

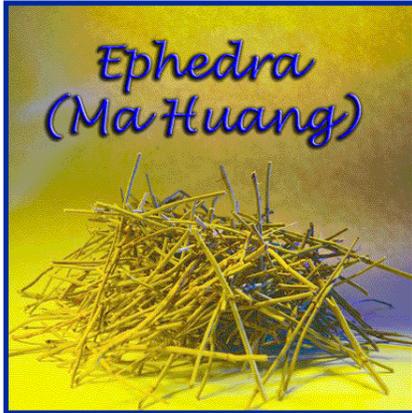


FDA & YOU

News for Health Educators and Students

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FDA Bans Ephedra

On April 12th FDA banned the sale of all dietary supplements containing ephedra. A thorough investigation into the effects of ephedra by FDA and independent investigators determined that ephedra presents an unreasonable risk of illness or injury, and should not be consumed.

This means people should stop buying and using ephedra products immediately. FDA is also working to remove these products from the market.

Americans and Dietary Supplements

Former FDA Commissioner Dr. Mark McClellan has noted that too many people are using dietary supplements as a quick fix for being overweight or obese. "Dietary supplements may help you lose weight, but they [can] also pose health risks."

In 1999 more than half of Americans used "dietary supplements," as the term is defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994. Dietary supplements include vitamins, amino acids, enzymes, and herbs and other botanicals. The use of most dietary supplements does not appear to be associated with any serious adverse health effects, and there is evidence that supplements can have health benefits. For example, it is well recognized that calcium helps build strong bones and prevent osteoporosis.

Ephedra, also called Ma huang, is a plant derived dietary supplement. Its principal active ingredient is ephedrine, which when chemically altered is regulated by FDA as a drug. While products containing natural ephedrine have long been used to treat certain respiratory symptoms in traditional Chinese medicine, in recent years ephedra products have been extensively promoted as weight loss aids and sports performance and energy boosters.

However, recent studies have found little evidence for ephedra's effectiveness other than for short-term weight loss. Studies also show that the substance raises blood pressure and otherwise stresses the heart, reactions linked to harmful health outcomes such as heart problems and strokes.

The Ephedra Ban

The ephedra ban is a continuation of a process that began in 1997 when FDA first proposed to require a statement on dietary supplements with ephedra, warning that they are hazardous and should not be used for more than 7 days. FDA modified this proposed rule in 2000, and in February 2003 it announced a series of measures that included strong enforcement actions against companies making unproven claims for their ephedra-containing products.

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By law (DSHEA), the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to "approve" dietary supplements for safety and effectiveness before they reach the consumer.

However, the law allows FDA to prohibit sale of a dietary supplement if it "presents significant or unreasonable risk of injury. FDA must determine if a product's known or supposed risks outweigh any known or suspected benefits. This decision is made based on available scientific evidence in light of claims the product makes and in light of the product's being sold directly to consumers without medical supervision.

Prior to the ephedra ban, FDA sent dozens of warning letters to companies marketing dietary supplements that contain ephedrine. The letters explained that any claims their products made about effects on the structure and function of the human body had to be truthful and not misleading.

The letters also warned firms not to make claims about a product's ability to treat or cure a disease or condition such as obesity. Under the Federal Food, Drug and Cosmetic Act, unapproved products making "disease claims" are unapproved new drugs and therefore subject to other regulatory actions. This includes the court ordered blockage of sales and the seizure of products.

Protecting Yourself

It is important to be well informed about any product before buying it. Because it can be difficult to know what information is reliable and what is questionable, you may first want to contact the manufacturer about a product you intend to buy. The name and address of the manufacturer or distributor can be found on the label of the dietary supplement.

Also know that any dietary supplement that is promoted on its label as a treatment, prevention or cure for a specific disease or condition is considered an illegal drug. Do not buy dietary supplements that make these, or similar, claims.

Reporting Problems with Dietary Supplements

If you think you have suffered a serious harmful effect or illness from a product FDA regulates, including dietary supplements, the first thing you should do is contact your doctor or other healthcare provider immediately. Then, you and your healthcare provider are encouraged to report this problem to FDA.

Your healthcare provider can call FDA's MedWatch hotline at 1-800-FDA-1088, by FAX to 1-800-FDA-0178 or online at: <http://www.fda.gov/medwatch/report/consumer/consumer.htm>.

For more information visit:
<http://www.fda.gov/oc/initiatives/ephedra/february2004/>



Did you know that a single organ donor can save or enhance the lives of up to 50 other people?

April is National Donate Life Month and this year marks the 50th anniversary of the first successful U.S. organ transplant.

With that in mind, there's no better time to learn about the organ donation process. The Department of Health and Human Services has launched a new website <http://www.organdonor.gov/student> to help teens make an informed decision about organ donation.



Weighing in on Obesity

Americans are getting fatter. We're putting on the pounds at an alarming rate, and sacrificing our health for the sake of supersize portions, biggie drinks, and two-for-one value meals, obesity researchers say.

According to the Centers for Disease Control and Prevention (CDC) about 15% of children and adolescents are overweight. Excess weight and physical inactivity account for more than 300,000 premature deaths each year in the United States, second only to deaths related to smoking. And the list of related health problems is long. People who are overweight or obese are at increased risk for high blood pressure, high cholesterol, diabetes, heart disease, certain cancers such as breast and colon, depression, and other illnesses.

Former FDA commissioner Dr. Mark McClellan has called the current policies and advice to the public on obesity ineffective. Recently Dr. McClellan called on researchers, the food industry, consumer groups, and the medical community to work with the FDA to tackle this epidemic.

Healthy Weight

Overweight refers to an excess of body weight, but not necessarily body fat. Obesity means an excessively high proportion of body fat. Health professionals use a measurement called body mass index (BMI) to classify an adult's weight as healthy, overweight, or obese (see the BMI chart, "Are You at a Healthy Weight?"). BMI describes body weight relative to height and is correlated with total body fat content in most adults.

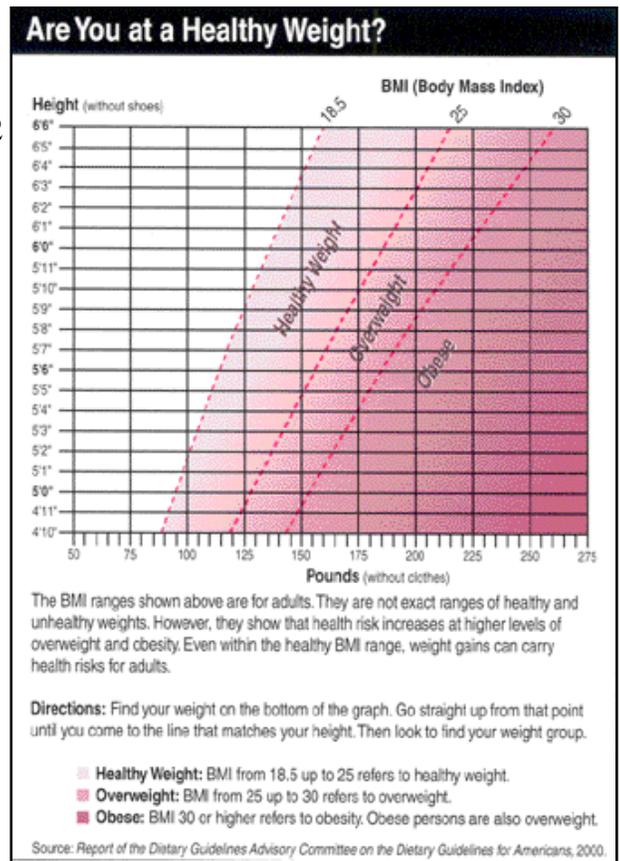
To get your approximate BMI, multiply your weight in pounds by 703, then divide the result by your height in inches, and divide that result by your height in inches a second time. (Or you can use the interactive BMI calculator at <http://www.nhlbisupport.com/bmi/bmicalc.htm>.)

A BMI from 18.5 up to 25 is considered in the healthy range, from 25 up to 30 is overweight and 30 or higher is obese. Generally, the higher a person's BMI, the greater the risk for health problems, according to the National Heart, Lung and Blood Institute (NHLBI). However, there are some exceptions. For example, very muscular people, like body builders, may have a BMI greater than 25 or even 30, but this reflects increased muscle rather than fat. "It is excess body fat that leads to the health problems such as type 2 diabetes, high blood pressure, and high cholesterol," says Eric Colman, M.D., of the Food and Drug Administration's Division of Metabolic and Endocrine Drug Products.

Obesity, once thought by many to be a moral failing, is now often classified as a disease. The NHLBI calls it a complex chronic disease involving social, behavioral, cultural, physiological, metabolic, and genetic factors. Although experts have many theories on how and why people become overweight, they generally agree that the key to losing weight is a simple message: Eat less and move more. Your body needs to burn more calories than you take in.

Setting a Goal

Studies show that if you are overweight you can improve your health with just a small amount of weight loss. The first step to weight loss is setting a realistic goal. By using a BMI chart and consulting with your health-care provider, you can determine what a healthy weight is for you.



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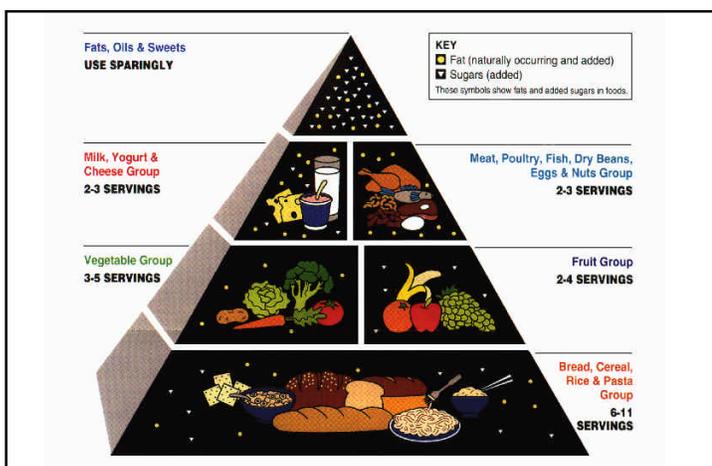
To reach your goal safely, plan to lose weight gradually. A weight loss of one-half to 2 pounds a week is usually safe, according to the Dietary Guidelines for Americans. This can be achieved by decreasing the calories eaten or increasing the calories used by 250 to 1,000 calories per day, depending on current calorie intake. (Some people with serious health problems due to obesity may lose weight more rapidly under a doctor's supervision.) If you plan to lose more than 15 to 20 pounds, have any health problems, or take medication on a regular basis, a doctor should evaluate you before you begin a weight-loss program.

Changing Eating Habits

Dieting may conjure up visions of eating little but lettuce and sprouts, but you can enjoy all foods as part of a healthy diet as long as you don't overdo it on fat (especially saturated fat), protein, sugars, and alcohol. To be successful at losing weight, experts say you need to change your lifestyle not just go on a diet.

Limit portion sizes, especially of foods high in calories, such as cookies, cakes and other sweets; french fries; and fats, oils and spreads. Reducing dietary fat without reducing calories will not produce weight loss, according to the NHLBI's guidelines on treating overweight and obesity in adults.

Use the Food Guide Pyramid, developed by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services, to help you choose a healthful assortment of foods that includes vegetables, fruits, grains (especially whole grains), fat-free milk, and fish, lean meat, poultry, or beans. Choose foods naturally high in fiber, such as fruits, vegetables, legumes (such as beans and lentils), and whole grains. The high fiber content of many of these foods may help you to feel full with fewer calories.



The Food Guide Pyramid can help you make healthy food choices.

All calorie sources are not created equal. Carbohydrate and protein have about 4 calories per gram, but fat has more than twice that amount (9 calories per gram). Just as for the general population, weight-conscious consumers should aim for a daily fat intake of no more than 30 percent of total calories.

Keep your intake of saturated fat at less than 10 percent of calories. Saturated fats increase the risk for heart disease by raising blood cholesterol. Foods high in saturated fats include high-fat dairy products (like cheese, whole milk, cream, butter, and regular ice cream), fatty fresh and processed meats, the skin and fat of poultry, lard, palm oil, and coconut oil.

Limit your use of beverages and foods that are high in added sugars, not naturally occurring sugars in foods such as fruit or milk. Foods containing added sugars provide calories, but may have few vitamins and minerals. In the United States, the major sources of added sugars include non-diet soft drinks, sweets and candies, cakes and cookies, and fruit drinks and fruitades.

Using the Food Label

Under regulations from the FDA and the USDA, the food label, found on almost all processed foods, offers more complete, useful and accurate nutrition information than ever before. Even when restricting calories and portions, you can use the part of the food label called the Nutrition Facts panel to make sure you get all the essential nutrients for good health.

You'll find the serving size and the number of servings per package listed at the top of the Nutrition Facts panel. The serving size affects all the nutrient amounts listed on the panel. For example, if there is one cup in a serving and the package contains two servings, you need to double the calories and other nutrient numbers if you eat the whole package. Many items sold as single portions--like a 20-ounce soft drink, a 3-ounce bag of chips, and a large bagel--actually provide two or more servings.

The Nutrition Facts panel also shows how much dietary fiber, vitamin A, vitamin C, calcium, and iron are contained in a serving. These are nutrients you need for good health.

Also listed on the Nutrition Facts panel are the amounts of carbohydrates, protein, and sugars contained in a serving. Use the panel to compare the amount of total sugars among similar products, and try to choose ones lower in sugars.

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In addition to listing some nutrients by weight, the panel also gives this information as a Percent Daily Value (%DV). The %DV shows how a serving of a food fits in with recommendations for a healthful diet and allows consumers to make comparisons between similar products.

For example, shoppers can use the %DV figures to find out which frozen dinner is lower in saturated fat--particularly when it involves a comparative nutritional claim, such as reduced-fat. Foods with 5 percent or less of the Daily Value are considered low in a nutrient, while those with 20 percent or more are high in the nutrient.

The %DVs are based on a 2,000-calorie daily diet. But even if you eat less than 2,000 calories, the %DV can be used to determine whether a food is high or low in a particular nutrient.

For further guidance on using the Nutrition Facts panel, visit FDA's Center for Food Safety and Applied Nutrition (<http://www.cfsan.fda.gov/list.html>).

Increasing Physical Activity

Most health experts recommend a combination of a reduced-calorie diet and increased physical activity for weight loss. Most adults should get at least 30 minutes and children should get 60 minutes of moderate physical activity on most, and preferably all, days of the week. But fewer than 1 in 3 U.S. adults gets the recommended amount of physical activity, according to The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity.

In addition to helping to control weight, physical activity decreases the risk of dying from coronary heart disease and reduces the risk of developing diabetes, hypertension, and colon cancer. Researchers also have found that daily physical activity may help a person lose weight by partially lessening the slow-down in metabolism that occurs during weight loss.

Exercise does not have to be strenuous to be beneficial. And some studies show that short sessions of exercise several times a day are just as effective at burning calories and improving health as one long session.

For More Information

Weight-control Information Network (WIN)
National Institute of Diabetes and Digestive and
Kidney Diseases
1-877-946-4627
<http://www.niddk.nih.gov/health/nutrit/win.htm>

Obesity Education Initiative
National Heart, Lung, and Blood Institute
301-592-8573
http://rover.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/

The Surgeon General's Call to Action To Prevent and Decrease Overweight and Obesity, 2001
U.S. Department of Health and Human Services
<http://www.surgeongeneral.gov/topics/obesity>



Sun Safety: Protect the Skin You're In!

Skin: we can't live without it. It's both the largest organ of the body and one of the most mistreated. It's vital for protecting and regulating the body and can provide amazing insight into a person's state of health. Yet some ignore the warnings of premature aging and worse to pursue a love affair with the sun.

The Effects of Tanning

Exposure to ultraviolet (UV) radiation, either from sunlight or by artificial sources, such as tanning beds and sunlamps, contributes to the risk of developing skin cancer. Prolonged exposure to the sun can cause wrinkling, loss of elasticity, and other signs of premature skin aging. Since sun damage may not be immediately visible, many people don't realize the dangers of tanning. In fact, any tan is a sign of

the skin adapting to potentially damaging UV radiation. Tanning occurs when the skin produces additional coloring (pigment), trying to adapt to protect itself against sunburn. The most serious outcome of overexposure to the sun is skin cancer, a delayed effect that usually doesn't show up for many years. Although some exposure to the sun is important to make sure a person gets enough vitamin D, about 20 minutes of sun a day on the face and hands is considered enough for this purpose.

Health and Human Services
Secretary Tommy G. Thompson

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strongly warns teens to take simple preventive steps now to help avoid skin cancer later. "Even a few serious sunburns," he says, "can increase a person's risk for skin cancer."

UVA v. UVB

Sunburn is associated with the shorter wavelengths of UV radiation, known as ultraviolet B (UVB). The longer wavelengths, known as ultraviolet A (UVA), however, can penetrate the skin and damage connective tissue at deeper levels, even if the skin's surface feels cool. It is important to limit exposure to both UVA and UVB.

Artificial Sun

Indoor tanning can be as harmful as outdoor tanning. More than 1 million people visit tanning salons on an average day, according to the American Academy of Dermatology (AAD). But many don't know that indoor tanning devices, such as tanning beds and sunlamps, emit UV radiation that's similar to and sometimes more powerful than the sun. As a result, the FDA discourages the use of tanning beds and sunlamps.

Be wary of claims about "safe rays" because there is no such thing. Both types of ultraviolet light, UVB and UVA, can cause wrinkling and other signs of premature skin aging, skin cancer, and damage to the eyes and the immune system.

Sunlamps used for tanning produce UV radiation. FDA policies require sunlamp product manufacturers to develop an exposure schedule and establish a maximum recommended exposure time based on the UV emission characteristics of their

products. FDA also warns that, while some tanning operators may claim that UVA sunlamps are safer than both the sun and UVB lamps, this has not been definitely shown. In fact, exposure to UV radiation from sunlamps adds to the total amount of UV radiation people get from the sun during their lifetimes and potentially increases their risk of cancer.

According to the National Cancer Institute, the incidence of skin cancer is already increasing each year, and melanoma, the most serious form, is increasing by 3 percent annually. In fact, statistics indicate that 1 out of 7 people in the United States will develop some form of skin cancer during their lifetimes, with the rate increasing as the population ages. People with pale skin, red hair and freckles are at the highest risk for skin cancer.

Spray-on Tans

During the last few years, some companies have offered a sunless option that involves spraying customers in a tanning booth with the color additive dihydroxyacetone (DHA). DHA interacts with the dead surface cells in the outermost layer of the skin to darken skin color.

DHA has been approved by the FDA for use in coloring the skin since 1977, and has typically been used in lotions and creams. Its use is restricted to external application, which means that it shouldn't be sprayed in or on the mouth, eyes, or nose because the risks, if any, are unknown. If you choose to use DHA spray at home or in tanning booths, be sure to cover these areas.

Tanning Pills

There are no tanning pills approved by the FDA. Some companies have marketed tanning pills that contain the color additive canthaxanthin. When large amounts of canthaxanthin are ingested, the substance can turn the skin a range of colors, from orange to brown. However, canthaxanthin is only approved for use as a color additive in foods and oral medications, and only in small amounts.

Tanning pills have been associated with health problems, including an eye disorder called canthaxanthin retinopathy, which is the formation of yellow deposits on the eye's retina. Canthaxanthin has also been reported to cause liver injury and a severe itching condition called urticaria, according to the AAD.

When Tanning, Beware of the Dangers

Harmful rays from the sun, sunlamps and tanning beds may cause:

- skin cancer, which can be deadly,
- eye problems,
- weakened ability to fight disease,
- unsightly skin spots, or
- wrinkles and "leathery" skin.

For more information on tanning and sun safety, visit:

<http://www.nlm.nih.gov/medlineplus/sunexposure.html>

<http://www.fda.gov/opacom/lowlit/sunsafty.html>

Decoding Sunscreen Labels

All of the abbreviations and terms on sunscreen bottles can make buying sunscreen confusing. Clip this section and take it with you the next time your family buys sunscreen to help you interpret the labels.

SPF Sun Protection Factor and the number next to it refer to the degree to which a sunscreen can protect the skin from sunburn. The higher the number, the more sunburn protection the sunscreen can provide. You should use a minimum of SPF 15 and reapply often.

UV or UVR Ultraviolet radiation from the sun that can cause sunburn, wrinkling, premature aging, and skin cancer and may also interfere with the body's immune system. Look for "broad spectrum" sunscreens that protect from the two types of UV rays.

UVA Ultraviolet A is longer wavelength UV radiation that can penetrate and damage the deeper layers of skin even if the skin feels cool and shows no signs of burning.

UVB Ultraviolet B is the shorter wavelength UV radiation associated with sunburn and other skin damage.

Water Resistant These sunscreens stay on the skin longer even if they get wet from pool water, ocean water or sweat. But water resistant doesn't mean waterproof. Sunscreens with this label still need to be reapplied. Check the label for reapplication times.

Protect Yourself with These Sun Safety Tips:

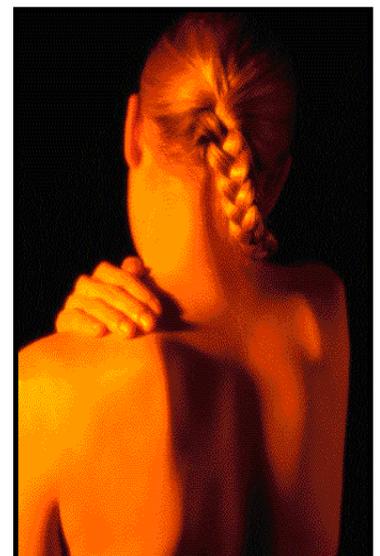
- ☀️ Avoid the sun, or seek shade, from 10 a.m. to 4 p.m. when the sun's rays are strongest. Even on a cloudy day, up to 80% of the sun's rays can get through.
- ☀️ Apply an SPF 15 or higher sunscreen evenly to all uncovered skin before going outside. Check the label for the correct amount of time to apply sunscreen before you go out. If the label does not give a time, allow about 15 to 30 minutes.
- ☀️ Don't forget to apply sunscreen to your eyelids, lips, nose, ears, neck, hands and feet.
- ☀️ Avoid getting sunscreen in your eyes. It can sting.
- ☀️ If you don't have much hair apply sunscreen to the top of your head or wear a hat.
- ☀️ Reapply sunscreen often. Read the label to see how often you need to reapply.
- ☀️ Wear protective clothing and a wide-brimmed hat to protect your head and face.
- ☀️ Wear sunglasses with 99% to 100 % UV protection to protect your eyes.
- ☀️ Avoid artificial tanning methods such as sunlamps, tanning beds, tanning pills and tanning makeup.
- ☀️ If you still choose to use sunlamps or tanning beds, follow the manufacturer's recommended exposure schedule and always wear FDA-compliant protective eyewear.
- ☀️ Check your skin regularly for signs of skin cancer.
- ☀️ Ask a doctor before applying sunscreen to children under 6 months of age.

Do a Skin Cancer Check

No matter how much time you spend in the sun, you should protect yourself by checking for signs of skin cancer. Do a thorough body check and look for changes in the size, shape, color or feel of birthmarks, moles and spots. If you find any changes or find sores that are not healing, let your doctor know right away.

Use a hand mirror or full-size mirror and follow these easy steps:

1. Check the back of your neck, ears and scalp.
2. Check your body and head- front, back and sides.
3. Bend your elbows and check the underside of your arms.
4. Check all in-view parts like fingers, hands and feet.



Focus On: Henna

Before you think about getting a henna tattoo this summer, you should consider the consequences. Products marketed as henna may contain other ingredients that can result in mild to severe allergic reactions and infections that can lead to permanent scarring.

What is henna?

Henna is a brown to reddish brown dye made from the leaves of the Lawsonia plant, a flowering shrub native to North Africa and Asia. Although decorating the skin with henna has become popular, henna is not approved for application to the skin, as in the body-decorating process known as "mehndi." Henna is approved by the FDA only for use as a hair dye.

Since henna typically produces a brown, orange-brown, or reddish-brown tint, other ingredients must be added to produce other colors, such as those marketed as "black henna" and "blue henna." So-called "black henna" may contain the "coal tar" color p-phenylenediamine, also known as PPD. This ingredient may cause allergic reactions in some people. The only legal use of PPD in cosmetics is as a hair dye (and that definitely does not include eyelashes or eyebrows, where such dyes may cause blindness). It is not approved for direct application to the skin. In addition to color additives, these skin-decorating products may contain other ingredients that can also cause allergic reactions.

Even brown shades of products marketed as henna may contain other ingredients intended to make them darker or make the stain last longer.

How do I know what's in a temporary tattoo or henna/mehndi product?

Cosmetics including temporary skin-staining products that are sold on a retail basis to consumers must list their ingredients on the label. Products that do not list ingredients violate the Fair Packaging and Labeling Act (FPLA) and cannot legally be sold in this way.



The FPLA does not apply to cosmetic samples and products used exclusively by professionals. For example, the requirement for ingredient listing does not apply to henna applied at a salon, or in a booth at a fair or boardwalk.

Does FDA approve color additives?

By law, except for coal tar colors used in hair dyes, color additives used in cosmetics must be approved by FDA to assure that they are safe and suitable for their intended uses. Some color additives may not be used unless FDA has certified in its own labs that the composition of each batch meets the regulatory requirements. For example, temporary tattoo products that do not comply with restrictions on color additives cannot legally be sold.

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

FDA urges the public and healthcare providers to report adverse reactions involving cosmetics, including henna and temporary tattoos by contacting their FDA district office (see the blue pages of your local phone directory) or FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Events Reporting System (CAERS) by phone at (301) 436-2405 or by email at CAERS@cfsan.fda.gov.

In addition, healthcare professionals and consumers may submit information about adverse events to MedWatch, the FDA Medical Products Reporting Program, as follows:

- By mail: Use the postage-paid MedWatch Form (<http://www.fda.gov/medwatch/safety/3500.pdf>)
- By phone: 1-800-FDA-1088
- By fax: 1-800-FDA-0178
- By Internet: <http://www.fda.gov/medwatch/>

Consumers may obtain MedWatch reporting forms by calling the following FDA toll-free number: (888) 463-6332 [888-INFO-FDA].

The Lowdown: Buying Medical Products Online

A healthy dose of common sense can help to protect you when shopping at pharmaceutical and other medical product websites.

The number of online pharmaceutical sites grows daily and many of these sites bypass the traditional procedures and safeguards for prescribing medications.

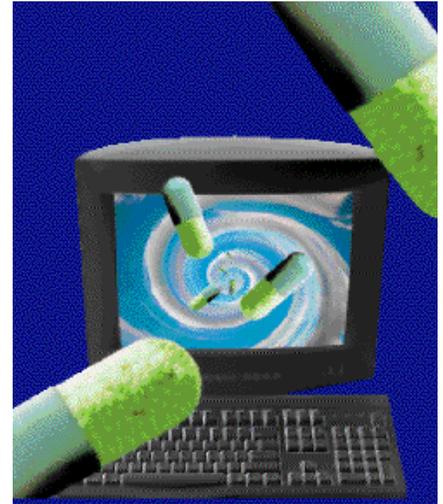
Some sites sell products that are not approved by the Food and Drug Administration, or if they deal in approved products, may sidestep established procedures designed to protect consumers.

"As we close down one illegal site, other illegal sites spring up," says Tom McGinnis, R.Ph., a pharmacist and FDA's deputy associate commissioner of health affairs. McGinnis added, "The best way for us to protect consumers is to educate them in the do's and don'ts of safe online shopping for medical products.

Here are some do's and don'ts to help you safely purchase medical products online:

- DO** use only medications that have been prescribed by your doctor or other authorized healthcare provider.
- DO** buy only from sites that require prescriptions from a physician or other authorized health care provider and that verify each prescription before dispensing medication.
- DO** use sites that provide convenient access to a licensed pharmacist who can answer you questions.
- DO** check with your state board of pharmacy or with the National Association of Boards of Pharmacy (NABP) at www.nabp.net. Some sites display the NABP VIPPS™ (Verified Internet Pharmacy Practice Sites™) seal, an assurance that such sites meet all applicable state and federal regulations.
- DO** buy only from U.S.-based sites.
- DO** report problems. If you suspect a site is not a licensed pharmacy, don't buy from it. Report the site and any complaints to the FDA at <http://www.fda.gov/oc/buyonline/buyonlineform.htm>.
- DON'T** buy from sites that offer to prescribe a medication for the first time without a physical exam by your doctor or that sell prescription medication without a prescription.
- DON'T** buy from sites that include undocumented case histories claiming amazing medical results.
- DON'T** buy from sites without posted customer service policies.

For more information, visit <http://www.fda.gov/oc/buyonline> or call 1-888-INFOFDA.



QUESTIONS?

Need more information on a topic in *FDA & YOU*?

Contact FDA by phone:

1-888-INFO FDA

(1-888-463-6332)

Or search the FDA website:

<http://www.fda.gov>

The Safe Use of Over-the-Counter Drugs

Pharmacy shelves are filled with medicines that can be bought without a prescription. But be aware that just because a drug is available over the counter (often abbreviated OTC) doesn't mean it's free of side effects.

OTC drugs should be taken with the same caution as drugs prescribed by your doctor. Special care is necessary if you use more than one of these products at the same time, or if you take an OTC product while also being treated with a prescription product. And there are some OTC drugs that shouldn't be taken by people with certain medical problems. If possible, ask your parent, pharmacist or physician for advice before taking any OTC product you haven't used before.

Besides getting expert advice, the most important thing you can do before buying an OTC drug is to read the label. The name of the product isn't always the same as the name of the drug it contains, and some products contain more than one ingredient. For example, a product for coughs and one for colds might each contain phenylpropanolamine. A person taking both products at the same time might get too much of this ingredient, which is also in some OTC diet pills.

Aspirin and Other Fever Reducers

Reading the label is especially important when it comes to products containing aspirin (acetylsalicylic acid) or their chemical cousins, other salicylates, which are used to reduce fever or treat headaches and other pain.



Teens (as well as children) should not take products containing aspirin or salicylates when they have chickenpox, flu, or symptoms that might be the flu (this includes most colds). Children and teenagers who take aspirin and other salicylates during these illnesses may develop a rare but life-threatening condition called Reye syndrome. (Symptoms usually occur near the end of the original illness and include severe tiredness, violent headache, disorientation, and excessive vomiting.)

Acetaminophen (sold under brand names such as Tylenol) can also reduce fever and relieve pain and has not been associated with Reye syndrome. Remember though, because fevers in most colds don't normally go above 100 degrees Fahrenheit and don't cause much discomfort, you usually don't have to take any drug for the fever. If you think you have a cold but your temperature is running higher, consult your doctor because you might have flu or a bacterial infection.

Sniffle and Cough Combinations

OTC drugs to relieve stuffy noses often contain more than one ingredient. Some of these products are marketed for allergy relief and others for colds. They usually

contain both an antihistamine and a nasal decongestant. The decongestant ingredient "un-stuffs" nasal passages while antihistamines dry up a runny nose. But some of these products may also contain aspirin or acetaminophen, and some contain a decongestant alone. Some of these drugs are "extended-release" or "long-acting" preparations that continue to work for up to 12 hours. Others are immediate-release products and usually work for four to six hours. It's important to read the label, and check with the pharmacist, to be sure you're getting the right product for your symptoms.

Most antihistamines can cause drowsiness, while many decongestants have the opposite effect. Still, it's hard to predict whether any one product will make you sleepy or keep you awake--or neither--because reactions to drugs can vary from one person to another. So it's best not to drive or operate machinery until you find out how the drug affects you. In addition, alcohol, sedatives and tranquilizers intensify the drowsiness effect of antihistamines, so it's best not to take them at the same time unless a doctor tells you to.

As you can see, selecting a product to treat a stuffy nose can be tricky. So can choosing a product to treat a cough. In addition to one or more ingredients specifically for coughs, many cold or cough syrups contain the same ingredients that are in allergy and cold pills. This means that if you're taking acetaminophen pills or cold pills, you should read the label or consult the pharmacist to make

Over-the-Counter Drugs - Continued from page 10

sure you're not getting a double dose of ingredients by taking a cold or cough syrup.

There are several different types of ingredients to treat coughs, depending on the kind of cough you have. Some ingredients make it easier for you to bring up phlegm, while others suppress the cough. Before taking any kind of cough medicine, it's a good idea to first try drinking plenty of liquids and adding moisture to the air by using a vaporizer or boiling water. Sometimes just doing these things will reduce the cough enough that you won't have to take any medicine. If a cough lasts more than a few days, see your doctor.

Stomach Help

When your stomach gets upset, you'll want the quickest relief possible. But unless the problem continues for several days or is severe, drugs are not usually necessary.

If you're constipated, drinking more water, getting more exercise, and eating high-fiber foods such as fruits and vegetables, will often solve the problem.

Though appropriate for some medical conditions, laxatives can be habit forming and can make constipation worse when overused. Not having a bowel movement every day does not necessarily mean that you're constipated, for some people it's normal.

If you have diarrhea, it's a good idea to rest, eat only small amounts of food at a time, and drink plenty of fluids to prevent dehydration. OTC products marketed to stop diarrhea may contain loperamide (Imodium A-D), or attapulgite (Diasorb, Kaopectate and others), or bismuth subsalicylate (Pepto-Bismol and others). Teens should avoid products with bismuth subsalicylate if they have flu or chickenpox symptoms because of the risk of Reye syndrome.

If you're running a fever above 100 F, or if your upset stomach symptoms are severe or continue for more than a day or two, consult your doctor. She may recommend one of the many OTC products available for these problems.

Skin Treatment

Rashes can be caused by many different things--including allergies, funguses, and poison oak or ivy. So it's best to get a doctor's opinion about what's causing your rash before treating it.

There are topical OTC products that you apply directly to the skin available specifically to treat poison ivy and oak. Some of these products contain calamine, which protects the skin, and benzocaine, which dulls the pain or itching. Other products contain an antihistamine or hydrocortisone, which relieve itching. Antihistamine creams, such as Benadryl, and hydrocortisone products, such as Cortaid and Caldecort, can also be used for rashes from allergies and insect bites, but you shouldn't use them for more than seven days without seeing a doctor.

Products Containing Salicylates

The following products don't have aspirin in their brand names but they contain aspirin or other salicylates and shouldn't be taken by teens who have symptoms of flu or chickenpox unless told to do so by a doctor. (Ingestion of salicylates during these illnesses increases children's and teens' risk of Reye syndrome.)

- Alka-Seltzer Effervescent Antacid and Pain Reliever (also the extra-strength version)
- Alka-Seltzer Plus Night-Time Cold Medicine
- Anacin Maximum Strength Analgesic Coated Tablets
- Ascriptin A/D Caplets (also the regular and extra-strength versions)
- Bayer Children's Cold Tablets
- Bufferin (all formulations)
- Excedrin Extra-Strength Analgesic Tablets and Caplets
- Pepto-Bismol
- Vanquish Analgesic Caplets

In addition, many products to treat arthritis contain aspirin.

(This list contains many common products, but isn't all-inclusive. So be sure to read the label before purchasing any OTC medication.)

Over-the-Counter Drugs - Continued from page 11

Acne, another type of skin problem, can also be treated with topical OTC products. Many of these lotions (such as Clearasil products and Oxy-5 and -10) contain benzoyl peroxide in strengths of 2.5, 5, or 10 percent. It's best to try the lower dosage level first, to keep your skin from getting too dry.

Benzoyl peroxide can also increase your sensitivity to sun, causing you to burn more easily. If you use a product with benzoyl peroxide remember to wear sunscreen during the day to protect your skin.

Expert Advice

These are just a few of the types of products available over the counter. Their number and uses can be confusing to adults and teens alike. Before buying any product you haven't already used, it's best to read the labeling and, if possible, ask the pharmacist how the product works and what it should be used for. And, if still in doubt, check with your doctor.

Calendar of National Health Events

MAY

- **National High Blood Pressure Education Month**
A National High Blood Pressure Education Program and materials kit are available at:
http://hin.nhlbi.nih.gov/nhbpep_kit/
- **Skin Cancer Awareness Month**
For the latest news and information from the Skin Cancer Foundation visit:
<http://www.skincancer.org>

JUNE

- **National Safety Month**
Safety and health solutions for your workplace, home, and community are available from the National Safety Council at:
<http://www.nsc.org/nsm.htm>

AUGUST

- **Immunization Awareness Month**
Materials and information from the National Partnership for Immunization are available at:
<http://www.partnersforimmunization.org/niam.html>

Word Find

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- Supplements
- Ephedra
- Sunscreen
- Tanning
- Obesity
- Healthy diet
- Exercise
- Buying online
- Henna
- Color Additives

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