FDA & YOU
News for Health Educators and Students
Issue Number 2 **Winter 2004**

Don't Let the Flu Catch You

If you haven't gotten a flu shot yet, it's not too late. The flu vaccine is still the best way to prevent and control flu and the sniffles, aches and fever that come with it.

Flu season in the United States runs from November to April. October to November is the time when most people get vaccinated for the flu. "But you can also get good results when the vaccine is used in December and January, even if influenza (flu) is already starting to spread through a community," says Roland A. Levandowski, M.D., a medical officer and virologist in the Food and Drug Administration's Center for Biologics Evaluation and Research.

The Flu Vaccine

Flu viruses are classified as types A, B, or C. Type A and B viruses are the most serious because they are most often responsible for cases of the flu and all of its complications. Type C viruses are mostly associated with cold symptoms.

There are two types of flu vaccines. The injectable flu shot contains killed viruses and is given in the arm with a needle. The nasal spray flu vaccine contains weakened live viruses, and is given by nasal sprayer. The injectable flu shot is made by two manufacturers. One product is approved for use in children over 6 months of age, as well for healthy people and those with chronic medical conditions. The other is approved for use in individuals at least four years and older. The nasal spray flu vaccine is approved for use only in healthy people between the ages of 5 and 49.

The protective effect of the vaccine starts working rapidly in people who have previously been infected with flu viruses or have gotten a flu shot in the past. Infection-fighting antibodies in the blood are strongest about three weeks after these people are vaccinated.

Injected flu vaccine is made of killed virus and can't cause the flu. The most common side effect is soreness in the area where the shot is given. Flu vaccines are not recommended for certain people, including those allergic to eggs, because the viruses for flu vaccines are grown in eggs.

Preventing the Flu

Both colds and flu can be passed through coughing, sneezing, and touching surfaces such as doorknobs and telephones, so it's wise to make a habit of **washing your hands**. This helps prevent you from spreading infections and picking them up from someone else.

Continued on page 2

An Alphabet of Viruses

There are three types of flu virus: A, B and C.

Types A and B are the most serious because they change more quickly than a person's immune system. The flu vaccine targets strains of type A and B viruses because they cause the most damage and infect the most number of people.

Type C is often mistaken for a cold because the illness it causes can be mild or even without symptom.

Preventing Flu - Continued from page 1

The Centers for Disease Control and Prevention (CDC) recommends regular scrubbing of your hands with warm, soapy water for about 15 seconds. Touching your nose, mouth, and eyes with contaminated hands makes it easy for cold and flu viruses to enter the body. Others can become ill just by coming in contact with someone who has been infected with a cold or flu virus or who has come in contact with a contaminated area.

Eating a balanced diet, getting enough sleep, and exercising can help the immune system fight off the germs that cause illness. Because smoking interferes with the mechanisms that keep bacteria and debris out of the lungs, those who use tobacco or who are exposed to secondhand smoke are more prone to respiratory illnesses and more severe complications than nonsmokers.

What if You Get the Flu

Your doctor has many methods of diagnosing the flu including using an FDA approved rapid influenza diagnostic test that can detect flu types A and B in about 30 minutes.

Children and teens suffering from flu-like symptoms, chickenpox and other viral illnesses shouldn't take aspirin or products containing aspirin because the pain reliever could mask symptoms of Reye's syndrome. When buying over-the-counter medications for use by children and teens look for aspirin-free products. Some medicine labels may refer to aspirin as salicylate or salicylic acid.

A person with Reye's syndrome will start vomiting and become drowsy within a few days of becoming sick. Reye's syndrome almost always occurs in children 4 to 12 years of age. Though rare in adults, it can affect all body organs and lead to brain damage and death.

Symptoms for colds and flu can be similar; both can cause a stuffy nose, sore throat, cough, and fever and generally last about a week or two.

Colds are usually marked by a runny nose and sneezing. The flu is more serious than a cold, lasts longer, and often leaves you with a wiped-out feeling, a headache, chills, dry cough, and body aches.

Focus on: Reye's Syndrome (RS)

What is Reye's Syndrome: RS is a disease that affects all organs of the body, especially the brain and liver. It causes an increase of pressure within the brain and can cause accumulations of fat in the liver and other organs. The disorder commonly occurs during recovery from a viral infection, such as flu or the chicken pox.

Symptoms: Persistent or recurrent vomiting, listlessness, personality changes such as irritability or combativeness, disorientation or confusion, delirium, convulsions, and loss of consciousness.

Who Gets it: Reye's syndrome (RS) is primarily a children's disease, although it can occur at any age.

Prevention: The cause of RS remains a mystery. However, studies have shown that using aspirin or salicylate-containing medications to treat viral illnesses increases the risk of developing RS.

Treatment: There is no cure for RS. Successful management, which depends on early diagnosis, is primarily aimed at protecting the brain against irreversible damage by reducing brain swelling, reversing the metabolic injury, preventing complications in the lungs, and anticipating cardiac arrest.

What to do if you think you have RS: If symptoms of RS are present during or soon after a viral illness, such as flu, call your doctor immediately.

For more information visit:

http://www.ninds.nih.gov/health_and_medical/disorders/reyes_syndrome.htm

http://www.reyessyndrome.org

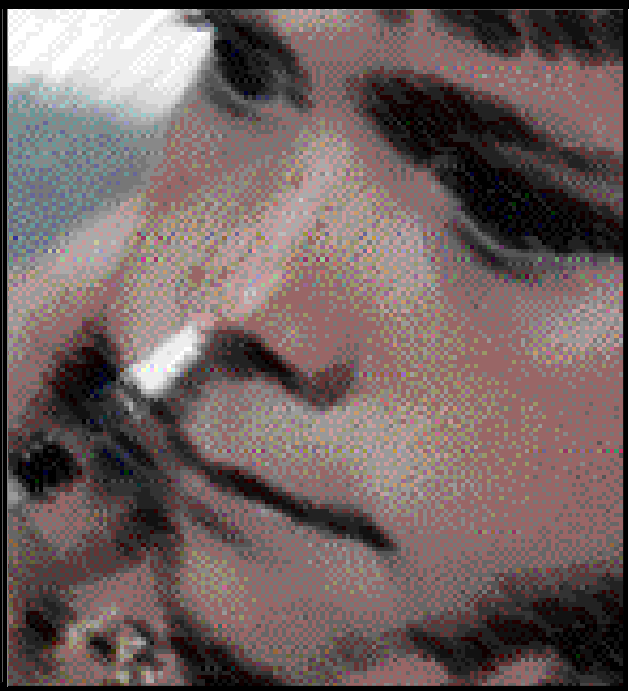
Flu Vaccines: More Options Mean Better Protection

The FDA recently approved FluMist, the first nasal flu vaccine to treat A and B flu viruses in people 5-49 years old.

Like the injected flu vaccine, each FluMist dose contains the three flu strains recommended for the 2003-2004 season. The strains of live virus are modified so they don't grow efficiently at body temperature, but replicate enough to produce immunity.

FluMist should not be given to people who:

- have immune suppression or take drugs that cause immunosuppression,
- have immune deficiency diseases (AIDS or cancer),
- have asthma or other reactive airway diseases,
- are 50 years old and over,
- have chronic medical conditions that may predispose them to severe flu infections, or
- have had an allergic reaction to eggs or a previous dose of the vaccine.



Tips on Caring For the Flu

Drink plenty of fluids
Fluids such as water, juice, soup, and non-caffeinated beverages can help loosen mucus, keep you hydrated, and make you feel better, especially if you have a fever.

Avoid alcohol and drinks with caffeine
Drinks containing alcohol and caffeine can have a dehydrating effect.

Throw out used tissues
Limit your exposure to used tissues and the bacteria they hold by disposing of them quickly.

Gargle salt water
Salt water can help relieve a sore throat.

Use a cool-mist humidifier
A cool-mist humidifier breaks water into droplets and releases them into the air, which may help relieve a stuffy nose.

Choose the correct over-the-counter medicines
Chose medicines that treat only the symptoms you have and avoid over-medicating.

Use only aspirin-free medicines in children and teens
Children and teens suffering from flu-like symptoms should avoid taking aspirin because it can mask the symptoms of Reye's syndrome, a potentially fatal illness.

Take the Flu Quiz...

Test your flu vaccine savvy with these true or false questions, then check your answers on page 8.

True or False?

Q1: People can die from the flu.

Q2: Even if I get the flu vaccine, I can still get a mild case of the flu.

Q3: The side effects of the flu vaccine are worse than the flu

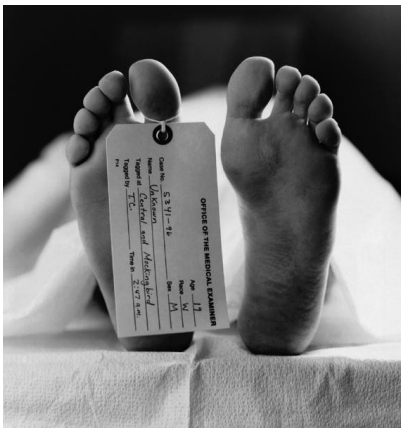
Q4: Not everyone can take the flu vaccine.

Q5: Only older people need flu vaccine.

Q6: You must get the flu vaccine before December.

Misuse of Prescription Pain Relievers: Think Twice-Because You Only Die Once

Prescription pain relievers, when used correctly and under a doctor's supervision, are safe and effective. But abuse them, or mix them with illegal drugs or alcohol, and the user could wind up in the morgue.



Even using prescription pain relievers with other prescription drugs (such as antidepressants) or over-the-counter medications (like cough syrups and antihistamines), can lead to life-threatening respiratory failure. That's why people can drop pills at parties, and then drop dead. They're not downing handfuls of pills, either. With some prescription pain relievers, all it takes is one pill.

Drugs to watch out for.

The most dangerous prescription pain relievers are those containing drugs known as opioids, such as morphine and codeine. Some common drugs containing these substances include Darvon, Demerol, Dilaudid, OxyContin, Tylenol with Codeine, and Vicodin. These drugs have many street names: ac/dc, coties, demmies, dillies, hillbilly heroin, o.c., oxy, oxycotton, percs and vics to name a few.

Symptoms of overdose.

Here are the danger signs to watch for:

- Slow breathing (less than ten breaths a minute is always serious)
- Small, pinpoint pupils
- Confusion
- Being tired, nodding off, or passing out
- Dizziness
- Weakness
- Apathy (they don't care about anything)
- Cold and clammy skin
- Nausea
- Vomiting
- Seizures

Many of these symptoms can make people think a person is drunk. They may be tempted to let a person sleep it off, or tell others that they had too much to drink. That's a bad idea. A person who overdoses could go to sleep and never wake up.

What to do if someone is overdosing.

- Make an anonymous call to 911 or to the person's parents if you're too scared to identify yourself.
- Try to get the person to respond by calling out his/her name.
- Make the person wake up and talk.
- Shake them if necessary. Otherwise, they could suffer brain damage, fall into a coma, or die.

Addiction can be a living death.

If a person abuses prescription pain relievers and is lucky enough to cheat death, they're still in big trouble. Prescription pain relievers can be addictive. The longer a person takes them, the more their body needs. Try to stop, and they could experience withdrawal symptoms.

Addiction to prescription pain relievers is like being hooked on heroin and the withdrawal isn't much different. Addicts in withdrawal can suffer agonizing muscle pain, diarrhea, vomiting, cold flashes and insomnia.

If you, or someone you know, is abusing or is addicted, get professional help. You can also ask for help from parents, doctors, relatives, teachers, or school guidance counselors. Substance abuse ruins lives. Don't let it happen to your friends -- or you.

If you, or someone you know, is hooked on prescription pain relievers, call the substance abuse treatment 24-hour helpline:

1-800-662-HELP
Or visit:
http://www.findtreatment.samhsa.gov

Antibiotics: A Misused Miracle?

When antibiotics first arrived on the market more than 50 years ago, they were hailed as miracle drugs; misused as disease and bacteria-killing cure-alls that patients relied on to treat everything from the common cold to an ear infection.

But with each passing decade, bacteria that resist not only single, but multiple, antibiotics--making some diseases particularly hard to control--have become increasingly widespread. In fact, according to the Centers for Disease Control and Prevention (CDC), many significant types of bacteria that cause infections are becoming more resistant to commonly prescribed antibiotics.

For some of us, bacterial resistance could mean more visits to the doctor, a lengthier illness, and possibly more toxic drugs. For others, it could mean death. The CDC estimates that each year, nearly 2 million people in the U.S. get an infection while in a hospital, resulting in 90,000 deaths. More than 70 percent of the bacteria that cause these infections are resistant to at least one of the antibiotics commonly used to treat them.

"More than 70 percent of the bacteria that cause these infections are resistant to at least one of the antibiotics commonly used to treat them."

"Antibacterial resistance is a serious and growing public health problem in the U.S. and worldwide," says FDA Commissioner, Mark McClellan, M.D., Ph.D. "Without effective antibiotic drugs, common infections, that were once easily treated, can create a serious health threat to children and adults alike."

"Several bacterial species have developed strains that are resistant to every approved antibiotic."

Many bacterial species, including the species that cause pneumonia and other respiratory tract infections, meningitis, and sexually transmitted diseases, are becoming increasingly resistant to the antibacterial drugs used to treat them. Several bacterial species have developed strains that are resistant to every approved antibiotic.

Yet, antibacterial resistance, also known as, antimicrobial or antibiotic resistance, is not a new phenomenon. Just a few years after the first antibiotic, penicillin, became widely used in the late 1940s, penicillin-resistant infections emerged that were caused by the bacterium *Staphylococcus aureus* (*S. aureus*). These "staph" infections range from urinary tract infections to bacterial pneumonia.

Preserving Antibiotics' Usefulness

In 1999, 10 federal agencies and departments, led by the Department of Health and Human Services, formed a task force to tackle the problem of antimicrobial resistance. The success of the plan--known as the Public Health Action Plan to Combat Antimicrobial Resistance--depends on the cooperation of many groups, such as state and local health agencies, universities, professional societies, pharmaceutical companies, health-care professionals, agricultural producers, and the public.

Two main types of germs--bacteria and viruses--cause most infections, according to the CDC. But while antibiotics can kill bacteria, they do not work against viruses--and it is viruses that cause colds, the flu, and most sore throats. In fact, only 15 percent of sore throats are caused by the bacterium *Streptococcus*, which also causes strep throat.

"...antibiotics can kill bacteria, they do not work against viruses--and it is viruses that cause colds, the flu, and most sore throats."

In addition, it is viruses that cause most sinus infections, coughs, and bronchitis. And fluid in the middle ear, a common occurrence in children, does not usually need treatment with antibiotics unless there are other symptoms.

Continued on page 6

Antibiotic Drugs - Continued from page 5

Antibiotics do not prevent or treat influenza (flu) which is also caused by a virus. FDA has approved several prescription anti-influenza antiviral drugs for the prevention and treatment of influenza.

To decrease both demand and over-prescribing, the FDA and the CDC have launched antibiotic resistance campaigns aimed at health-care professionals and the public. A nationwide ad campaign developed by the FDA's Center for Drug Evaluation and Research encourages health-care professionals to use antibiotics cautiously, and offers them an educational brochure to distribute to patients (http://www.fda.gov/cder/consumerinfo/antibiot-resist-brochure.pdf or http://www.fda.gov/cder/consumerinfo/antibiot-resist-brochure.htm .)

The FDA published a final rule in February 2003 that requires specific language on antibiotics labeled for human use to encourage doctors to prescribe them only when truly necessary. The rule also requires a statement in the labeling asking doctors to counsel their patients about the proper use of these drugs.

To find out more about antibiotic resistance, see the FDA's Web site at http://www.fda.gov/oc/opacom/hottopics/anti_resist.html, and the CDC's Web site at http://www.cdc.gov/drugresistance/.

Will Antibiotics Treat Your Illness?

Most upper respiratory infections are usually caused by viruses--germs that cannot be killed by antibiotics.

Illness	Antibiotic Needed?
Cold	No
Flu	No
Chest Cold (in otherwise healthy children and adults)	No
Sore Throats (except strep)	No
Bronchitis (in otherwise healthy children and adults)	No
Runny Nose (with green or yellow mucus)	No
Fluid in the Middle Ear (otitis media with effusion)	No

How Bacteria Become Resistant

Bacteria are organisms so small that they are invisible to the naked eye. They live all around us--in drinking water, food, soil, plants, animals-- and in us.

Most bacteria are not harmful. Some are even useful because they can help our bodies function such as in digesting food. But many bacteria are capable of causing severe infections.

The ability of antibiotics to stop an infection depends on killing or halting the growth of harmful bacteria. But some bacteria resist the effects of drugs and multiply and spread.

Some bacteria have developed resistance to antibiotics naturally, long before the development of commercial antibiotics.

After testing bacteria found in an arctic glacier and estimated to be over 2,000 years old, scientists found several of them to be resistant to antibiotics. This evidence most likely indicates a naturally occurring resistance.

If they are not naturally resistant, bacteria can become resistant to drugs. The more you use antibiotics, the more likely bacteria are to become resistant to the antibiotics. For instance, they may develop resistance to certain drugs spontaneously through mutation. Mutations are changes that occur in the genetic material, or DNA, of the bacteria. These changes allow the bacteria to fight or inactivate the antibiotic. Using antibiotics may kill normal bacteria, but the mutated versions can still live and multiply.

Trans Fats: The Truth May Be Hard to Swallow

Everyone should be aware of the risks posed by consuming too much saturated fat, *trans* fat, and cholesterol.

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 US.

In 1993 FDA began requiring that saturated fat and dietary cholesterol be listed on food labels. With *trans* fat added to the Nutrition Facts panel, consumers now know how much of all three-- saturated fat, *trans* fat, and cholesterol--are in the foods they eat.

Identifying saturated fat, *trans* fat, and cholesterol on the food label gives you information you need to make healthy food choices. But what is *trans* fat, and how can you limit the amount of this fat in your diet?

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. Unlike other fats, the majority of *trans* fat is formed when food manufacturers turn liquid oils into solid fats like shortening and hard margarine. A small amount of *trans* fat is found naturally in dairy products, some meat, and other animal-based foods.

Are All Fats the Same?

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

As a food ingredient, fat provides taste, texture, and stability and helps you feel full. Fats are an especially important source of calories and nutrients for infants and toddlers (up to 2 years of age), who have the highest energy needs per unit of body weight of any age group.

Saturated and *trans* fats raise LDL (or "bad") cholesterol levels in the blood, thereby increasing the risk of heart disease. Dietary cholesterol also contributes to heart disease. Unsaturated fats, such as monounsaturated and polyunsaturated, do not raise LDL cholesterol and are beneficial when consumed in moderation. Therefore, it is wise to choose foods low in saturated fat, *trans* fat, and cholesterol as part of a healthful diet.

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

Continued on page 6

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.

Trans Fats - Continued from page 7

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?

Although some food products already have *trans* fat on the label, food manufacturers have until January 2006 to list it 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, don't 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

Decoding Fats

The chart below outlines the main types of fats and the products they are commonly found in.

Type of Fat	Source	Food Examples
Trans fats (aka trans fatty acids)	Hydrogenated oils found in commercially processed foods and foods prepared with hydrogenated oils	- Cookies - French fries - Stick margarine - Vegetable shortening
Saturated	Found mostly in animal and some plant-derived products	- Fatty meat - Dairy products - Coconut and Palm oil
Unsaturated • Monounsaturated • Polyunsaturated	Plant products and fish	- Olive and canola oils - Soybeans and corn oils - Peanuts - Sunflower seeds

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 poly-unsaturated 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, carbohy-drates and protein have only 4 calories per gram.

Flu Quiz: Answers

A1: True

Flu is a highly infectious disease of the lungs, and it can lead to pneumonia. Each year about 114,000 people in the U.S. are hospitalized and about 36,000 people die because of the flu.

A2: True

Flu vaccine protects most people from the flu. People who receive flu vaccine can get the flu but will be far less sick than someone who has flu and has not received flu vaccine. Flu vaccine does not protect you from other viruses that sometimes feel like the flu.

A3: False

The worst side effect you are likely to get with injectable vaccine is a sore arm. The nasal-spray flu vaccine might cause nasal congestion, runny nose, sore throat or cough.

A4: True

You might not be able to get this protection if you are allergic to eggs, are very sick with a high fever, or have had a severe reaction to the flu vaccine in the past.

A5: False

Adults and children with conditions like asthma, diabetes, heart disease, and kidney disease need to get flu vaccine. People who are active and healthy can also benefit from the protection of the flu vaccine offers.

A6: False

Flu vaccine can be given before or during the flu season. While the best time to get flu vaccine is October or November, getting vaccinated in December or later can still protect you against the flu.

Silicone Implants Get Bounced

After careful consideration and weighing expert and public opinion FDA has decided not to approve the use of silicone breast implants, leaving saline implants the only widely available option.

Instead, FDA has released a new guidance document for breast implants that will help doctors, implant manufacturers and the public evaluate breast implant safety and effectiveness (http://www.fda.gov/cdrh/ode/guidance/1239.html).

The FDA recommends that patients considering implantation carefully assess the risks and benefits with their doctor. For reasons of safety, FDA discourages the use of any breast implant in a patient younger than 18.

For more information on breast implants visit, http://www.fda.gov/cdrh/breastimplants/ and http://www.fda.gov/cdrh/bicl/

Calendar of National Health Events

- **February is American Heart Month**
  For the latest news and events from the American Heart Association visit:
  http://www.americanheart.org
- **March 12-18 National PTA Alcohol & Drug Awareness Week**
  Check your school calendar for awareness events.
- **March is National Nutrition Month**
  Find healthy eating tips and events through the National Institutes of Health (NIH) at:
  http://dnrc.nih.gov/nutrition_month.htm.
  Learn to live a longer, better, and healthier life.
  Register for the **National Steps to a Healthier U.S. Summit**, April 29-30 in Baltimore, MD:
  http://healthierus.gov

Visit the *FDA & YOU* booth at the NASSP Annual Convention & Exposition - Booth 1237

See you in sunny Orlando, Florida!!!

Word Find

T	S	L	I	G	U	H	K	L	R	K	G	J	L	H
P	A	X	N	F	A	I	R	E	T	C	A	B	T	A
A	Z	Y	F	O	O	D	L	A	B	E	L	Q	M	N
I	L	O	L	M	T	R	A	Z	L	I	S	E	M	A
N	M	O	U	W	K	X	Z	W	H	U	S	L	S	T
R	E	Y	E	S	S	Y	N	D	R	O	M	E	C	P
E	S	S	N	T	O	C	K	I	A	Y	C	M	I	O
L	R	O	Z	M	R	I	V	Z	L	I	N	V	T	U
I	P	Q	A	A	M	W	O	M	W	A	B	R	O	I
E	L	M	R	P	Y	M	L	T	I	N	A	B	I	X
V	S	T	L	X	Y	O	K	C	E	N	O	L	B	H
E	Z	A	X	E	O	N	I	I	S	C	A	R	I	A
R	N	C	U	L	I	L	D	F	K	L	A	V	T	T
T	P	O	P	H	A	E	A	P	R	S	T	M	N	I
L	O	M	T	A	N	T	H	E	N	I	C	C	A	V

Reye's Syndrome
Influenza
Virus
Vaccine
Trans Fat
Antibiotics
Think Twice
Pain Reliever
Food Label
Bacteria
CVM
Implant

About *FDA & You*

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

The publication's contents may be freely reproduced. Comments should be sent to the Editor.

Editor: Alicia Witters
Assistant Editor: Edie Seligson
Researcher: Carol Clayton

Email: FDAandyou@cdrh.fda.gov
Read us online at:
http://www.fda.gov/cdrh/fdaandyou.html

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

Special thanks to CBER, CDER and CFSAN for contributing to this issue.