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Health Tip: FDA warning regarding OTC weight loss drugs



To many in the medical profession, "over-the-counter" (OTC) weight loss products have long been under a veil of suspicion regarding their safety and effectiveness. Ephedra, a stimulant that was a component of a number of OTC products, was banned from the market when it was found to be linked to an increased risk for stroke and heart attack. Hydroxycut products, which had been marketed as "fat burners" and as "energy-enhancers," were recently

removed from the market by its manufacturer because of reports of liver damage. Even orlistat, which is still available in both OTC and prescription form (Alli and Xenical), is being evaluated by the FDA due to concerns regarding potential liver problems. This is in addition to the well-known side effects of this medication that includes oily spotting on underwear, flatulence, urgent bowel movements, fatty or oily stools, increased number of bowel movements, abdominal pain and inability to control stool.

The new problem of "contaminated" OTC Weight Loss Products. Perhaps even more troubling than the issues surrounding these products, however, is the recent finding of "contaminants", mostly prescription drugs, in OTC weight loss products. A recent [FDA alert](#) listed more than 70 OTC weight loss products that could be harmful because they contain prescription medications. Several of these weight loss products made the claim that they were "natural" or contained only "herbal" ingredients when, in fact, laboratory testing performed by the FDA revealed the presence of prescription drugs including sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein.

What are the potential dangers of some of these drugs?

- Sibutramine is the active ingredient in Meridia, a prescription medication that is approved to treat obesity. Problems that could arise if taken in the dosages recommended on the labels of some of these OTC products include increased blood pressure, palpitations, and seizure.
- Fenproporex is a stimulant-type of weight loss drug that has not yet been approved for marketing in the United States. Adverse effects of

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stimulants include headache, increased heart rate, elevated blood pressure, sweating, diarrhea, dizziness, insomnia, palpitations, and possible sudden death.

- Fluoxetine is the active ingredient in the prescription antidepressant, Prozac. While this medication has been used widely with great effectiveness to treat depression, it can also produce an increased risk of suicidal thinking and suicide in children, adolescents, and young adults.
- Bumetanide and furosemide are both potent diuretics that bring about "weight loss" through loss of body fluid. Potential adverse effects of these medications include dehydration, electrolyte loss, low blood pressure, allergic reactions and interactions with other medications.
- Cetilistat is an experimental obesity drug not approved for marketing in the United States which works in a similar manner and with similar side effects as orlistat.
- Phenolphthalein is a solution which was used in some OTC laxatives in the past. It is a suspected cancer-causing agent.

Why were these products allowed to be sold? Most of the tainted weight loss products are sold as "nutritional supplements" rather than medications. In doing so, they were able to bypass many of the FDA requirements for assuring purity, safety and effectiveness. The internet has become a major outlet for these products also, which may help to keep them off of the FDA's "radar screen." Because of the sheer numbers of the products, the FDA has been unable to test all of them for potentially harmful contaminants. Undoubtedly, more will be identified with additional surveillance. In addition to recalls and efforts to remove these products from the market, it is anticipated that the FDA will be required to take more drastic steps, including seizure of products and filing criminal charges.

How can you be sure that an OTC product is safe? Consumers should consult with their health care professional any time that they consider taking a dietary supplement for obesity or other diseases. The claims that a product is "natural" or "herbal" does not guarantee that it is either safe or effective. In fact, as has recently been discovered by the FDA, some of these products may even contain controlled substances. The FDA encourages consumers to be aware of the following signs of health fraud:

- Promises of an "easy" fix for problems like excess weight, hair loss, or impotency.
- Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient," and "ancient remedy."
- Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight loss product.
- Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results.
- Promises of no-risk, money-back guarantees.

If you have concerns regarding the safety of an OTC weight loss supplement,

see the list of contaminated weight loss products and their undeclared ingredients that have been identified by the FDA.

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