

MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

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Older Adults Must Get Ready Now for the Flu Season

Influenza (flu) is a contagious disease of the respiratory tract caused by the influenza virus. Most people probably begin to think about the flu season in the fall. But, government agencies work year-round to prepare for each influenza season and ensure that enough vaccine is available to protect the American public, especially adults over 50 and small children.

This season's approved formulation for the U.S. vaccine is identical to that recommended by both the World Health Organization and FDA's Advisory Committee. It is best to be immunized in October or November, but getting the vaccine in the winter months when flu season often peaks is also recommended. One of FDA's Center for Biologics Evaluation and Research's (CBER) highest priorities is ensuring an adequate, safe, and effective supply of influenza vaccine each year.

Vaccination Recommendations

Vaccination is the best protection against influenza.

Each spring, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommends who should get influenza vaccines in the upcoming flu season. After considering the ACIP guidance, the CDC issues its recommendations during the summer. According to the CDC, among those people who should get vaccinated each year include those:

- who are at high risk for complications from the flu including:
 - people ages 50 and older
 - children ages 6 months to 59 months
 - people of any age with certain chronic medical conditions, and
 - people who live in nursing homes and other long term care facilities.
- who are in contact with these high-risk individuals

The current recommendation for healthy children expands last season's recommendation to vaccinate children from ages 6 months to 23 months. Children under 6 months of age are very likely to be hospitalized if they get influenza. Since no influenza vaccine is approved for children younger than 6 months of age, it is important to immunize all family members, daycare workers, and others who have close contact with them.

Influenza Facts

Although anyone can come down with the flu, infection rates are highest in children, according to the CDC. Children can spread the virus for a week or

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longer. Children usually shed more influenza virus, making them flu carriers and sources of infection for others. For this reason, older adults should be very careful about their contact with small children and babies.

Flu season in the United States can begin as early as October and can last as late as May, according to the CDC. The season generally peaks between late December and early March. The 2005-2006 flu season started off with low levels of activity in October and November 2005, with activity picking up considerably in December. The season peaked in early March 2006 and continued at low levels into May.

The CDC reports that each year in the United States, 5 to 20 percent of the population gets the flu. Most people recover in a week or two without complications. But more than 200,000 are hospitalized with flu complications, and about 36,000 Americans die each year from the flu.

What Are Flu Symptoms?

Symptoms may include some or all of the following:

- sudden onset of headache and chills
- respiratory symptoms like nasal congestion, cough and sore throat
- extreme fatigue and muscle aches in the back and legs
- fever between 100 and 103 degrees Fahrenheit in adults (sometimes higher in children).

Selecting the Strains

New flu vaccine is made each year. Because the virus changes, each year's vaccine may be different from the preceding year's. The vaccine is a blend of three different influenza virus strains, and the formulation depends on the virus strains that are predicted to spread during that upcoming flu season.

It takes at least six months to produce a flu vaccine. So early in the year, the FDA's Vaccines and Related Biological Products Advisory Committee meets to recommend which three strains of the virus should be included in the vaccine, based on data from the World Health Organization. The formulation selected for the 2006-2007 season will include one virus from last year's vaccine and two new viruses.

The FDA has licensed five manufacturers to make flu vaccine for the 2006-2007 season. The vaccine manufacturers estimate that between 100 million and 120 million doses will be produced, at least a 16 percent increase over last season's 86 million doses. The increased production will help accommodate expanding vaccination recommendations as well as reduce the risk of shortages.

For More Information

- *FDA Consumer* September/October 2006 http://www.fda.gov/fdac/features/2006/506_influenza.html
- <http://www.fda.gov/oc/opacom/hottopics/flu.html>
- <http://www.cdc.gov/flu/about/qa/>

Source: *FDA Consumer* July/August 2006

**Nationwide Counterfeit Alert - One Touch Basic/Profile
and One Touch Ultra Blood Glucose Test Strips**

The FDA is alerting the public about fake (counterfeit) blood glucose test strips being sold in the U.S. for use with various models of One Touch Brand Blood Glucose Monitors made by LifeScan, Inc. and used by people with diabetes to measure their blood glucose. The fake test strips could possibly give incorrect blood glucose values--either too high or too low--which might result in a patient's taking either too much or too little insulin and lead to a serious injury or death. To read more, visit <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01490.html>

Driving When You Are Taking Medicines

Driving is a complex skill. Your ability to drive safely can be affected by changes in your physical, emotional and mental condition. When you are taking medicines, talk to your healthcare professional about how each may affect your ability to drive safely.

Some of the many reasons people use medicines include:

- allergies
- anxiety
- colds
- depression
- diabetes
- fever
- heart and cholesterol conditions
- high blood pressure
- muscle spasms
- pain
- Parkinson's disease
- Schizophrenia



How can medicines affect my driving?

Medicines include those that your doctor prescribes and over-the-counter medicines. Many individuals also take herbal supplements. Some of these medicines and supplements may cause a variety of reactions that may make it more difficult for you to drive a car safely. These reactions may include:

- sleepiness
- blurred vision
- dizziness
- slowed movement
- fainting
- inability to focus or pay attention
- nausea

Often people use more than one medicine at a time. The combination of different medicines can cause problems for some people. This is especially true for older adults because they use more medicines than any other age group. Due to changes in the body as people age, older adults are also more likely to have medicine related problems. The more medicines you use, the greater your risk that your medicines will affect your ability to drive safely. To help avoid problems, it is important that at least once a year you talk to your healthcare professional about all the medicines - both prescription and over-the-counter - you are using. It is very important to let your healthcare professional know what herbal supplements, if any, you are using. Do this even if your medicines and supplements are not currently causing you a problem.

Can I still drive safely if I am taking medicines?

Yes, most people can drive safely when taking medicines. It depends on the effect those medicines - both prescription and over-the-counter - have on you and your driving. In some cases, you may not even be aware of the effects. However, in many instances, your healthcare professional can help lessen the negative impact of your medicines on your driving in several ways. Your healthcare professional may be able to:

- adjust the dose
- adjust the timing of doses or when you use the medicine
- add an exercise or nutrition program to lessen the need for medicine
- change the medicine to one that causes less drowsiness or some other unwanted side effects

What can I do if I am taking medicines?

Talk to your healthcare professional honestly.

When your healthcare professional prescribes a medicine for you, ask about its side effects. Ask, "How should I expect the medicine to affect my ability to drive?" Remind your healthcare professional of other medicines - both prescription and over-the-counter - and herbal supplements you are using, especially if you are seeing

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more than one healthcare professional. Tell your healthcare professional if you are not using all or any of the prescribed medicines. Do not stop using your medicine unless your healthcare professional tells you to.

Ask your healthcare professional if you should drive - especially when you first take a medicine.

Using a new medicine can cause you to react in a number of ways. It is recommended that you do not drive when you first start using a new medicine until you know how that drug affects you. Some over-the-counter medicines and herbal supplements can make it difficult for you to drive safely.

Talk to your pharmacist.

Get to know your pharmacist. Ask the pharmacist to go over your medicines with you and to remind you of the effects they may have on your ability to drive safely. Be sure to request printed information about the side effects of any new medicine.

Remind your pharmacist of other medicines and herbal supplements you are using. Pharmacists are available to answer your questions wherever you get your medicine. Many people buy medicines by mail. Mail-order pharmacies have a toll-free phone number and a pharmacist available to answer your questions.

Monitor yourself.

Learn to know how your body reacts to the medicine and supplements. Keep track of how you feel after you use the medicine. For example, do you feel sleepy? Is your vision blurry? Do you feel weak and slow? When do these things happen?

Let your healthcare professionals know what is happening.

No matter what your reaction is to using a medicine - good or bad - tell your healthcare professionals. Both prescription and over-the-counter medicines are powerful - that is why they work. Each person is unique. Two people may respond differently to the same medicine. If you are experiencing side effects, your healthcare professional needs to know this information in order to adjust your medicine. Another medicine may be prescribed that works better for you.

What if I have to cut back or give up driving?

You can keep your independence even if you have to cut back or give up on your driving due to your need to take a medicine. It may take planning on your part, but you will get to the places you want to go and the people you want to see. Consider:

- rides with family and friends
- taxi cabs
- shuttle buses or vans
- public buses, trains and subways
- walking

Also, senior centers, religious, and other local service groups often offer transportation services for older adults in the community.

Who can I call for help with transportation?

- Call the ElderCare Locator at 1-800-677-1116 and ask for the phone number of your local Office on Aging, or go to their website at <http://www.eldercare.gov>.
- Contact your regional transit authority to find out which bus or train to take.
- Easter Seals Project ACTION (Accessible Community Transportation In Our Nation) can direct you to transportation resources near you. Call 1-800-659-6428 or visit online at <http://www.projectaction.org>.

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Where do I find out more about medicines?

Your first step is to talk with your healthcare professional. You also can contact the:

- U.S. Food and Drug Administration at 1-888-INFO-FDA (1-888-463-6332) or visit online at <http://www.fda.gov/cder>.
- You also can get a copy of the "Age Page On Older Drivers" from the National Institute on Aging by calling 1-800-222-2225, or by going to their website at <http://www.niapublications.org>.



Source: *Driving When You Are Taking Medications* http://www.fda.gov/cder/consumerinfo/driving_taking_meds.htm

Buying Prescription Medicine Online: An Updated Consumer Safety Guide

Buying your medicine online can be easy. Just make sure you do it safely.

Buying products on the Internet can be quick to do. It can also be easy to compare products and their prices. And you never have to leave home to make a purchase. **But when it comes to buying medicine online, it is important to be very careful.** Some websites sell medicine that may not be safe to use and could put your health at risk.

Some websites that sell medicine:

- are not U.S. state-licensed pharmacies or are not pharmacies at all
- may give a diagnosis that is not correct and sell medicine that is not right for you or your condition
- will not protect your personal information

Some medicines sold online:

- are fake (counterfeit or "copycat" medicines)
- are too strong or too weak
- have dangerous ingredients
- have expired (are out-of-date)
- are not FDA-approved (have not been checked for safety and effectiveness)
- are not made using safe standards
- are not safe to use with other medicine or products you use
- are not labeled, stored, or shipped correctly



MEET AND TALK WITH YOUR DOCTOR

- **Talk with your doctor** and have a physical exam before you get any medicine for the first time.
- **Use ONLY medicine that has been prescribed** by your doctor or another trusted professional who is licensed in the U.S. to write prescriptions for medicine.
- **Ask your doctor** if there are any special steps you need to take to fill your prescription.

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These tips will help protect you when buying medicines online:

KNOW YOUR SOURCE TO MAKE SURE IT IS SAFE

Make sure a website is a state-licensed pharmacy and that it is located in the United States. Pharmacies and pharmacists in the United States are licensed by a state's board of pharmacy. Your state board of pharmacy can tell you if a website is a state-licensed pharmacy, is in good standing, and is located in the United States. Find a list of state boards of pharmacy on the National Association of Boards of Pharmacy (NABP) website at <http://www.nabp.info>.

The NABP is a professional association of the state boards of pharmacy. It has a program to help you find some of the pharmacies that are licensed to sell medicine online. Internet websites that display the NABP seal of this program have been checked to make sure they meet state and federal rules. For more on this program and a list of pharmacies that display the Verified Internet Pharmacy Practice Sites™ Seal, (VIPPS® Seal), go to: <http://www.vipps.info>.



Look for a website with practices that protect you. A safe website should:

- **be licensed by a state board of pharmacy** and be located in the United States (check <http://www.nabp.info> for a list of state boards of pharmacy).
- **have a licensed pharmacist** to answer your questions
- **require a prescription** from your doctor or other healthcare professional who is licensed in the United States to write prescriptions for medicine
- **have a way for you to talk to a person** if you have problems

BE SURE YOUR PRIVACY IS PROTECTED

- **Look for privacy and security policies** that are easy-to-find and easy-to-understand.
- **Do not give any personal information** (such as social security number, credit card, or medical or health history), unless you are sure the website will keep your information safe and private.
- **Make sure that the website will not sell your information.**

PROTECT YOURSELF AND OTHERS

Report websites you are not sure of, or if you have a particular complaint about a website that you think is illegally selling FDA regulated products:

Go to <http://www.fda.gov/buyonline> and click on "Notify FDA about problem website."

Buying your medicine online can be easy. Just make sure you do it safely.

For more information on buying medicines and medical products over the Internet, go to <http://www.fda.gov> and click on "Buying Medicines Online," or go directly to <http://www.fda.gov/buyonline>.

For related information, go to:

- Imported medicine <http://www.fda.gov/importeddrugs>
- Counterfeit medicine <http://www.fda.gov/counterfeit>
- Generic drugs <http://www.fda.gov/cder/ogd>
- Buying Prescription Medicines On Line is in Spanish at:
[http://www.fda.gov/cder/consumerinfo/buyOnlineGuide_text span.htm](http://www.fda.gov/cder/consumerinfo/buyOnlineGuide_text_span.htm)

Source: *Buying Prescription Medicine Online. An updated Consumer Safety Guide.*

http://www.fda.gov/cder/consumerinfo/buyOnlineGuide_text.htm

Americans Over 50 at Risk for Bone Fractures

The U.S. Surgeon General has recently warned that by 2020, half of all Americans older than 50 will be at risk for fractures from osteoporosis and low bone mass if no immediate action is taken by individuals at risk, doctors, health systems, and policymakers. The warning appeared in an October 2004 report, *Bone Health and Osteoporosis: A Report of the Surgeon General*.

The report says that 10 million Americans over the age of 50 have osteoporosis, the most common bone disease, while another 34 million are at risk for developing osteoporosis. And each year, roughly 1.5 million people suffer a bone fracture related to osteoporosis.

This report is the first-ever Surgeon General's report on the topic of bone health. Osteoporosis and other bone diseases can lead to a downward spiral in physical health and quality of life, including losing the ability to walk, stand up, or dress. Some bone diseases (neoplastic) can also lead to premature death.

Falls and Older Adults

Every year, more than 1.6 million older adults have fall-related injuries that require visits to the emergency room. In this age group, falls are the number one cause of fractures, hospital admissions for trauma, loss of independence and injuries related to deaths. NIH has added information about the risk of falling. Learn what you can do to prevent falls by visiting NIHSeniorHealth.

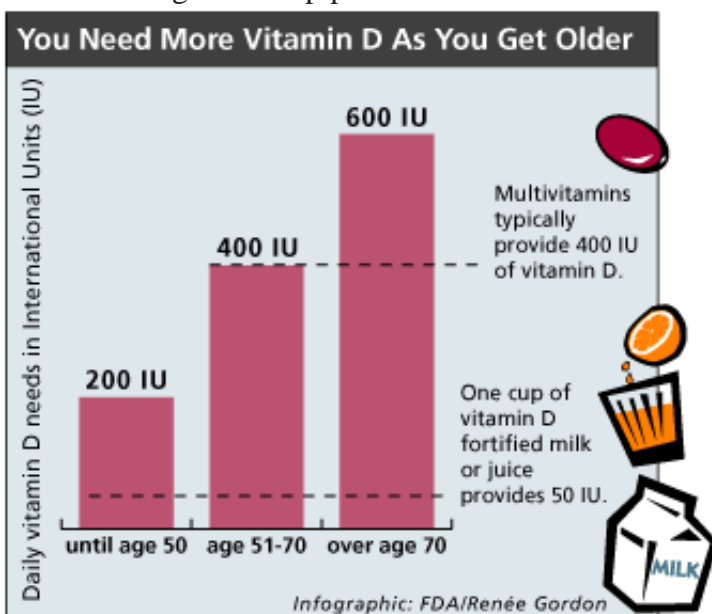
<http://nihseniorhealth.gov/falls/toc.html>

Some findings in the report include:

- One in five older Americans who suffer a hip fracture die within a year of the fracture.
- One in five people with a hip fracture end up in a nursing home within a year, either permanently or for rehabilitation.
- Hip fractures account for 300,000 hospitalizations annually.

The Surgeon General's report will shape the way we approach, talk, and act about bone diseases. The more we learn, the more we realize that so many diseases such as obesity, many types of cancer, and bone disease are preventable.

Osteoporosis is no longer just your grandmother's disease. We all need to take better care of our bones. The good news is that you are never too old or too young to improve your bone health. With healthy nutrition, physical activity every day, and regular medical checkups and screenings, Americans of all ages can have strong bones and live longer, healthier lives. Likewise, if it's diagnosed in time, osteoporosis can be treated with new drugs that help prevent bone loss and rebuild bone before life-threatening fractures occur.



According to the report, osteoporosis is a "silent" condition because many Americans are unaware that they have poor bone health. In fact, the number of people who have osteoporosis is much greater than the number who report having the disease. It is estimated that four times as many men and nearly three times as many women have unreported osteoporosis. One of the most dangerous myths about osteoporosis is that only women need to worry about bone health. Osteoporosis affects men and women of all races. Bone weakness is more common in older Americans, but building strong bones begins in childhood.

The Surgeon General's report is a call for Americans to take action to improve and maintain healthy bones. The report includes recommendations

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on what Americans can do to decrease the likelihood of developing osteoporosis, such as:

- Get the recommended amounts of calcium. High levels of calcium can be found in milk, leafy green vegetables, soybeans, yogurt, and cheese and even diet supplements, if needed.
- Get the recommended amounts of Vitamin D. It is produced in the skin by exposure to the sun - just 10 minutes a day is needed. You can also get Vitamin D from diet supplements.
- Maintain a healthy weight.
- Keep physically active by exercising at least 30 minutes a day for adults. Include weight-bearing activities to improve strength and balance.

Your Body Needs Calcium*	
If your age is,	then you need this much calcium each day (mg)
0 to 6 months	210
6 to 12 months	270
1 to 3 years	500
4 to 8 years	800
9 to 18 years	1,300
18 to 50 years	1,000
Over 50 years	1,200
(A cup of milk or fortified orange juice has about 300 mg of calcium.)	

Are You at Risk for Weak Bones?

If you have any of these "red flags," you could be at high risk for weak bones. Talk to your health-care professional.

- I am older than 65.
- I have broken a bone after age 50.
- My close relative has osteoporosis or has broken a bone.
- My health is "fair" or "poor."
- I smoke.
- I am underweight for my height.
- I started menopause before age 45.
- I have never gotten enough calcium.
- I have more than two drinks of alcohol several times a week.
- I have poor vision, even with glasses.
- I sometimes fall.
- I am not active.
- I have one of these medical conditions:
 - hyperthyroidism
 - chronic lung disease
 - cancer
 - inflammatory bowel disease
 - chronic liver or kidney disease
 - hyperparathyroidism
 - vitamin D deficiency
 - Cushing's disease
 - multiple sclerosis
 - rheumatoid arthritis
- I take one of these medicines:
 - oral glucocorticoids (steroids)
 - cancer treatments (radiation, chemotherapy)
 - thyroid medicine
 - antiepileptic medications
 - gonadal hormone suppression
 - immunosuppressive agents

- Take steps to minimize the risk of falls by removing items that might cause tripping and by improving lighting
- Have regular vision tests.

The report also calls on healthcare professionals to help Americans maintain healthy bones by evaluating risks for patients of all ages. The report recommends bone density tests for women over the age of 65 and for men and women over 50 who suffer even a minor fracture. Bone density tests use X-rays or sound waves to measure how strong the bones are. These tests are quick, safe, and painless.

Healthcare professionals should also look for "red flags" that may indicate that someone is at risk, including people who are under 50 who have had multiple fractures, people who take medications, or those who have a disease that can lead to bone loss.

The Surgeon General published a companion to the 2004 report called "People's Piece," specifically written for the American public. The magazine-style, full-color booklet offers ready-to-use information on how people can improve their bone health.

The entire **2004 Surgeon General's Report on Bone Health and Osteoporosis: What It Means To You** is available at <http://www.surgeongeneral.gov/library/bonehealth/>. *The People's Piece*, is an easy-to-read supplement to the Surgeon General's report and is designed to increase health literacy about disabilities. It is available by calling 866-718-BONE (2663) or by visiting <http://www.surgeongeneral.gov/library/disabilities/calltoaction/whatitmeanstoyou.pdf>.

Source: FDA Consumer January/February 2005

*The 2004 Surgeon General's Report on Bone Health and Osteoporosis: *What It Means to You*.

Artificial Sweeteners: No Calories... Sweet!



Artificial sweeteners can help older consumers cut down on calories and control weight, help to manage chronic conditions such as diabetes, and potentially prevent dental cavities, according to the American Dietetic Association (ADA).

To date, five artificial sweeteners are approved by the Food and Drug Administration:

- Aspartame
- Saccharin
- acesulfame-K
- neotame
- sucralose

The agency regulates artificial sweeteners as food additives, which must be approved as safe before they can be marketed.

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 laboratory 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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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.

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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The FDA and the Food and Agriculture Organization/World Health Organization (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. The brand name is 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

FDA Approves New Treatment for Colorectal Cancer That Has Spread

FDA has approved Vectibix to treat patients with colorectal cancer that has spread to other parts of the body following standard chemotherapy. The drug has shown effectiveness in slowing tumor growth and, in some cases, reducing tumor size. According to the FDA, colorectal cancer is the third most common cancer in the United States and the third leading cause of cancer deaths.

For more information go to:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01468.html>

FDA Warns Consumers About High-Strength Hydrogen Peroxide Use

FDA has issued a warning to consumers not to purchase or to use high-strength hydrogen peroxide products, including a product marketed as "35 Percent Food Grade Hydrogen Peroxide," for medical purposes. When swallowed, this product can cause serious harm or death. FDA recommends that consumers who are currently using high-strength hydrogen peroxide stop immediately and consult their healthcare professional.

To read more, visit:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01420.html>

FDA Responds to JAMA Article on AEDs

A recent article in the Journal of American Medical Association (JAMA) entitled *Recalls Safety and Alerts Affecting Automated External Defibrillators* (<http://jama.ama-assn.org/cgi/content/abstract/296/6/655>) helps inform the public about the safety of AEDs. FDA supports this kind of research and most of the conclusions reached in the JAMA article are consistent with FDA's own findings. However, there are a few points on which the agency differs. FDA replied to the JAMA article in a statement made August 10, 2006 entitled, *Journal of American Medical Association Article on Recalls and Safety Alerts Affecting Automated External Defibrillators Recalls*.

First, the authors state that manufacturers are unable to track AED units, making it impossible to know how many AED units were actually fixed or taken out of service. However, under FDA regulations, manufacturers are required to track AEDs and are doing so with processes in place to identify the location of a device in the event of a recall.

FDA's records show that these devices are being tracked with a high level of accuracy. In fact, more than 95 percent of the AEDs affected by Class I recalls in 2005 were returned to the manufacturers or taken out of service. Fewer than three percent were lost or stolen. For more information on FDA recalls, please visit: <http://www.fda.gov/cdrh/recalls/learn.html>.

Second, the authors state that there has been an increase in the number of AEDs affected by advisories during the study period. This is true, however, FDA believes that improvements in the devices' ability to self-diagnose hardware and software problems may contribute to this trend. This capability may result in users reporting problems before a device is ever used on a patient. Also, while more than 21 percent of AEDs were affected by an advisory, it does not necessarily mean that they malfunctioned. A device advisory is issued when a medical device has the potential to exhibit a certain failure mode, not only when a device has, in fact, failed.

FDA continues to depend on its ability to work with owners of AEDs when these devices are subject to a recall and has taken steps in recent months to improve its communication and collaboration with the broader community. AED users should continue to report device malfunctions to the manufacturer and to FDA. In addition, users should pay attention to device error messages and warnings during regular device self-checks and respond appropriately to recall notices and safety alerts.

Source: FDA Statement - August 10, 2006

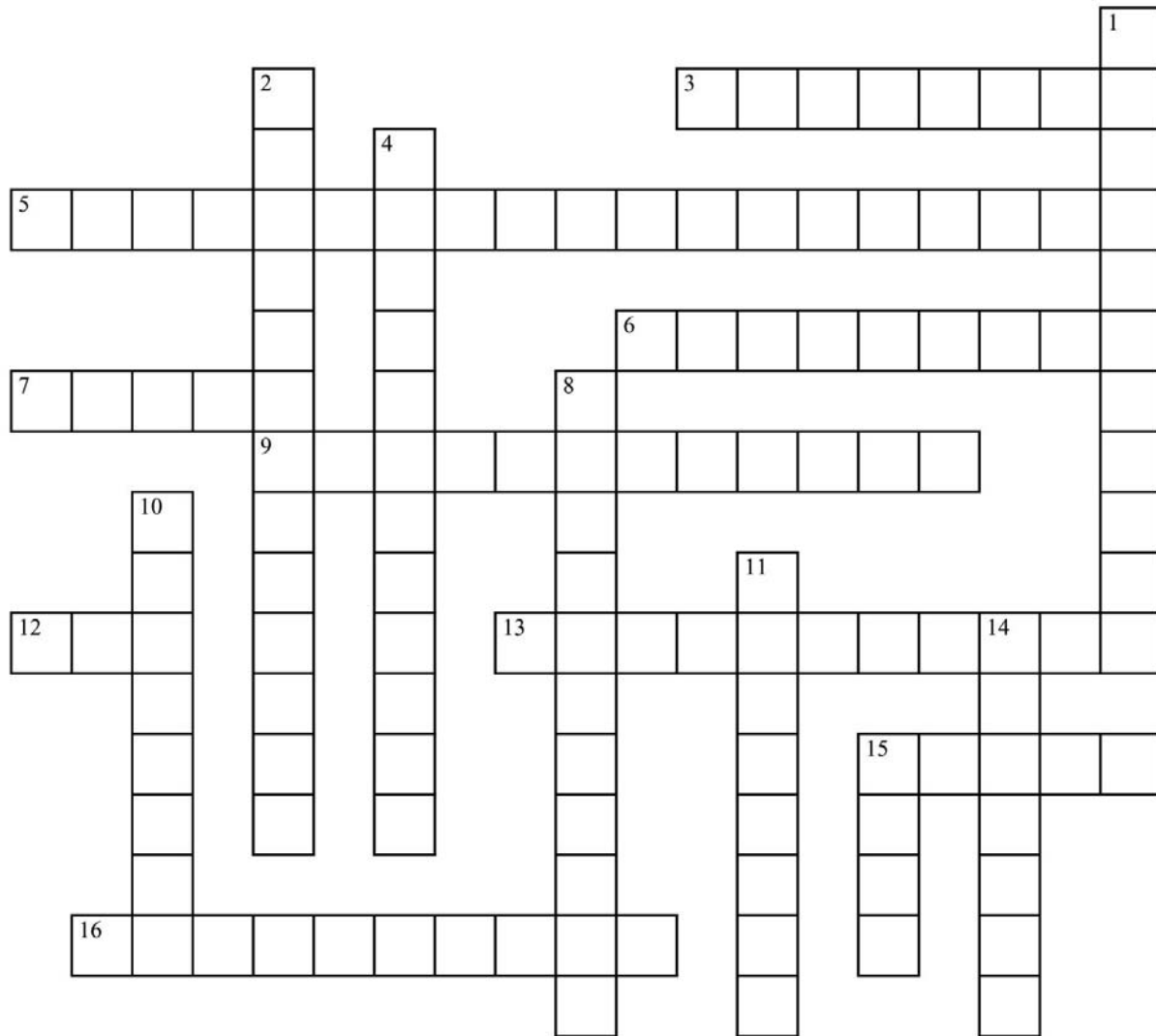
Automatic external defibrillators (AEDs) are important medical devices. Numerous studies have shown that thousands of lives are saved each year using these devices to treat patients in sudden cardiac arrest. In the past decade, these devices have become simpler to use and have been placed in more public places like airports and schools. For more information on AEDs, see article in the Inaugural Issue of *Maturity Health Matters*: <http://www.fda.gov/cdrh/maturityhealthmatters/issue1.html#5>

FDA Advises About Aspirin Plus Ibuprofen Use

FDA is advising consumers who take aspirin to help prevent a heart attack that taking ibuprofen at the same time for pain relief might interfere with aspirin benefits. The two drugs can be used but consumers should discuss with their doctors about the best timing to ensure that both medicines will be effective. To read more, visit:

<http://www.fda.gov/cder/drug/infopage/ibuprofen/default.htm>

Maturity Health Matters - Crossword



ACROSS

- 3 The NABP is a professional organization that makes sure your online pharmacy meets state and federal rules; if authorized the pharmacy will display this. (2 words)
- 5 This is absolutely needed by your doctor or another trusted professional to write prescriptions. (3 words)
- 6 A contagious disease of the respiratory tract caused by a virus.
- 7 Usual number of influenza virus strains selected each year and based on predictions for the particular flu season.
- 9 Accounts for 300,000 hospitalizations annually. (2 words)
- 12 This medical device has saved thousands of lives for people in sudden cardiac arrest.
- 13 When your healthcare professional prescribes a medicine for you, always ask about these. (2 words)
- 15 The number one cause of fractures, hospital admissions, loss of independence and injuries related to deaths.
- 16 The U.S. Surgeon General's report says that this number of Americans over the age of 50 have osteoporosis. (2 words)

DOWN

- 1 Population of people that has the most trouble with taking medicines. (2 words)
- 2 If you are over 50 years, you will need this many milligrams of calcium each day. (2 words)
- 4 Many Americans are unaware that they have this "silent" condition or poor bone health.
- 8 The best protection against influenza and can prevent many illnesses and deaths.
- 10 Be very careful when buying this online.
- 11 FDA has approved this drug to treat patients with colorectal cancer that has spread to other parts of the body following standard chemotherapy.
- 14 Americans can decrease the likelihood of developing osteoporosis by adding Vitamin D and _____ to their diet.
- 15 At this time, there are this number of artificial sweeteners approved by the Food and Drug Administration.

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

- 3 NABP Seal
- 5 United States License
- 6 Influenza
- 7 Three
- 9 Hip Fractures
- 12 AED
- 13 Side Effects
- 15 Falls
- 16 Ten Million

DOWN

- 1 Older Adults
- 2 Twelve Hundred
- 4 Osteoporosis
- 8 Vaccination
- 10 Medicine
- 11 Vectibix
- 14 Calcium
- 15 Five