

HANDS-ON Health

Health Wave Newsletter, February 2010

Visit us on our website at www.healthwaveinc.com

February is National 'Wise Health Consumer Month'

Warning: Counterfeit Alli

The Food and Drug Administration (FDA) is warning the public about a counterfeit version of the weight-loss drug Alli 60 mg capsules (120 count refill pack) being sold over the Internet, particularly at online auction sites.

The counterfeit product is illegal and unsafe. FDA advises people who believe that they have a counterfeit product not to use the drug. There is no evidence at this time that the counterfeit Alli product has been sold in retail stores.

Dangers of Counterfeit Alli

Alli is an FDA-approved, over-the-counter weight-loss drug that contains orlistat as its active ingredient. The counterfeit version of Alli does not contain orlistat; instead it is made with varying amounts of sibutramine, a stimulant drug.

Although sibutramine is the active ingredient in another FDA-approved prescription weight-loss drug, it is only to be used in specific doses and under the supervision of a physician.

FDA first warned consumers about the counterfeit product on Jan. 18, 2010, based on preliminary laboratory tests that revealed the counterfeit version contained sibutramine and not orlistat. Since that time, FDA lab tests on the counterfeit product show that people may be taking three times the usual daily dose (and twice the recommended maximum dose) of sibutramine if they are following the dosing directions for Alli.

This excessive amount of sibutramine is dangerous to people who have a

How to Recognize the Counterfeit Alli

The counterfeit Alli has

- a missing LOT code on the outer cardboard packaging
- an expiration date that includes a MONTH, DAY, and YEAR—the expiration date of the real Alli only contains a MONTH and a YEAR
- a plain foil for the inner safety seal without any words on it—the safety seal of the real Alli has the words "SEALED FOR YOUR PROTECTION" prominently printed on it.
- large capsules with white powder, as opposed to small white pellets found in the real Alli
- a slightly taller plastic bottle with a wider cap and coarser ribbing on the cap than what is seen with the real Alli

history of cardiovascular disease and can lead to

- elevated blood pressure
- stroke
- heart attack

Even healthy people who take this much sibutramine can experience

- anxiety
- nausea
- heart palpitations
- a racing heart
- insomnia
- small increases in blood pressure

FDA Recommendations

Check to make sure you are not taking counterfeit Alli. If you think you might have the counterfeit product:

- stop taking the drug
- contact your health care professional if you are experiencing more than mild side effects, especially if you have a history of cardiovascular disease
- call FDA's Office of Criminal Investigations (OCI) at 800-551-3989 or by visiting the OCI Web site; you may also contact Alli's maker, GlaxoSmithKline at 800-671-2554

In This Newsletter:

Counterfeit Weight-loss product, Alli

(page 1) Learn the facts and protect yourself from this internet scam.

Indoor Tanning

(pages 2-3) The risks of ultraviolet rays are serious and long term. Read the latest recommendations of the IARC.

Health Wave Publishing Company

39 Davenport Street
Stamford, CT 06902
Tel: 203-975-7810 or
800-374-7953
Fax: 203-975-7946
e-mail: hpwinfo@healthwaveinc.com
healthwaveinc.com



Indoor Tanning: The Risks of Ultraviolet Rays

Sunlamps and tanning beds promise consumers a bronzed body year-round, but the ultraviolet (UV) radiation from these devices poses serious health risks.

"Although some people think that a tan gives them a 'healthy' glow, any tan is a sign of skin damage," says Sharon Miller, M.S.E.E., a Food and Drug Administration (FDA) scientist and international expert on UV radiation and tanning.

A tan is the skin's reaction to exposure to UV rays," says Miller. "Recognizing exposure to the rays as an 'insult,' the skin acts in self-defense by producing more melanin, a pigment that darkens the skin. Over time, this damage will lead to prematurely aged skin and, in some cases, skin cancer."

Two types of UV radiation that penetrate the skin are UV-B and UV-A rays.

- **UV-B** rays penetrate the top layers of skin and are most responsible for sunburns.

- **UV-A** rays penetrate to the deeper layers of the skin and are often associated with allergic reactions, such as a rash.

Both UV-B and UV-A rays damage the skin and can lead to skin cancer.

Tanning salons use lamps that emit both UV-A and UV-B radiation.

Cancer Risk

In July 2009, the International Agency for Research on Cancer (IARC), part of the World Health Organization, concluded that tanning devices that emit UV radiation are more dangerous than previously thought. IARC moved these devices into the highest cancer risk category: "carcinogenic to humans." Previously, it had categorized the devices as "probably carcinogenic to humans."

Development of cancer is a long process that may take decades.



Therefore, IARC also recommended banning commercial indoor tanning for those younger than 18 years to protect them from the increased risk for melanoma and other skin cancers.

IARC's conclusions and recommendations were based on its 2006 review of 19 studies conducted over 25 years on the use of indoor tanning equipment. The review found evidence of

- an association between indoor tanning and two types of skin cancer: squamous cell carcinoma and melanoma
- an association between UV-emitting tanning devices and cancer of the eye (ocular melanoma)
- both UV-A and UV-B rays causing DNA damage, which can lead to skin cancer in laboratory animals and humans
- the risk of melanoma of the skin increasing by 75 percent when tanning bed use started before age 35

"It's well established that UV radiation from the sun causes skin cancer," says Miller. "Since lamps used in tanning beds emit UV radiation, the use of indoor tanning devices also increases your risk of skin cancer."

Tanning in Children and Teens

FDA is particularly concerned about children and teens being exposed to UV rays. Intermittent exposures to intense UV radiation leading to sunburns, especially in childhood and teen years, increase the risk of melanoma, according to NCI.

FDA believes that limiting sun exposure and using sunscreen or sunblock are particularly important for children since these measures can prevent sunburn at a young age.

NCI reports that women who use tanning beds more than once a month are 55 percent more likely to develop melanoma. Teenage girls and young women make up a growing number of tanning bed customers.

"Young people may not think they are vulnerable to skin cancer," says Kaczmarek. "They have difficulty thinking about their own mortality." Yet of the more than 68,000 people in the United States who will learn they have melanoma this year, one out of eight will die from it, according to NCI estimates. In addition, the American Academy of Dermatology reports that melanoma is the second most common cancer in women 20 to 29 years old.

Some states are considering laws to ban those under age 18 from using tanning beds. And many states now have laws that require minors to have a parent's consent or be accompanied by a parent to the tanning facility.

FDA's current performance standard requires that a sunlamp product's label include a recommended exposure schedule. FDA has advised manufacturers that this schedule should provide for exposures of no more than three sessions in the first week.

Other Risks

In addition to the serious risk of skin cancer, tanning can cause:

- **Premature aging.** Tanning causes the skin to lose elasticity and wrinkle prematurely. This leathery look may not show up until many years after you've had a tan or sunburn.
- **Immune suppression.** UV-B radiation may suppress proper functioning of the body's immune system and the skin's natural defenses, leaving you more vulnerable to diseases, including skin cancer.
- **Eye damage.** Exposure to UV radiation can cause irreversible damage to the eyes.
- **Allergic reaction.** Some people who are especially sensitive to UV radiation may develop an itchy red rash and other adverse effects.

The Riskiest Practices

FDA, NCI, the American Academy of Dermatology, and other health organizations advise limiting exposure to natural UV radiation from the sun and avoiding artificial UV sources such as tanning beds entirely.

All use of tanning beds increases the risk of skin cancer. Certain practices are especially dangerous. These include:

- Failing to wear the goggles provided, which can lead to short- and long-term eye injury.
- Starting with long exposures (close to the maximum time for the particular tanning bed), which can lead to burning. Because sunburn takes 6 to 48 hours to develop, you may not realize your skin is burned until it's too late.
- Failing to follow manufacturer-recommended exposure times on the label for your skin type.
- Tanning while using certain medications or cosmetics that may make you more sensitive to UV rays. Talk to your doctor or pharmacist first.