

Beware of Products Promising Miracle Weight Loss

“This year, I’m going to lose some weight.”

If you find yourself making this common New Year’s resolution, know this: many so-called “miracle” weight loss supplements and foods (including teas and coffees) don’t live up to their claims. Worse, they can cause serious harm, say FDA regulators. The agency has found hundreds of products that are marketed as dietary supplements but actually contain hidden active ingredients (components that make a medicine effective against a specific illness) contained in prescription drugs, unsafe ingredients that were in drugs that have been removed from the market, or compounds that have not been adequately studied in humans.

“When the product contains a drug or other ingredient which is not listed as an ingredient we become especially concerned about the safety of the product,” says James P. Smith, M.D., an acting deputy director in FDA’s Office of Drug Evaluation.

Tainted Products

For example, FDA has found weight-loss products tainted with the prescription drug ingredient sibutramine. This ingredient was in an



FDA-approved drug called Meridia, which was removed from the market in October 2010 because it caused heart problems and strokes.

“We’ve also found weight-loss products marketed as supplements that contain dangerous concoctions of hidden ingredients including active ingredients contained in approved seizure medications, blood pressure medications, and antidepressants,” says Jason Humbert, a senior regulatory manager at FDA. Most recently, FDA has found a number of products marketed as dietary

supplements containing fluoxetine, the active ingredient found in Prozac, a prescription drug marketed for the treatment of depression and other conditions. Another product contained triamterene, a powerful diuretic (sometimes known as “water pills”) that can have serious side-effects and should only be used under the supervision of a health care professional.

Many of these tainted products are imported, sold online, and heavily promoted on social media sites. Some can also be found on store shelves.

FDA has received numerous reports of harm associated with the use of weight loss products, including increased blood pressure, heart palpitations (a pounding or racing heart), stroke, seizure and death.

And if you're about to take what you think of as "natural" dietary supplements, such as bee pollen or Garcinia cambogia, you should be aware that FDA has found some of these products also contain hidden active ingredients contained in prescription drugs.

"The only natural way to lose weight is to burn more calories than you take in," says James P. Smith, M.D. That means a combination of healthful eating and physical activity.

Dietary Supplements are not FDA-Approved

Under the Federal Food, Drug and Cosmetics Act (as amended by the Dietary Supplement Health and Education Act of 1994), dietary supplement firms do not need FDA approval prior to marketing their products. It is the company's responsibility to make sure its products are safe and that any claims made about such products are true.

But just because you see a supplement product on a store shelf does not mean it is safe, Humbert says. FDA has received numerous reports of harm associated with the use of weight loss products, including increased blood pressure, heart palpitations (a pounding or racing heart), stroke, seizure and death. When safety issues are suspected, FDA must investigate and, when warranted, take steps to have these products removed from the market.

FDA has issued over 30 public notifications and recalled 7 tainted weight loss products in 2014. The agency also has issued warning letters, seized products, and criminally prosecuted people responsible for marketing these illegal diet products. In addition,

FDA maintains an online list of tainted weight-loss products (www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm).

To help people with long-term weight management, FDA has approved prescription drugs such as Belviq, Qysmia, and Contrave, but these products are intended for people at least 18 years of age who:

- have a body mass index (BMI, a standard measure of body fat) of 30 or greater (considered obese); or
- have a BMI of 27 or greater (considered overweight) and have at least one other weight-related health condition.

Moreover, if you are going to embark on any type of weight control campaign, you should talk to your health care professional about it first, Smith says.

Know the Warning Signs

Look for potential warning signs of tainted products, such as:

- promises of a quick fix, for example, "lose 10 pounds in one week."
- use of the words "guaranteed" or "scientific breakthrough."
- products marketed in a foreign language.
- products marketed through mass e-mails.
- products marketed as herbal alternatives to an FDA-approved drug or as having effects similar to prescription drugs.

Advice for Consumers

Generally, if you are using or considering using any product marketed as

a dietary supplement, FDA suggests that you:

- check with your health care professional or a registered dietitian about any nutrients you may need in addition to your regular diet.
- ask yourself if it sounds too good to be true.
- be cautious if the claims for the product seem exaggerated or unrealistic.
- watch out for extreme claims such as "quick and effective" or "totally safe."
- be skeptical about anecdotal information from personal "testimonials" about incredible benefits or results from using a product.

If you suspect a product marketed as a dietary supplement sold online may be tainted, FDA urges you to report that information online (www.fda.gov/Safety/ReportAProblem/ucm059315.htm). You or your health care professional can also report an illness or injury you believe to be related to the use of a dietary supplement by calling 1-800-FDA-1088 or visiting FDA online (www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm).

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