory fibers of a single nerve, the rash usually appears in a well-defined band on one side of the body, typically the torso, or on one side of the face, around the nose and eyes. If a diagnosis is in doubt, lab tests can confirm the presence of the virus.

The rash usually begins as clusters of small bumps that soon develop into fluid-filled blisters. In turn, the blisters fill with pus, break open, and form crusty scabs. In about four or five weeks, the disease runs its course, the scabs drop off, the skin heals, and the pain fades. Most healthy individuals make an uneventful, if not particularly pleasant, recovery.

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Not everyone sails through without incident, however. Although it is difficult to resist scratching the itchy rash, it is better to keep hands off, as the damaged skin may develop a bacterial infection requiring antibiotic treatment. After such an infection, the skin may be left with significant scarring, some of it serious enough to require plastic surgery.

Another complication called the Ramsay Hunt syndrome occurs when the virus spreads to the facial nerve, causing intense ear pain. The rash can appear on the outer ear, inside the ear canal, on the soft palate (part of the roof of the mouth), around the mouth and on the face, neck and scalp. The hearing loss, vertigo and facial paralysis that may result are usually, but not always, temporary.

Occasionally, the rash will appear as a single spot or cluster of spots on the tip of the nose, called Hutchinson's sign. This is not good news. It means that the ophthalmic nerve is probably involved and the eye may become affected, possibly causing temporary or permanent blindness. It can be very painful. In people whose immune systems are extremely weakened, the shingles virus can also spread to the internal organs and affect the lungs, central nervous system, and the brain, sometimes causing death.

Chickenpox Revisited

Like other members of the herpes family (such as the herpes simplex viruses that cause cold sores and genital herpes), the virus that causes chickenpox never completely leaves the body. Most people do not get chickenpox a second time. However, anyone who has had chickenpox has the potential to develop shingles, because after recovery from chickenpox, the virus settles in the nerve roots.

Researchers are not sure exactly what triggers the virus to suddenly start reproducing in nerve cells later in life and reappear as shingles. However, they do know the virus may reactivate when the immune system is weak.

Certain factors can cause the immune system to let down its guard. Age is one of them. Immunity declines with aging, so older adults are more at risk to disease. The incidence of shingles and of resulting PHN rises with increasing age. More than 50 percent of cases occur in people over 60. Older people may also lack exposure to children with chickenpox, thereby losing an opportunity to boost immunity and prevent virus reactivation. Although most people have only one attack of shingles, about four percent will have further attacks.

People who have had chickenpox cannot "catch" shingles from someone who has it. However, people who have never had chickenpox can be infected with chickenpox if exposed to someone with an active case of shingles. The rash sheds the virus and can be contagious. A caregiver or other person who lacks immunity developed from a prior case of chickenpox or the vaccine must avoid coming into contact with the rash or contaminated materials.

Also at risk for shingles are people with leukemia, lymphoma, or Hodgkin's disease, and those whose immune systems have been weakened because they are HIV-positive, or have undergone chemotherapy, radiation, transplant surgery with immunosuppression, or treatment with corticosteroids. Moreover, about five percent of people with shingles are found to have an underlying cancer, about twice the number of people in the population expected to have undiagnosed cancer.

Controlling the Outbreak

Although viral diseases cannot be cured, doctors can prescribe oral antiviral medications, such as Zovirax (acyclovir), Famvir (famciclovir) and Valtrex (valacyclovir) that help control the infection by hindering reproduction of the virus in the nerve cells. Antiviral therapy may shorten the course of an episode of shingles,



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however, therapy must be started as early as possible after symptoms develop, within 48 hours, in order to have an effect.

Treating the Pain

To relieve pain, the doctor may recommend over-the-counter analgesics (pain-relieving drugs), such as acetaminophen or one of the class of medications known as nonsteroidal anti-inflammatory drugs (NSAIDs). Over-the-counter NSAIDs include ibuprofen and naproxen. The doctor may also recommend a lidocaine cream or a prescription-strength dose of an NSAID.

If the pain is severe, doctors may prescribe opioid medications, such as hydrocodone or oxycodone. The scientific literature describes good outcomes from trials of prescription medicines not specifically approved for PHN, including tricyclic antidepressants (e.g. amitriptyline) and anticonvulsants (e.g. lamotrigine).

Medicines approved by the FDA for PHN include Lyrica (an anticonvulsant), Neurontin (an anti-convulsant), and LidodermQ (a lidocaine patch).

As a last resort, invasive procedures called nerve blocks may be used to provide temporary relief from the pain. These procedures usually entail the injection of a local anesthetic into the area of the affected nerves. There is some evidence that they work, but the real goal is to catch and treat the patient in the acute shingles phase. PHN appears mostly in older adults who are often unable to tolerate some of the medications prescribed. Nerve blocks may be useful in these cases.

This section was updated by the Center for Drug Evaluation and Research on June 8, 2006.

Prevention, Almost Perfect

Before the FDA approved the chickenpox vaccine in 1995, about 95 percent of the U.S. population developed chickenpox before age 18. Since then, more than 60 percent of American youngsters have been vaccinated against chickenpox.

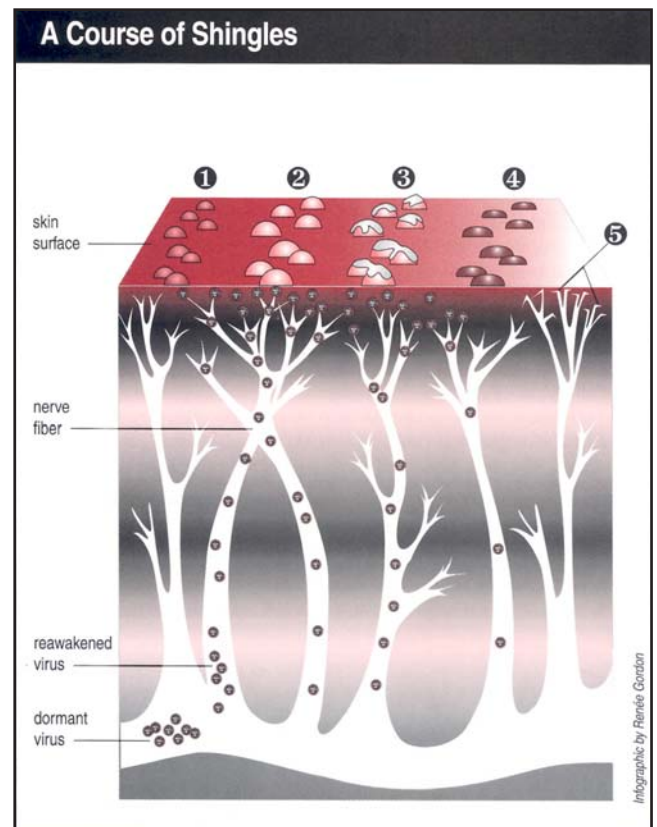
Now that we have a chickenpox vaccine, are shingles and PHN on their way out? FDA has not evaluated the effects of the vaccine on shingles. But, if we can prevent enough people from getting the natural type of chickenpox, there is a likely beneficial effect on the incidence of shingles and post-herpetic neuralgia. It may, however, take several generations for this to happen. For more information on shingles visit: <http://www.nlm.nih.gov/medlineplus/shingles.html>

On May 25, 2006, the Food and Drug Administration (FDA) licensed Zostavax, a new vaccine to reduce the risk of shingles (herpes zoster) for use in people 60 years of age and older. To learn more about this new shingles vaccine go to: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01378.html>

For more information on vaccines, see the article in this issue entitled *FDA Ensures Vaccines Are Safe and Effective*.

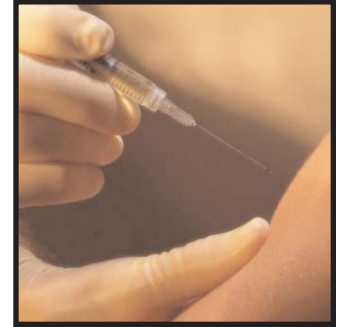
This section was updated by the Center for Drug Evaluation and Research on June 8, 2006.

Excerpted from FDA Consumer - updated June 2005



FDA Ensures Vaccines Are Safe and Effective

Vaccination saves millions of lives. In the U.S., vaccination programs wiped out smallpox and polio and reduced many diseases like measles, mumps, diphtheria, and whooping cough by 95 percent. Thanks to vaccination, the elderly and chronically ill are less likely to suffer from flu and pneumonia. But vaccines, which contain weakened or killed disease-causing bacteria, viruses, or their components, have to be thoroughly evaluated for safety and effectiveness. This is another important task that is part of the public health mission of the Food and Drug Administration (FDA).



Here is how FDA helps ensure vaccines are safe and effective:

- Approves the designs of studies for testing new vaccines.
- Ensures that the clinical trials that establish the vaccines' safety and effectiveness are well designed and carefully conducted.
- Reviews the data, the proposed labeling, and the manufacturing protocols, following the completion of the studies; may conduct their own tests of the product.
- Inspects to ensure that the manufacturing facility properly produces the vaccine before it is licensed and sold.
- Carries out spot-testing of newly produced vaccines and requires the company to test samples from each lot for safety, potency and purity.

FDA also cooperates with the Centers for Disease Control and Prevention (CDC) and other institutions in research to develop even safer vaccines. Together FDA and CDC operate the Vaccine Adverse Event Reporting System (VAERS). VAERS receives 800 to 1,000 reports a month of suspected problems associated with the use of vaccines. The FDA reviews and evaluates these reports and monitors overall reporting patterns, as well as trends for individual vaccine lots. The VAERS data make an important contribution to vaccine safety.

Source: <http://www.fda.gov/opacom/factsheets/justthefacts/19vaccine.html> Center for Biologics Evaluation and Research

FDA Cautions Consumers Against Filling U.S. Prescriptions Abroad

FDA is warning healthcare professionals and consumers that filling their prescriptions abroad may have adverse health consequences because of confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. An FDA investigation has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the United States. Taking a different active ingredient may not help, and may even harm, the user.

Press release:

<http://www.fda.gov/bbs/topics/news/2006/NEW01295.html>

Public health advisory:

<http://www.fda.gov/oc/opacom/reports/confusingnames.html>



Be An Active Member of Your Healthcare Team

When taking medicines, it is important to know that no medicine is completely safe. The U.S. Food and Drug Administration (FDA) judges a drug to be safe enough to approve when the benefits of the medicine outweigh the known risks for the labeled use. Doctors, physician assistants, nurses, pharmacists, and YOU make up your healthcare team. To reduce the risks from using medicines and to get the most benefit, you need to be an active member of the team.

To reduce the risk of taking medicine: remember **SAFER**:

- **S**peak up
- **A**sk questions
- **F**ind the facts
- **E**valuate your choices
- **R**ead the label and follow directions

SPEAK UP

The more information your healthcare team knows about you, the better the team can plan the care that is right for you.

The members of your team need to **know your medical history**, such as illnesses, medical conditions (like high blood pressure or diabetes), and the operations you have had.

They also need to know **all the medicines you use and treatments you receive**, whether you take it all the time or only some of the time. Before you add something new, talk it over with your team. Your team can help you with what works well and what does not.

It helps to give a **written list** of all your medicines and treatments to all your doctors, pharmacists and other team members. Keep a copy of the list for yourself and give a copy to a loved one.

Be sure to include:

- prescription medicines, including any samples your doctor may have given you
- over-the-counter (OTC) medicines (medicines you can buy without a prescription such as antacids, laxatives, or pain, fever, and cough/cold medicines)
- dietary supplements, including vitamins and herbs
- any other treatments
- any allergies, and any problems you may have had with a medicine
- anything that could have an effect on your use of medicine, such as trouble swallowing, trouble remembering, or cost

ASK QUESTIONS

Your healthcare team can help you make the best choices, but you have to ask the right questions. When you meet with a team member, have your questions written down and take notes on the answers. You also may want to bring along a friend or relative to help you understand and remember.



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Use the Question Guide at the end of this article to help you get the answers you need from your healthcare team. If you do not understand an answer, ask again.

**FIND THE FACTS**

Before you and your healthcare team decide on a prescription or OTC medicine, learn and understand as much as you can about your medicine including:

- brand and non-brand (generic) names
- its inactive ingredients
- when not to use (contraindications)
- possible interactions
- possible tolerance, dependence, or addiction
- directions for use
- expiration date
- its active ingredients
- when to use (indications)
- warnings (precautions) about its use
- side effects (adverse reactions)
- overdose (more than doctor prescribed)
- storage instructions

Your pharmacy, the library, the bookstore, the medicine manufacturer, and the Internet have information about medicines that is written for consumers. If you have questions, ask your healthcare team.

**EVALUATE YOUR CHOICES - Weigh the Benefits and Risks**

After you have all the information, think carefully about your choices. Think about the helpful effects as well as the possible unwanted side effects. Decide which are most important to you. This is how you weigh the benefits and risks. The expert advice from your healthcare team and the information you give the team can help guide you and your team in making the decision that is right for you.

READ THE LABEL AND FOLLOW DIRECTIONS

Read the label to know what active ingredient(s) is (are) in the medicine. The active ingredient in a prescription or OTC medicine might be in other medicines you use. *Using too much of any active ingredient may increase your chance of unwanted side effects.*



Read the label each time you buy an OTC medicine or fill your prescription. When buying an OTC, read the "Drug Facts" label carefully to make sure it is the right medicine for you. Prescription and OTC medicines do not always mix well with each other. Dietary supplements (like vitamins and herbals) and some foods and drinks can cause problems with your medicines too. Ask your pharmacist if you have questions.

Before you leave the pharmacy with your prescription, be sure you have the right medicine, know the right dose to use, and know how to use it. If you have bought the medicine before, make sure that this medicine has the same shape, color, size, taste, and packaging. If you notice anything different, talk with your pharmacist and tell your healthcare team.

Read and save all the information you get with your medicine.

Read the label each time before you use the medicine. Be sure it is right in five ways:

1. the right medicine
2. for the right patient
3. in the right amount
4. at the right time
5. in the right way (for example, swallow instead of chew a pill)

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Follow directions on the label and from your healthcare team. When you are ready to use the medicine, make the most of the benefits and lower the risks by following the directions.

If you want to stop a medicine your doctor told you to use or to use it in a different way than directed, talk to a team member. Some medicines take longer to show that they are working. With some medicines, such as antibiotics, it is important to finish the whole prescription, even if you feel better sooner. When you stop using some medicines, you must reduce the dose little by little to prevent unwanted side effects. Pay attention to how you feel. If you have an unwanted side effect, tell your healthcare team right away. A change in the dose or a change in medicine may be needed.

QUESTION GUIDE

Use the following guide with your healthcare team to find out what you need to know about the medicines you use, and about the medicines you are thinking about using. Be sure to find the answers to these questions for any sample medicine your doctor gives you.

- What are the brand and generic (non-brand) names of the medicine?
- Could I use a generic form?
- What is the active ingredient?
- What is the medicine for and what will it do for me?
- When should I start to feel better?
- When should I report back to the team?
- Will this medicine take the place of any other medicine I have been using?
- Should I avoid any drinks, foods, other substances, or activities while using this medicine?
- Can this medicine be used safely with the other medicines and treatments I already use? (prescription, OTC medicines, vitamins, herbals, or dietary supplements)
- What are the possible side effects from this medicine?
- What do I do if I experience a side effect?
- Is there any chance that I could become tolerant, dependent or addicted to this medicine? What can I do to avoid this?
- How and when should I use the medicine, in what amount, and for how long? (special directions)
- Will I need any tests (blood tests, x-rays, other tests) to make sure the medicine is working as it should? How will I get the results?
- What should I do if I miss a dose?
- What should I do if I use too much by mistake?
- How and where should I keep this medicine? (**Remember: Always put medicines out of reach of children and pets.**)
- Where and how can I get more information about this medicine?

Center for Drug Evaluation and Research and Council on Family Health, August 17, 2005

MEDICAL DEVICE RECALL INFORMATION

Infusion Pumps

There has been a Class 1 recall for two Baxter Healthcare Corp. infusion pumps due to defects that may lead to inadvertent shutdown and interruption of infusion. Consumers with questions may contact the company at 800-422-9837. For more information, visit: <http://www.fda.gov/cdrh/recalls/recall-121305.html>

FDA will update recall information when new information becomes available.

Trans Fats

The Truth May Be Hard to Swallow



Scientific evidence shows that eating saturated fat, *trans* fat (*trans* fatty acid), and dietary cholesterol raises low-density lipoprotein (LDL), or "bad" cholesterol levels and increases the risk of coronary heart disease (CHD). According to the National Heart, Lung, and Blood Institute of the National Institutes of Health, more than 12.5 million Americans have CHD, and more than 500,000 die each year. That makes CHD one of the leading causes of death in the U.S.

In 1993, FDA began requiring that saturated fat and dietary cholesterol be listed on the Food Ingredients label and the Nutrition Facts panel. With *trans* fat added to the Nutrition Facts panel, you will now know how much of all three-- saturated fat, *trans* fat, and cholesterol--are in the foods you eat. You will have the information you need to make healthy food choices.

There are differences in the Nutrition Facts panel and the Food Ingredients label: You will find in the Food Ingredients list either partially hydrogenated or hydrogenated oils. These same oils will appear on the Nutrition Facts panel as *trans* fat. You may see, for example, that the Nutrition Facts panel declares 0 *trans* fats, but when you read the Food Ingredients label you may find partially hydrogenated oils listed as 0.5g. Why is this? The current regulations state that the manufacturer must identify any product that contains 0.5g or less per serving.

What is *Trans* Fat?

Basically, *trans* fat is made when manufacturers add hydrogen to vegetable oil--a process called hydrogenation. Hydrogenation increases the shelf life and flavor stability of foods containing these fats.

Trans fat can be found in vegetable shortening, some margarines, crackers, cookies, snack foods, and other foods made with, or fried in, partially hydrogenated oils.

Are All Fats the Same?

No. Fat is a major source of energy for the body and aids in the absorption of vitamin A and carotenoids, and vitamins D, E, and K. Both animal and plant based foods contain fat. When eaten in moderation, fat is important for proper growth, development, and maintenance of good health.

Saturated fats, *trans* fats and dietary cholesterol raise LDL (or "bad") cholesterol levels in the blood and increase the risk of heart disease. Saturated fats are found in animals and some plant-derived products such as fatty meats, dairy products, and coconut and palm oils. Unsaturated fats do not raise LDL cholesterol and are beneficial when consumed in moderation. Unsaturated fats, such as monounsaturated and polyunsaturated are found in plant products and fish. Some examples are: olive, canola, and corn oils; soybeans.

Choose foods low in saturated fat, *trans* fat, and cholesterol as part of a healthful diet for you.

How Do Your Choices Stack Up?

The following table illustrates total fat, saturated fat and *trans* fat content per serving for selected food products.

Product	Common Serving Size	Total Fat g	Sat. Fat g	Trans Fat g
French Fries± (Fast Food)	Medium (147 g)	27	7	8
Potato Chips±	Small bag (42.5 g)	11	2	3
Doughnut±	1	18	4.5	5
Cookies± (Cream Filled)	3 (30 g)	6	1	2
Candy Bar±	1 (40 g)	10	4	3

± 1995 USDA Composition Data.

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Cutting the Fat: Nutrition Tips

Here are some practical tips you can use to keep your consumption of saturated fat, *trans* fat, and cholesterol low.

- Choose foods lower in saturated fat, *trans* fat, and cholesterol.
- Choose alternative fats. Replace saturated and *trans* fats in your diet with monounsaturated and polyunsaturated fats.
- Choose vegetable oils (except coconut and palm kernel oils) and soft margarines (liquid, tub, or spray).
- Consider fish. Most fish are lower in saturated fat than meat.
- When eating out, ask which fats are being used in your food.

Watch calories. Fat is high in calories. All sources of fat contain 9 calories per gram. By comparison, carbohydrates and protein have only 4 calories per gram.

How Can You Choose Your Fats Wisely?

When comparing foods, look at the Nutrition Facts panel, and choose the food with the lower amounts of saturated fat, *trans* fat, and cholesterol. Health experts recommend that you keep your intake of saturated fat, *trans* fat, and cholesterol as low as possible while maintaining a nutritional diet. However, these experts recognize that eliminating these three components entirely from your diet is not practical because they are unavoidable in ordinary diets.

Where Can You Find *Trans* Fat on the Food Label?

Beginning January 2006, food manufacturers were required to list *trans* fat on all their products. You will find *trans* fat listed on the Nutrition Facts panel directly under the line for saturated fat.

As a general rule, do not assume similar products are the same. Be sure to check the Nutrition Facts panel because even similar foods can vary in calories, ingredients, nutrients, and the size and number of servings in a package.

For more information on *trans* fats visit:
<http://www.cfsan.fda.gov/~dms/transfat.html>

Excerpted from FDA Consumer - updated June 17, 2004

MedWatch

FDA's Safety Information and
Adverse Event Reporting Program



What products does FDA regulate?

FDA is responsible for ensuring that foods are safe, nutritious, and correctly labeled. It also oversees medicines, medical devices (from bandages to pacemakers), electronic products that emit radiation (such as microwave ovens and cell phones) blood products, vaccines, cosmetics, and veterinary drugs. FDA ensures that these products are safe and effective. FDA also ensures that animal feeds must be safe, contain no harmful substances, and be truthfully labeled.

Why should I report?

Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action.

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Where do I get more information?

When you go to the site below, you will find:

- **What's New** about FDA products
- **Safety Information**
- **Join the E-List** to receive safety alerts by e-mail
- **Submit Report**
- **How to Report**
- **Download Forms** needed to submit your reports

<http://www.fda.gov/medwatch/index.html>



How do I report an emergency?

If the situation is an emergency that requires immediate action, such as a case of food-borne illness or a drug product that has been tampered with, call the Agency's main emergency number, staffed 24 hours a day, 301-443-1240.

You also can report all emergencies and non-emergencies to the FDA consumer complaint coordinator (<http://www.fda.gov/opacom/backgrounders/complain.html>) in your geographic area.

How do I voluntarily report non-emergencies?

Foods, medicines, medical devices, electronic products that emit radiation, blood products, biologics, online (<https://www.accessdata.fda.gov/scripts/medwatch/>), by telephone (1 800-FDA-1088), or by submitting the MedWatch 3500 form by mail or fax. Visit the MedWatch site (<http://www.fda.gov/medwatch/index.html>) for more details.

Blood transfusions and donations - FDA's Center for Biologics Evaluation and Research (<http://www.fda.gov/cber/transfusion.htm>).

Non-emergencies about vaccines - Report to Vaccine Adverse Event Reporting System; call 1-800-822-7967.

Veterinary products - FDA's Center for Veterinary Medicine at 1-888-FDA-VETS (1-888-332-8387). If the problem involves meat or poultry, which is regulated by the U.S. Department of Agriculture, call the USDA hotline at 1-800-535-4555.

Non-emergencies about cosmetics - FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) by phone at 301-436-2405 or by email at CAERS@cfsan.fda.gov.

Products sold online - Report it to FDA using the form on the MedWatch Website (<http://www.fda.gov/oc/buyonline/buyonlineform.htm>).

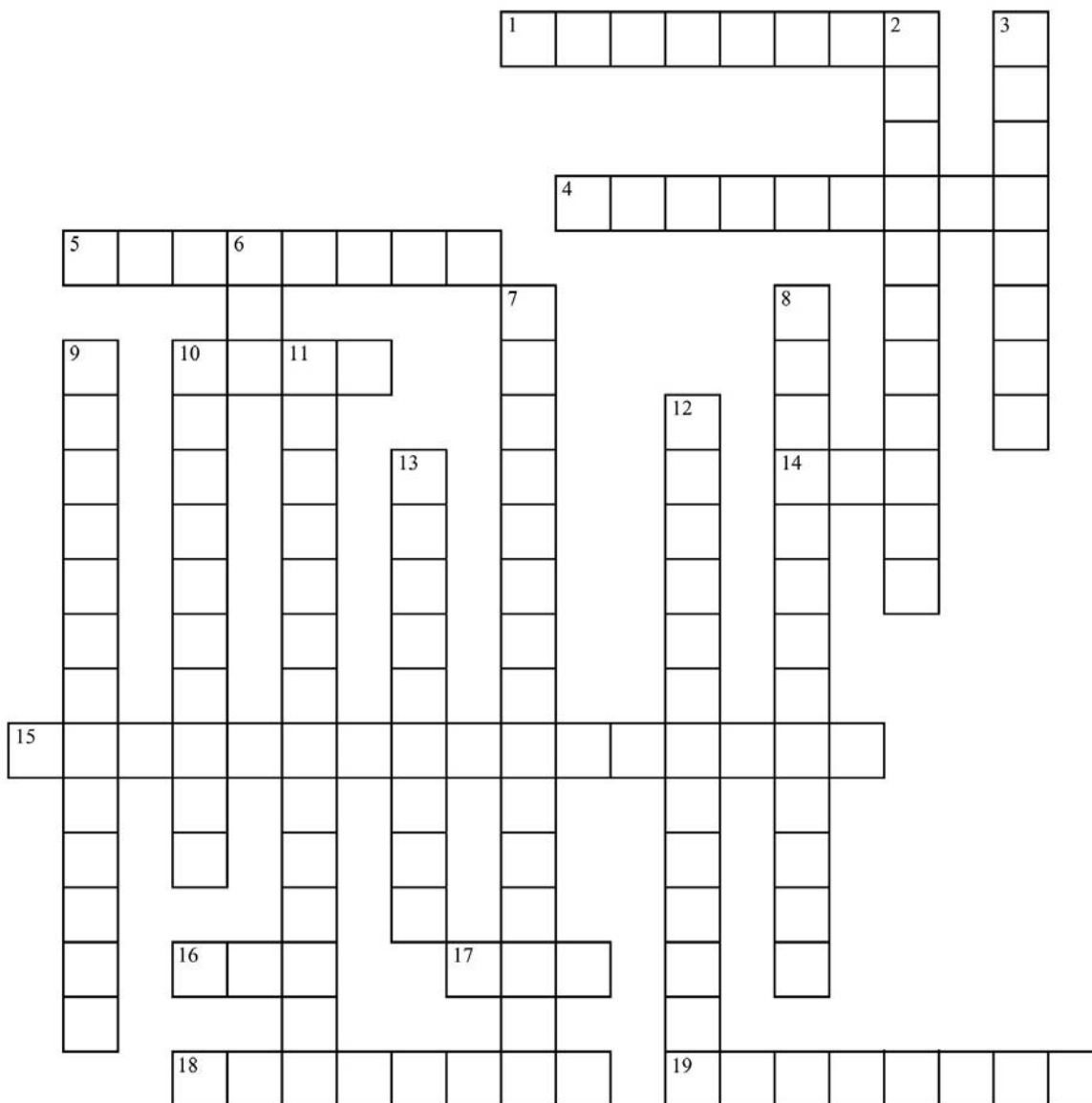
Don't Miss Future Issues

If you have found this newsletter by "surfing the net," add <http://www.fda.gov/cdrh/maturityhealthmatters/> to your favorites. At the site you can subscribe to the newsletter and receive email notification when new issues are published.

While you are online, check our website <http://www.fda.gov/cdrh/consumer/index.html> where you will find many topics of interest especially for consumers.

Products FDA regulates - If you have a general question about an FDA-regulated product, call toll-free 1-888-INFO-FDA (1-888-463-6332).

Maturity Health Matters - Crossword



ACROSS

- 1 Caused by the same virus that causes the childhood disease chickenpox (1 word)
- 4 President in 1906 who signed the Federal Food and Drugs Act (1 word)
- 5 Contains weakened or killed disease-causing bacteria, viruses or their components (1 word)
- 10 Fat aids in the absorption of vitamins of these four vitamins (4 letters)
- 14 Medicines you can buy without a prescription, such as antacids and cough/cold medicines (3 letters)
- 15 Therapy to treat shingles needed within 48 hours after symptoms develop (2 words)
- 16 The U.S. agency that regulates products accounting for 25 cents of every dollar spent by Americans (3 letters)
- 17 Major source of energy for the body (1 word)
- 18 Taking too much medicine (1 word)
- 19 Made when manufacturers add hydrogen to vegetable oil or hydrogenation (2 words)

DOWN

- 2 Unwanted effects caused by medicine (2 words)
- 3 Device that enables people without use of their legs to function at an eye-level height and climb stairs (2 words)
- 6 One of leading causes of death in the U.S. (3 letters)
- 7 Type of fat that does not raise LDL cholesterol; beneficial in moderation (2 words)
- 8 A relatively new medication worn on skin to alleviate pain of shingles (2 words)
- 9 Increases the shelf life and flavor stability of foods containing fat (1 word)
- 10 Over-the-counter pain-relieving drugs (1 word)
- 11 Date after which the medicine may not work or may be harmful to use (2 words)
- 12 Eating saturated fat, trans fat (trans fatty acid) and dietary cholesterol can raise the risk of this disease (2 words)
- 13 What to do each time you buy an OTC medicine or fill your prescription (2 words)

Maturity Health Matters

Maturity Health Matters is an FDA publication for older adults, their families and caregivers. We provide our readers with current information on FDA-regulated medical products. This publication can be reproduced. If you have comments about our publication, please send them to the editors.

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Crossword Answers

ACROSS

- 1 Shingles
- 4 Roosevelt
- 5 Vaccines
- 10 A, D, E, K
- 14 OTC
- 15 Antiviral therapy
- 16 FDA
- 17 Fat
- 18 Overdose
- 19 Trans Fat

DOWN

- 2 Side effects
- 3 IBOT 4000
- 6 CHD
- 7 Unsaturated fats
- 8 Lidoderm patch
- 9 Hydrogenation
- 10 Analgesics
- 11 Expiration date
- 12 Coronary heart
- 13 Read label

Crossword Answers for Inaugural Issue

The answers to the Crossword in our Inaugural issue have now been added. Open the link below to find the answers. Starting with the Spring issue 2006, the answers for the Crossword will be included in each new issue.

<http://www.fda.gov/cdrh/maturityhealthmatters/issue1.pdf>