

MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

Issue 8

Spring 2008

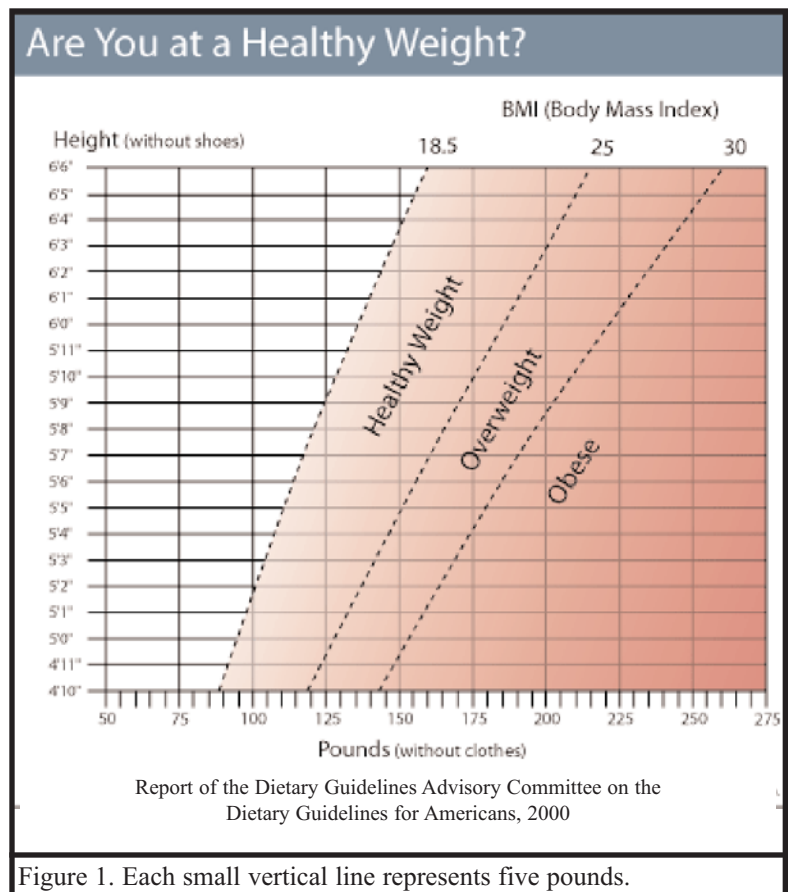
Healthy Weight - What It Means to You

According to the Centers for Disease Control and Prevention, based on a nationwide survey conducted from 2001 to 2004, approximately 71 percent of Americans over 50 years old are either overweight or obese, as compared with 64 percent from the 1988-1994 survey.

Overweight refers to a person who has an excess of body weight and obesity means having a very high amount of body fat in relation to lean body mass. Health professionals use a measurement called body mass index (BMI) to classify an adult's weight as healthy, overweight, or obese. BMI is based on height and weight.

The BMI ranges shown in the graph (Figure 1) to the right are for adults. Even within the healthy BMI range, weight gains can carry health risks for adults.

Directions: Find your weight on the bottom of the graph. Go straight up from that point until you reach the line that matches your height. Then look to find your weight group.



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- Monovision LASIK
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- **Healthy Weight:** BMI from 18.5 up to 25 refers to healthy weight.
- **Overweight:** BMI from 25 up to 30 refers to overweight.
- **Obese:** BMI 30 or higher refers to obesity.

Another way to compute your BMI is to use the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) BMI calculator at www.nhlbisupport.com/bmi/bmicalc.htm. While on this Web page, open up other Web pages, including the interactive menu planner and portion distortion (at the top of the page), as well as “Aim for a Healthy Weight.” This section includes:

- Assessing Your Risk
- Limitations of the BMI
- Control Your Weight
- Recipes (including African-American and Latino style)

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Weight - continued from page 1

Effects of Being Overweight or Obese

Obesity is often classified as a disease. NHLBI describes it as a complex chronic disease involving social, behavioral, cultural, physiological, metabolic, and genetic factors. Being overweight or obese increases the risk of many diseases and health conditions, including the following:

- Hypertension (high blood pressure)
- Osteoarthritis (a degeneration of cartilage and its underlying bone within a joint)
- High total cholesterol or high levels of triglycerides
- Type 2 diabetes
- Coronary heart disease
- Stroke
- Gallbladder disease
- Sleep apnea and respiratory problems
- Some cancers (endometrial, breast, and colon)



Successful 'Losers' How Do They Do It?

Although experts may have different theories on how and why people become overweight, they generally agree that the key to losing weight is a simple message: Eat less and increase your physical activity. According to the 2005 Dietary Guidelines for Americans, it is recommended that adults engage in approximately 60 minutes of moderate to vigorous intensity activity on most days of the week. These are the keys to manage body weight. Your body needs to burn more calories than you take in. Before starting any exercise program, talk with your healthcare professional.

Successful weight losers usually do the following:

- | | |
|--|--|
| <ul style="list-style-type: none"> • eat a low-calorie, low-fat diet • eat breakfast • monitor themselves by weighing in frequently | <ul style="list-style-type: none"> • eat smaller portions • drink water instead of sugary drinks • be physically active |
|--|--|

The typical pattern for the average overweight person who is trying to diet is to eat little or no breakfast and a light lunch. As the day progresses, they get hungry and eat most of their calories late in the day. Successful weight losers have managed to change this pattern.

Tips for Eating Out

- Before you order, ask for nutrition information or information on calories, saturated fat, and sodium, when available.
- Choose foods that are steamed, broiled, baked, roasted, poached, or stir-fried, but not deep-fat fried.
- Share food, such as a main dish or dessert, with your dining partner.
- Take part of the food home with you and refrigerate immediately. You may want to ask for a take-home container when the meal arrives. Spoon half the meal into it, so you are more likely to eat only what's left on your plate.
- Request your meal to be served without gravy, sauces, butter or margarine.
- Ask for salad dressing on the side, and use only small amounts of full-fat dressings.

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Weight- continued from page 2

Set a Goal

The first step to weight loss is setting a realistic goal. By using a BMI chart and talking with your healthcare professional, you can determine what a healthy weight is for you.

Studies show that you can improve your health with just a small amount of weight loss. Physical activity in combination with reduced calorie consumption can lead to a 5 to 10 percent weight loss. Even modest weight loss can improve blood pressure and help control diabetes and high cholesterol in overweight or obese adults.

Source: http://www.fda.gov/fdac/features/2002/102_fat.html FDA Consumer magazine, January-February 2002 Issue with revisions made in April 2002, March 2003, and April 2004.

Additional Information

- Department of Health and Human Services' Small Step Program
Tools and information for eating better and living a healthier lifestyle.
<http://www.smallstep.gov/>
- U.S. Department of Agriculture's MyPyramid.gov
Offers personalized eating plans, interactive tools to help you plan and assess your food choices, and advice to help you.
<http://www.mypyramid.gov>
- NIH National Institutes on Aging
NIHSeniorHealth offers tips on eating well as you get older.
<http://nihseniorhealth.gov/eatingwellasyougetolder/toc.html>



Treating Severe Obesity - Stomach Band Devices

FDA has approved (to date) two surgically implanted devices to help severely obese people to lose weight. An inflatable band is placed around the upper stomach to create a small gastric pouch that can hold only a small amount of food. This limits food consumption and creates an earlier feeling of fullness.

To read about these two devices please go to:

<http://www.fda.gov/cdrh/mda/docs/p000008.html> (2001)

<http://www.fda.gov/cdrh/mda/docs/P070009.html> (2007)

From NIH's National Library of Medicine:

See a Live Internet Broadcast of a Lap-Band Surgery for Obesity (1 hour) - Tampa General Hospital

<http://www.or-live.com/distributors/NLM/rnh.cfm?id=409> - Requires media player - 03/06/2007

Important Reminder for Users of Blood Glucose Meters

The FDA wants to remind users of blood glucose meters that you must use **only** the brand of test strips that is recommended for your meter. If the correct test strips are not used, you may receive inaccurate results or no results.

To read more about this important message, go to:

<http://www.fda.gov/cdrh/oivd/test-strips.html>



FDA Approves CustomVue Monovision LASIK

The FDA approved for marketing the first LASIK device designed for treating one eye to see far away objects and the other eye for close-up vision.

“The approval of the CustomVue Monovision LASIK expands permanent vision correction options for nearsighted adults who also have trouble focusing on objects close-up,” said Daniel Schultz, M.D., Director of FDA’s Center for Devices and Radiological Health. “Unlike traditional LASIK, monovision LASIK may reduce the need for reading glasses in some people over 40.”

LASIK, or laser in-situ keratomileusis, is a permanent procedure in which the surgeon cuts a flap in the outer layers of the cornea, removes a small amount of the tissue beneath it with the laser, and then replaces the flap. CustomVue Monovision LASIK is for monovision correction in nearsighted adults, with or without astigmatism, ages 40 years or older with normal age-related loss of ability to focus on near objects.

Monovision occurs when all nearsightedness in the patient’s dominant eye and only part of the nearsightedness in the non-dominant eye is corrected. This allows the patient to use the fully corrected eye for distance vision and the under-corrected eye for seeing close up. After a period of time, the brain adjusts to the difference in perception between the two eyes.

As people age, their ability to change focus from distance to near decreases, requiring stronger reading glasses to make up for the difference. Similarly, even after monovision LASIK correction, as people get older, their near vision may change over time, and they may eventually need reading glasses or contact lenses.

People considering monovision LASIK should first wear monovision contact lenses for at least a week to determine if they can tolerate having one eye under-corrected. Following monovision surgery, the two eyes may not work together as well as they did before in some patients, especially in dim light or when performing tasks requiring very sharp vision or fine depth perception. Patients may need to wear glasses or contact lenses for some activities such as night driving or reading small type.

Some possible side effects of LASIK, including monovision LASIK, are glare from bright lights, rings around lights (halos), light sensitivity, difficulty driving at night, ghost images, double vision and other changes in eyesight.

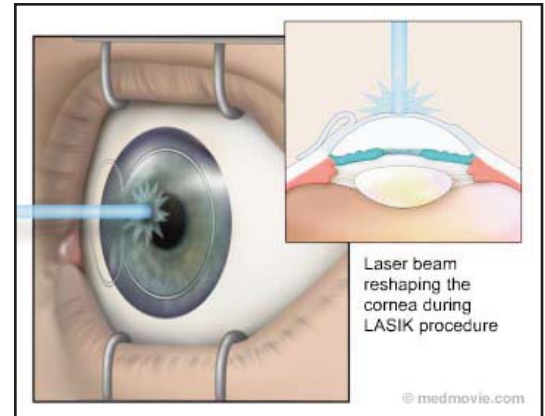
The VISX Star IR Laser with the WaveScan WaveFront System, which was approved by the FDA for performing CustomVue Monovision LASIK, is manufactured by AMO/VISX Inc., based in Santa Clara, Calif. FDA based its approval of this device for LASIK monovision correction on the review of a clinical study of safety and effectiveness outcomes submitted by the company.

A condition of the approval was that AMO/VISX conduct a post-approval study following 500 patients for six months after surgery to characterize quality of vision and quality of life issues associated with permanent LASIK monovision correction. The objective of the study is to estimate the proportion of monovision LASIK patients who experience eyesight disorders that are severe enough to limit activities or adversely affect a patient’s quality of life.

Source: FDA News, July 12, 2007 <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01665.html>

To learn more about LASIK eye surgery, visit <http://www.fda.gov/cdrh/lasik/>

To see a consumer article called "First LASIK Device for Monovision," visit <http://www.fda.gov/consumer/updates/lasik071207.html>



Consumers Continue to Buy Risky and Costly Drugs Online

Self-medication a concern; FDA-approved generics may be cheaper alternative



A year-long FDA investigation into drugs mailed to the United States from foreign countries suggests that consumers may be buying drugs online to avoid the need for a prescription from their physician. FDA urges consumers to beware of unregulated Internet drug sellers, because many of their products might not contain the correct ingredients and could contain toxic substances. The FDA sampling of imported drugs also indicates that consumers continue to spend money unnecessarily on potentially risky drug products bought over the Internet.

The investigation found 88 percent of the 2,069 drug packages examined appeared to be prescription medicines available in the United States. Of the remaining products, some were dietary supplements, some were foreign products with labeling that was difficult to read or could not be understood, and some were medications not available in the United States. More than half (53 percent) of the products sampled have FDA-approved generic versions, usually sold at lower costs. Earlier studies have shown that generics in the United States to be generally cheaper than a comparable drug in Canada or Western Europe. In fact, approved generic versions of approximately half (47 percent) of the sampled products can be bought for \$4 at several national chain pharmacies, a price often lower than the shipping costs for the same drugs purchased online.

Source: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html> FDA News

This release was updated on Nov. 1, 2007

For more information:

- FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet
<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html>
- Buying Medicines and Medical Products Online
<http://www.fda.gov/buyonline/>
- FDA Warns Seven Companies Importing/Marketing Over the Internet Drugs that Fraudulently Claim to Prevent/Treat STDs
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01803.html>

FDA's Initiative to Improve Availability of Generics

On October 4, 2007, FDA launched the Generic Initiative for Value and Efficiency, or GIVE. The initiative focuses on existing resources to help FDA modernize and streamline the generic drug approval process. GIVE aims to increase the number and variety of generic drug products available to consumers.

What Is The Truth About Generic Drugs?

People tend to have the wrong impression about generic drugs. It is generally believed that if something costs more, it must be of better quality. In the case of generic drugs, this is not true. The standards for quality are the same for brand-name and generic products. In fact, many traditionally brand name manufacturers also manufacture generic products.



Continued on page 6

GIVE - continued from page 5

Here are the facts:

- Generic drug applications undergo a rigorous review by FDA before they can be approved.
- Generic drugs are of the same quality as, and are equivalent in safety and effectiveness to, their brand-name counterparts.
- A generic drug must also be the same dosage, and must be taken and used for the same reasons as its brand-name product.
- A company that markets a generic drug must show that the product delivers the same amount of its active ingredient over the same amount of time as the brand-name product.
- Generic products are used to fill more than 50% of all prescriptions in the United States.

Why Do Generic Drugs Cost Less?

Generic drugs usually cost less than brand-name drugs. Manufacturers of generic drugs do not have to pay for:

- the large clinical trials necessary to initially prove a drug works
- the development of the active drug product
- extensive advertising often related to a new drug

What Is Bioequivalence?

Makers of generic drugs are required to scientifically demonstrate that their product delivers the same amount of drug in the same time frame to the site of action as the brand-name drug--or be bioequivalent. This assures the same safety and effectiveness as the brand-name drug. Makers of generic drugs are not required to repeat the extensive clinical trials that have already been used in the development of the original drug.

As mentioned above, all generic drugs are still put through a rigorous, multi-step review process that includes a review of scientific data on the generic drug's ingredients and performance. FDA also conducts periodic inspections of the manufacturing plant, and monitors drug quality – even after the generic drug has been approved.

Why Must Generic Drugs' Appearances Be Different from Brand-names?

In the United States, trademark laws prevent generic drugs from looking exactly like its brand-name counterpart. Thus, colors, flavors, and certain other characteristics may be different. But, these differences do not affect the way the drugs work or the way they are evaluated by FDA. The generic drug must have the same active ingredients but may simply look different. Consumers and their healthcare professionals can decide whether it is best for an individual to use the brand-name or generic version of a medicine.

Source: <http://www.fda.gov/consumer/updates/generics100407.html>

For more information about generic drugs, visit these FDA Web sites:

- Facts About Generic Drugs
http://www.fda.gov/cder/consumerinfo/generic_FactsAbout_text.htm
- Savings from Generic Drugs Purchased at Retail Pharmacies
<http://www.fda.gov/cder/consumerinfo/savingsfromgenericdrugs.htm>
- CDER Office of Generic Drugs
<http://www.fda.gov/cder/ogd/>



Advice for Patients: Denture Cleansers

Because of 73 severe reactions linked to denture cleansers and at least one death, FDA is asking the manufacturers of denture cleansers to

- consider appropriate alternatives to an ingredient in their products
- revise the instructions for use

One problem may be the ingredient persulfate, which is known to cause allergic reactions. Another problem may be due to product misuse.

Labeling revisions will help to ensure that denture wearers clearly understand that these products are to **clean dentures in a container -- not while still in the mouth.** For example, some cleansers that contain mouthwash

- are described as minty fresh
- may have graphics such as fizzing bubbles

Consumers may think that the product may be chewed, gargled or swallowed.

Who Is at Risk?

- people who are allergic to persulfates
- people who are unable to read or understand the product label and proper product use

What Are the Symptoms of Reaction?

Symptoms of an allergic reaction may include:

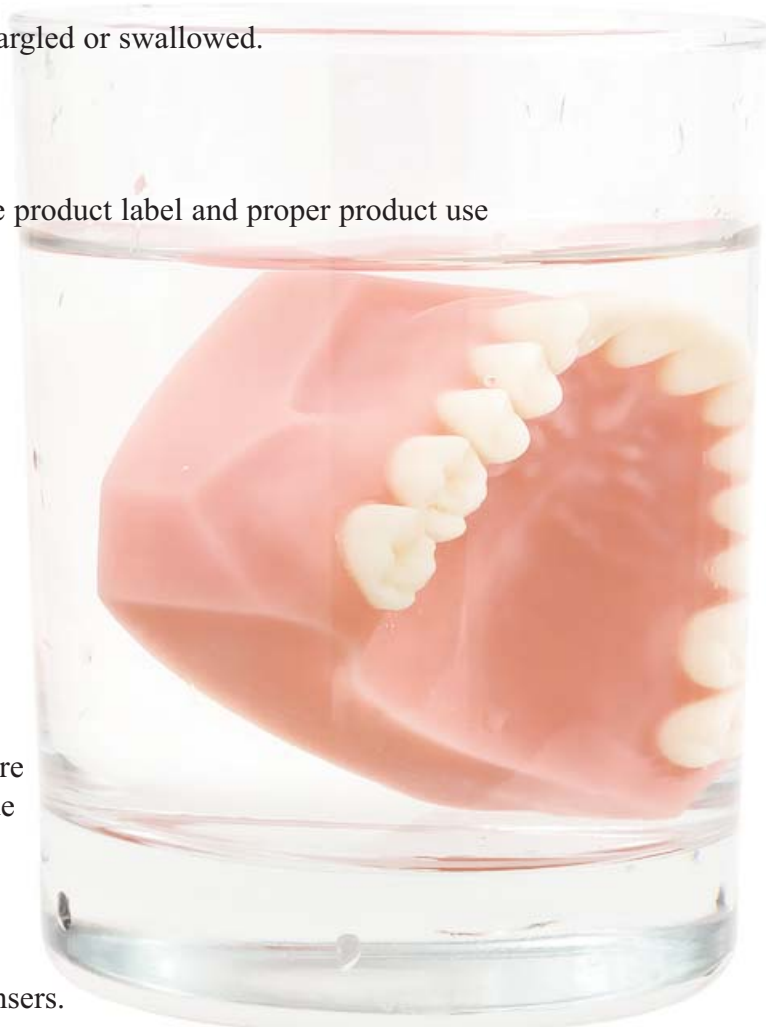
- Irritation
- Tissue damage
- Breathing problems
- Low blood pressure
- Rash
- Hives
- Gum tenderness

Symptoms from product misuse may include:

- Damage to the esophagus
- Abdominal pain
- Breathing problems
- Vomiting
- Internal bleeding
- Burns
- Seizures
- Blood in urine
- Low blood pressure
- Bleaching of tissue

What Should Denture Wearers Do?

- Read all instructions carefully.
- Never chew, swallow, or gargle with denture cleansers.
- Always thoroughly rinse dentures and other dental appliances before placing them in your mouth.
- Remember that reactions might not occur right away.
- If symptoms do occur, remove dentures and contact your dentist.
- Ask your dentist about using an alternative method for cleaning dentures.



What Is Your X-Ray Savvy?



X-rays are a form of electromagnetic radiation made up of waves or particles that travel through the air like light, radio signals and microwaves. These x-rays are strong enough that some of them pass through objects (clothing, body tissues, and internal organs) and some are absorbed. The x-rays either expose areas on an x-ray film or are captured by a detector linked to a computer and monitor. In general, objects that are more dense, such as bones, calcium deposits, and contrast media dye, absorb more of the x-rays and do not allow as much to pass through them. These more dense objects look white while less dense objects, like air in the lungs or the liver, look gray or black. Radiologists or other experienced physicians can read these images to diagnose medical conditions or injuries.

Procedures

Medical x-rays are used in many types of examinations and procedures. Some examples include:

- x-ray radiography (to find broken bones, tumors, pneumonia, foreign objects, etc.)
- mammography (to image the internal structures of breasts)
<http://www.fda.gov/cdrh/radhealth/products/mammography.html>
- CT (computed tomography) (to produce images of the body in “slices”)
<http://www.fda.gov/cdrh/ct/what.html>
- fluoroscopy (for example, to see where to remove plaque from coronary arteries, where to place stents to keep those arteries open, or to look at the stomach or colon)
<http://www.fda.gov/cdrh/radhealth/products/fluoroscopy.html>
- radiation therapy in cancer treatment

Risks/Benefits

Medical x-rays have increased the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. When applied and performed appropriately, these procedures can improve health and may even save a person’s life.

X-ray energy also has a small potential to harm living tissue. The most significant risks are:

- a small increase in the possibility that a person exposed to x-rays will develop cancer later in life
- skin burns, but only at very high levels of radiation exposure and in only very few procedures which are generally life-saving or life-prolonging

Does a Doctor Always Have to Refer a Patient to a Mammography Facility?

No. A patient can have a mammography exam and receive the follow-up report without a doctor's referral (this is called a "self referral"). Before selecting a facility, however, please verify that the facility accepts self-referred patients because some facilities do not.

For more on mammography, see
<http://www.fda.gov/CDRH/MAMMOGRAPHY/>

Source: FDA News Digest 7/30/07

X-ray Savvy - continued from page 8

The risk of developing cancer from radiation exposure is generally small, and it depends on at least three factors—the amount of radiation dose, the age at exposure, and the sex of the person exposed.

- The lifetime risk of cancer increases the larger the dose and the more x-ray exams a patient undergoes.
- The lifetime risk of cancer is greater for a patient who received x-rays at a younger age than for one who receives them at an older age.
- Women are at a somewhat higher lifetime risk than men for developing radiation-associated cancer after receiving the same exposures at the same ages.

Information for Patients

In most circumstances, the benefits of an x-ray or x-ray procedure recommended by your physician far outweigh the risks. You can reduce your radiation risks and contribute to your successful examination or procedure by:

- Keeping a “medical x-ray history” with the names of your radiological exams or procedures, the dates and places where you had them, and the physicians who referred you for those exams
- Making your current physicians aware of your medical x-ray history
- Asking your physician if there are alternatives to x-ray exams that would be appropriate for your medical situation
- Providing your physicians with recent x-ray images and radiology reports
- Informing radiologists or x-ray technologists in advance if you are pregnant or think you may be pregnant

Source: <http://www.fda.gov/cdrh/radhealth/products/medicalxray.html>

Updated February 5, 2008



HHS Unveils Plan to Strengthen, Update Food Safety Efforts

This HHS food safety plan uses science and a risk-based approach to meet the demands of a global economy and to protect American consumers.

The plan is based on the theory of preventing harm before it can occur, intervening at key points in the food production system, and strengthening response when problems are identified. Within these three overarching areas of protection, the plan contains a number of action steps as well as a set of legislative proposals. Taken together, these efforts will provide a food protection framework that ensures that the U.S. food supply remains safe.

Press release: <http://www.hhs.gov/news/press/2007pres/11/pr20071106a.html>

Released on Tuesday, November 6, 2007

Last revised: January 08, 2008

To learn more about FDA's Food Protection Plan, go to:

www.fda.gov/oc/initiatives/advance/food/factsheet.html

NOTE: There are audio and video attachments to the Fact Sheet above.

Recent News from the FDA

FDA Approves Drug-Eluting Stent for Clogged Heart Arteries

The FDA approved the Endeavor Zotarolimus-Eluting Coronary Stent for use in treating patients with narrowed coronary arteries, the blood vessels supplying the heart. The Endeavor is the first drug-eluting stent approved since 2004.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01787.html>

FDA Issues Public Health Advisory on Chantix, a Smoking Cessation Medication

The FDA issued a Public Health Advisory to alert health care providers, patients, and caregivers to new safety warnings concerning Chantix (varenicline), a prescription medication used to help patients stop smoking. Chantix may cause worsening of existing psychiatric illness even if it is currently under control. It may also cause an old psychiatric illness to recur.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01788.html>

FDA Approves Generic Fosamax

The FDA approved the first generic versions of Fosamax (alendronate sodium tablets), used to treat osteoporosis, a condition that causes thinning and weakening of a person's bones.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01793.html>

FDA Clears for Market First Decellularized Heart Valve

The FDA cleared for marketing the first replacement heart valve from donated human tissue in which the cells have been removed.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01794.html>

FDA Approves the First Compact Heart Assist Device

The FDA has approved the Thoratec HeartMate II Left Ventricular Assist System, a first-of-its-kind heart-assist device that is only three inches in length and weighs about one pound.. It uses a continuous flow pump that constantly moves blood with a single moving part, a spinning rotor. Previous heart-assist device models were too large to be placed in the upper abdomen of some women and small-sized men.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01820.html>

FDA Clears Coronary Artery Plaque Imaging Device

The FDA cleared for marketing a device that a doctor can use to see inside a blood vessel to assess the fat content of the plaque which builds up on the wall of the coronary arteries.

Source: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01827.html>

Manufacturer Recalls Icy Hot Therapy Products

Chattem, Inc. announced a voluntary nationwide recall of its Icy Hot Heat Therapy products, including consumer "samples" that were included on a limited promotional basis in cartons of its 3 oz. Aspercreme® product. Chattem is recalling these products because it has received reports of first, second, and third-degree burns, as well as skin irritation.

Source: http://www.fda.gov/consumer/updates/icyhot_recall021908.html

FDA's New Home Page

In March, the FDA unveiled its new “front door.” The redesigned Web site home page has a new look and new ways of getting you quickly to the information you want and need. Changes were made after extensive testing with real site users. Among those tested were adults aged 50 and above, who participated in two types of tests to evaluate the home page:

- Card-sorting exercises – a key method to help label and arrange material on the page
- Usability testing – a scientific method to measure the performance of a page design.

One home page change that performed well in testing and was incorporated into the new design is a list of special menus that show up when your cursor touches the name of one of the product categories (for example, “Drugs” or “Medical Devices”) featured on the top left of the page. These menus provide quick access to information elsewhere on the Web site. Other changes include new categories such as “Most Popular” and “In the Spotlight.”

This new home page is just the beginning. During the coming months, FDA Web site staff and outside experts will continue working on improving many more of FDA’s Web pages. This includes a tool to allow users to change text size to make the Web site easier for older adults to read. The new and improved Web site will be a more effective tool for FDA to communicate an array of health information our visitors are seeking.

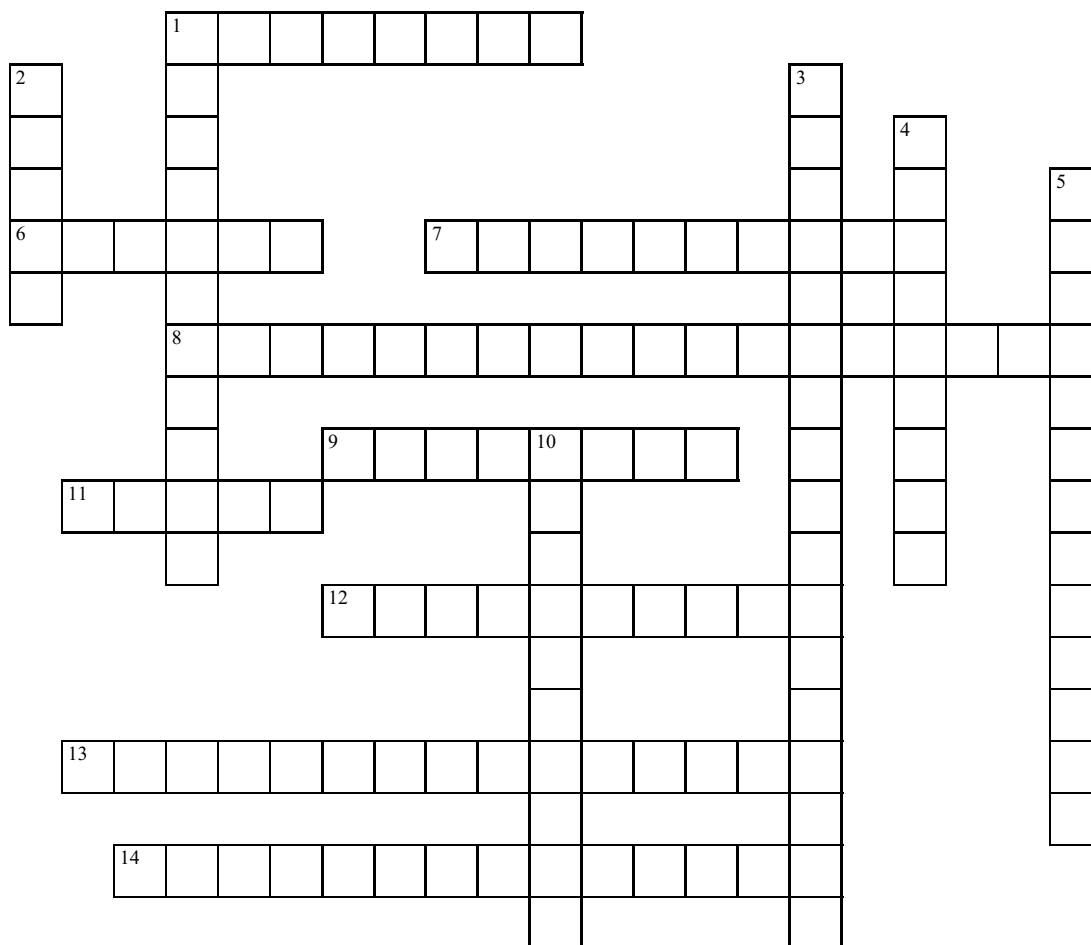
The FDA Web site address will still be www.fda.gov. We hope you will visit the FDA Web site often.

Most Popular - Easy reference to organized content by user access.

FDA For You - Delivers matching content for the intended audience.

To read more about FDA’s homepage redesign, please go to: <http://www.fda.gov/redesign/default.html>

Maturity Health Matters - Crossword*



ACROSS

- 1 This category of drugs undergo a rigorous review before approval.
- 6 Any number over this represents obesity on the BMI chart.
- 7 FDA has recently approved LASIK for this type of vision.
- 8 This type of x-ray produces body images in "slices." (two words)
- 9 Newly designed Web site just unveiled by FDA.
- 11 The parts of the body that show-up as white in an x-ray.
- 12 People who have blood glucose meters must use the correct brand of this accessory. (two words)
- 13 A woman can get a mammogram without this. (two words)
- 14 HHS unveiled this plan to meet the demands of a global economy and to protect American consumers. (three words)

DOWN

- 1 A type of implanted device that has been approved for obese people to lose weight. (two words)
- 2 The percentage of generic products used to fill prescriptions in the United States.
- 3 A buying practice that is risky and is costing consumers unnecessary spending. (three words).
- 4 Denture should only be cleaned in this.
- 5 BMI stands for this measurement of people's weight. (three words)
- 10 The denture cleaner ingredient that may cause an allergic reaction.

***All answers are taken from this issue.**

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 freely reproduced and distributed. Comments about our publication should be sent to the editors. The information published in this issue was current as of the date of publication.

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May is Older Americans Month

To read the President's proclamation, visit:
<http://www.whitehouse.gov/news/releases/2008/04/20080423-2.html>

CROSSWORD ANSWERS

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