

## **Dietary Weight-Loss Supplements — What the Labels Don't Tell You** By Lisa S. Brown, PhD, RD, LDN

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The use of dietary weight-loss supplements is common in the United States as consumers search for ways to combat expanding waistlines. In 2011, US consumers spent more than \$30 billion on dietary supplements, including those intended to promote weight loss.<sup>1</sup> A 2008 study found that 34% of people making a serious attempt to lose weight had tried dietary weight-loss supplements. Also, those more likely to use such supplements are women, individuals aged 25 to 34, blacks, Hispanics, individuals in lower income households, and individuals with less education.<sup>2</sup>

Many consumers believe that weight-loss supplements available for purchase in the United States must be safe and effective. Most don't know that supplements aren't regulated as strictly as prescription medications, and that many supplements are both ineffective and potentially unsafe. In one survey, approximately one-half of respondents believed that the FDA evaluated the safety and efficacy of supplements, and approximately two-thirds assumed that the government required supplements to list warnings about potential side effects on their labels.<sup>2</sup> Only one-third of consumers using weight-loss supplements reported discussing the use with a health professional.<sup>3</sup>

Dietitians play a key role in helping consumers understand the risks of using dietary weight-loss supplements and how they differ from regulated medications. To that end, this continuing education course reviews the basic regulatory issues pertaining to dietary weight-loss supplements, the ingredients commonly used in these supplements, and new concerns regarding contamination. It also provides a brief overview of FDA-approved dietary weight-loss supplements.

### **FDA Regulation**

In the United States, most weight-loss pills are regulated as dietary supplements. The FDA defines a dietary supplement as "a product ... intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient mentioned above."<sup>4</sup>

Although supplements often are sold in pill form, they're regulated as food, not as medication. In contrast to its role pertaining to over-the-counter and prescription medications, the FDA can't require supplement manufacturers to prove a product's safety and efficacy before distribution. Supplements can be marketed without any documented scientific evidence

proving that they work and are safe as long as they don't contain any ingredients that weren't on the market as of October 15, 1994.<sup>5</sup>

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). This legislation placed the onus of ensuring supplement safety on a product's manufacturer before it offers a product for sale, but it grants the FDA power to investigate a product associated with reports of adverse events and prohibit its sale if safety concerns warrant such action.<sup>6</sup> Regulation is markedly different from that of over-the-counter and prescription medications, for which manufacturers must extensively prove both safety and efficacy first on animals and then on humans.<sup>7</sup>

Once approved by the FDA and put on the market, a medication goes into a phase 4 trial intended to monitor its long-term safety. The manufacturer must collect reports of adverse events and disclose them to the FDA. If enough adverse events are reported, the FDA may conduct its own investigation and may choose to ban the medication from the market depending on its findings.

In contrast, supplement manufacturers don't need to test the safety and efficacy of their products before distributing them to consumers and need to comply only with postmarket testing similar to the phase 4 trial of medications. Even that level of monitoring has been required only since 2007.<sup>7</sup>

The Dietary Supplement and Nonprescription Drug Consumer Protection Act was passed in 2006 as an amendment to the Federal Food, Drug, and Cosmetic Act. This amendment set in place requirements for nonprescription drug companies and supplement manufacturers to collect and report adverse events related to their products' use.<sup>7</sup> For the purposes of removing a product from the market, the term "serious adverse event" is defined as including a life-threatening experience possibly resulting in death, inpatient hospitalization, a persistent or significant disability or incapacity, or congenital anomaly or birth defect.<sup>7</sup> The 2006 law also mandates that the product label contain the name and address of the manufacturer or distributor responsible for collecting information about adverse events caused by a supplement.

The manufacturer must report serious adverse events to the FDA no more than 15 business days after learning of those events.<sup>8</sup> The FDA may remove a product if the agency can conclude there's a direct link to reported serious adverse events. Several events must be reported to trigger an investigation, and then the FDA may decide whether there's enough evidence that the supplement caused the events and remove the product from the market.

While this process has led to the removal of at least one product—the original formulation of the weight-loss supplement Hydroxycut, which will be discussed further below—consumer advocates believe many adverse events go unreported and many unsafe products remain on the market. Most consumers are unaware of the reporting process, while others may associate adverse events with concurrent prescription use rather than supplement use.<sup>9</sup>

The DSHEA also grants the FDA some authority over product labeling. Supplement labels are required to list all active and inactive ingredients, but even these minimal requirements aren't followed consistently. A 2007 study found that only 84% of the supplement labels examined included all active ingredients, and less than 50% contained all inactive ingredients.<sup>10</sup> A 2013 Canadian study found that out of 44 herbal supplements tested, 59% of the products had incorrect labels, meaning they contained ingredients not listed. Of the 44 products, 32% contained substitute ingredients defined as unlisted ingredients added to the product in place of a listed ingredient, which was omitted from that batch, and 21% contained fillers that were known allergens such as wheat, rice, and soy.<sup>11</sup>

The DSHEA clarified the FDA's role in regulating supplements, and amendments to the DSHEA have since strengthened the act and given the FDA more power to ban supplements before marketing. However, the amendments didn't give the FDA the authority to regulate supplements in the way many consumer advocates wanted.

One added provision to the DSHEA is the Current Good Manufacturing Practices (cGMPs), which set forth specific mandatory quality-control measures during the manufacturing and distribution process for all domestic and foreign companies that distribute products in the United States. The cGMPs include standards for plant design, manufacturing operations, final product testing, records maintenance, and processes for handling consumer complaints. The FDA can ban companies that don't meet the cGMPs.<sup>6</sup>

In addition to the FDA, the Federal Trade Commission (FTC) has limited jurisdiction over dietary supplements. The FTC can sanction companies that make unsubstantiated claims regarding their products' effectiveness in advertisements and ban them from selling their products in the United States.<sup>12</sup>

While the current regulatory process provides some consumer protections, supplements remain "buyer beware" items.

### **Categories of Supplements and Common Ingredients**

Widespread supplement use is a concern because many products contain ingredients that may be dangerous for susceptible individuals or can become dangerous in combination with other ingredients. Individuals with cardiovascular problems may experience adverse effects from dietary weight-loss supplements, as many products cause increased metabolism, which stresses the circulatory system.

Other such supplements interfere with appetite and may cause issues for individuals with thyroid problems or conditions that affect the body's hormonal function. And some supplements may disrupt normal nutrient absorption and metabolism, causing problems for individuals with diabetes and other metabolic abnormalities.

Based on their mechanisms of action, dietary weight-loss supplements and ingredients can be classified in the following categories: stimulants/metabolism boosters, appetite suppressants, and ingredients that alter the metabolism of specific nutrients.

### ***Stimulants/Metabolism Boosters***

The most common class of ingredients added to weight-loss supplements are stimulants, which are meant to boost the metabolic rate. The most infamous stimulant, *Ephedra sinica*, also known as ma huang, modestly impacts short-term weight loss when combined with caffeine (about 1 kg/month); no long-term trials are available.<sup>13</sup>

In 2002, Health Canada banned the sale of products containing ephedra amid growing concerns that those containing the caffeine/ephedra combination caused serious cardiovascular events. The FDA followed suit in the United States in 2004.

After issuing warning statements regarding ephedra's safety, the FDA ruled that recent studies "confirmed that ephedra use raises blood pressure and otherwise stresses the circulatory system, effects that have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes."<sup>14</sup>

Bitter orange extract (*Citrus aurantium*) was used in weight-loss supplements before the ban on ephedra, but it became more widely used after the ban as a substitute ingredient in ephedra-free products. It contains synephrine, which is similar to ephedrine and may boost metabolic rate while also suppressing appetite.

While the FDA still allows bitter orange to be used in weight-loss supplements, there have been concerns that it may be unsafe in a similar manner as ephedra. A well-known 2006 study tested a single dose of bitter orange on a group of 15 young healthy adults and found that it elevated blood pressure and heart rate for up to five hours.<sup>15</sup>

However, other studies using lower doses of the extract haven't found adverse effects on blood pressure and heart rate. A 2012 review looked at 23 studies involving 360 overweight/obese and normal-weight individuals and found that bitter orange alone or in combination with other ingredients didn't appear to raise blood pressure or heart rate in subjects who consumed it for up to 12 weeks.<sup>16</sup> The authors of the review stressed that studies finding adverse effects used very high doses.

While it appears from this review that bitter orange likely is safe to use for up to 12 weeks, it isn't clear whether it leads to clinically meaningful weight loss. Most studies reviewed in this paper found no weight-loss difference between the treatment and placebo groups, and of those who did lose weight, the biggest difference was 1.4 kg (3.1 lbs) over the course of eight weeks.<sup>16</sup>

Caffeine is another common stimulant and exists naturally in foods such as coffee, tea, guarana, and yerba mate, which are ingredients commonly used in weight-loss supplements. The FDA sets limits on the levels of isolated caffeine added to soft drinks and alcohol but sets no limit for dietary supplements, including energy drinks and weight-loss supplements.

Caffeine is believed to influence weight loss by increasing energy output and suppressing appetite; however, little research has been done on caffeine's long-term effects on weight loss. Some evidence suggests that caffeine increases weight loss when combined with other ingredients. Several studies have found an impact from caffeine in combination with other agents, such as ephedra and green tea extract. But concerns remain regarding the safety of these combinations given the known hazard of the ephedra/caffeine mixture.<sup>17</sup>

Individuals taking a weight-loss supplement should be screened for habitual caffeine intake from all sources and cautioned that the combination of the supplement and caffeine could be dangerous.

Green tea extract commonly is included in weight-loss formulas either as a source of caffeine or for its catechin known as epigallocatechin gallate (EGCG). An antioxidant, EGCG inhibits the breakdown of norepinephrine, which acts as a hormone and neurotransmitter in the central nervous system. Maintaining higher circulating norepinephrine increases both body thermogenesis and fat oxidation and therefore increases metabolic rate.

Several countries, including France and Spain, have banned green tea extract because of concerns about hepatotoxicity. The United States evaluated green tea extract but didn't pursue further action after a 2008 review found that the extract didn't appear to increase liver damage when used properly.<sup>18</sup>

In addition to lingering safety concerns, it's unclear whether green tea extract markedly impacts human weight loss. Research supporting its efficacy primarily comes from animal studies. A 2012 Cochrane review found no statistically significant benefit for consuming green tea extract for weight loss in humans.<sup>19</sup>

### ***Appetite Suppressants***

Many dietary weight-loss supplements contain ingredients that boost metabolism and influence appetite at the same time. There have been a few high-profile supplements on the market in the past few years that target only appetite, though, and these products often are marketed as safer alternatives for weight loss.

Hoodia is a succulent plant native to southern Africa and a featured ingredient commonly promoted as suppressing appetite. Of the many types of hoodia, only *Hoodia gordonii* contains P57, the active ingredient associated with appetite reduction. P57 appears to act on the hypothalamus portion of the brain, increasing adenosine-5'-triphosphate (ATP) in nerve cells, which sends satiety signals that cause individuals to feel as if they've just eaten.<sup>20</sup>

Although advertisements about hoodia's purported weight-loss benefits also claim that such products cause no side effects, current research suggests otherwise. There have been no randomized controlled trials involving humans and only insufficient data with which to understand dose, duration, and short- or long-term safety.<sup>21</sup> One of the few studies comparing hoodia with a placebo in women found similar amounts of weight loss, but the group consuming the hoodia reported significantly more nausea and vomiting.<sup>22</sup>

There also are concerns about potential complications related to long-term hoodia use. Since hoodia acts on the hypothalamus, which also regulates thirst and body temperature, its use may lead to dehydration as a result of suppressed thirst. Other concerns have surfaced regarding the impact of hoodia on liver function and blood sugar control. No studies are available to determine safety in this regard.

Even if hoodia were safe and effective, production would be limited based on availability. Hoodia is a rare and protected plant in most of the countries where it grows, and it takes many years to mature. Because of the difficulty in obtaining true *Hoodia gordonii* (pure plant form), it's likely that most products advertised are counterfeit or contain a nonactive form. Over the past several years, the FTC has banned several manufacturers from selling hoodia in the United States because of false claims that their product contained *Hoodia gordonii* or a lack of compliance with good manufacturing processes.<sup>23</sup>

Another appetite suppressant, Sensa, which was created and marketed by neurologist Alan Hirsch, MD, consists of small particles called tastants that are sprinkled on food to enhance the smell. In theory, by enhancing the smell, it will cause individuals to reach satiety earlier.

Hirsch presented his research at the 2008 annual meeting of the National Endocrine Society. Individuals in Hirsch's study lost an average of 30 lbs in six months without changing their diet or lifestyle. This study was never published in a peer-reviewed journal and hasn't been duplicated by independent researchers. Furthermore, the study presented to the Endocrine Society involved the use of an inhaled version of the product and had a select subject population. This group primarily was female (87.4%) and borderline obese. The study group of 1,436 was compared with a control group of approximately 100 subjects. The trial used a convenience sample and wasn't a randomized controlled design.<sup>24</sup>

Sensa is made with both milk and soy, so allergic reactions may occur in sensitive individuals. Beyond the disclosed allergens, Sensa also contains a natural food dye known as carmine or natural red 4, which can cause anaphylaxis in susceptible people. Other more common reactions noted in customer product reviews appearing on Amazon.com include loose and frequent stools, upset stomach, gas, bloating, and dizziness.

### ***Supplements That Change Nutrient Absorption and Metabolism***

While the majority of weight-loss supplements on the market either boost metabolism or suppress appetite, several products available are intended to alter the process of nutrient absorption and/or subsequent metabolism.

Advertised as a "fat magnet," chitosan is used to block fat absorption in the intestine. While there's evidence that this indigestible polysaccharide derived from lobster, crab, and shrimp shells may block some fat absorption in the gut, it appears that the amount present in dietary supplements is too low to significantly impact weight. A 2008 Cochrane review found that when studies of higher quality and longer duration were examined, chitosan minimally impacted body weight.<sup>25</sup>

Individuals wishing to try chitosan should be alerted that it's derived from shellfish and can be problematic for those with allergies. Another potential side effect is gastrointestinal upset based on nutrient malabsorption. Fat-soluble vitamin absorption also should be assessed in individuals using this product, since many of the fat-soluble vitamins will pass through the digestive track bound to fat attached to the chitosan.

Chromium picolinate supposedly promotes weight loss by altering carbohydrate metabolism. A 2013 review and meta-analysis that looked at 20 human trials found a statistically significant reduction of body weight in individuals who took chromium compared with a placebo. However, the authors questioned its clinical significance given the mere 0.5-kg (1.1-lb) difference from the placebo. Moreover, several adverse side effects were attributed to the chromium supplements, including watery stool, vertigo, headaches, and urticaria (commonly known as hives).<sup>26</sup>

Conjugated linoleic acid, a fatty acid commonly found in beef and dairy, has lipogenesis-suppression properties. It causes a decrease in the formation of adipose cells and progression of preadipose cells to mature adipose cells. In addition, it may decrease appetite by acting on the hypothalamus.

Rodent studies using conjugated linoleic acid have shown improved body composition with more lean body mass and less free fat mass. However, a 2010 review found that human studies don't show similar results. The authors theorized that dose was the major difference between the animal and human studies. They also raised a concern that conjugated linoleic acid increases the amount of free fatty acids in the blood and could be problematic for individuals who don't burn the increased fuel provided by the fatty acids for physical activity, thereby resulting in hyperlipidemia, hyperglycemia, and lipodystrophy (disturbance of fat metabolism causing fat to distribute in an abnormal pattern).<sup>27</sup>

A 2012 review and meta-analysis found that among well-designed human studies lasting at least six months, there was no clinically relevant impact on weight loss—only a 1.3-kg (2.9-lb) additional weight loss in the treatment group—and body composition.<sup>28</sup>

Green coffee bean extract comes from raw, unprocessed green coffee beans and contains the antioxidant chlorogenic acid, which appears to disrupt the glucose 6 phosphatase enzyme and reduce the amount of glucose absorbed in the gut. It gained popularity in 2012 when it was featured on ***The Dr. Oz Show***. Host Mehmet Oz, MD, had two groups of women either take a placebo or green coffee bean extract for two weeks. The group taking the coffee bean extract lost an average of 2 lbs per person compared with the placebo group, which lost 1 lb.

A 2011 meta-analysis found in three high-quality human studies that green coffee bean extract had a statistically significant impact on weight loss but only a modest clinical impact: approximately 2.5 kg (5.5 lbs) over six weeks.<sup>29</sup>

Safety concerns remain for this supplement based on a 2013 rodent study investigating chlorogenic acid combined with a high-fat diet. The study found no impact on weight in mice that took it for 12 weeks, but the mice on a high-fat diet developed early changes associated with diabetes, including decreased insulin sensitivity and higher blood sugar levels between meals.<sup>30</sup>

## **Products**

In addition to looking at the individual ingredients in dietary weight-loss supplements, the actual production formulations also may be important because of interactions between ingredients that change the effect of individual components. Weight-loss products continually are coming in and out of the marketplace and often contain ingredients that may interact and cause problems. Currently, a reformulation of Hydroxycut, Xenadrine, Zantrex-3, and Herbalife are well-known and widely available products, but their longevity doesn't necessarily mean they're safe. Case reports suggest an association with adverse side effects for all of these products.

There's a suggested association between Xenadrine EFX, which contains caffeine, guarana, and bitter orange, with headaches, high blood pressure, vasospasm, and stroke.<sup>31,32</sup> Twenty case reports between 2003 and 2010 suggest an association between liver damage and Herbalife.<sup>33</sup> One case report indicates that a woman suffered blurred vision and seizures after using Zantrex-3 for more than two months; the product contains caffeine, niacin, and different herbs.<sup>34</sup> The seizures stopped with product discontinuation.

## **Hydroxycut: A Case Study**

One of the best-known, widely advertised and used dietary weight-loss products on the market is Hydroxycut. Its evolution provides insight into how the supplement market has adapted to FDA oversight.

Hydroxycut has undergone two major reformulations in response to safety concerns. In 2004, Hydroxycut voluntarily removed its ephedra-containing product from the market when the FDA announced the ban on ephedra. It introduced an ephedra-free formula almost immediately, which remained on the market until 2009.

In May 2009, the FDA warned consumers to stop using the new Hydroxycut formulation because of 23 complaints of liver injury associated with its use.<sup>35</sup> Other reported side effects included seizures and cardiovascular problems.

In 2010, a case report discussed a 63-year-old woman who presented with atrial fibrillation symptoms after using Hydroxycut for two weeks. The ingredient EGCG was cited as the suspected causative component, which may have blocked a potassium channel.<sup>36</sup>

The manufacturer of Hydroxycut voluntarily reformulated its products again after the 2009 warning. Most of the current formulas contain a blend of four herbs: Lady's mantle extract (*Alchemilla vulgaris*), wild olive extract (*Olea europaea*), Komijn extract (*Cuminum cyminum*), and wild mint extract (*Mentha longifolia*). Research on the efficacy of the four-herb blend by Lovate, the maker of Hydroxycut, found that individuals who took Hydroxycut in an eight-week



trial lost an average of 16.5 lbs compared with those in the placebo group, who lost an average of 2.1 lbs. A similar unpublished study done on Weightlevel, which contains the same blend of herbs, found similar results.<sup>37</sup>

Although the new formulations of Hydroxycut appear to be somewhat effective in inducing weight loss compared with a placebo, questions remain regarding safety. A 2013 case report documented a case of ischemic colitis connected with Hydroxycut use.<sup>38</sup>

### **FDA-Approved Prescription Weight-Loss Medications**

One reason for the widespread use of over-the-counter dietary weight-loss supplements may be a lack of prescription medications. Those that are available are limited in efficacy, may produce serious side effects, and may be contraindicated for the individuals who need them most based on medical comorbidities.

Four FDA approved prescription weight-loss medications are available: phentermine; phentermine and topiramate extended release (Qsymia); orlistat (Xenical), and lorcaserin (Belviq). There also are two others in late-stage trials: liraglutide injection (Victoza) and bupropion/naltrexone (Contrave).

Orlistat is the only obesity medication currently approved by the FDA for long-term use. Orlistat and its lower-dose over-the-counter version known as alli reduce fat absorption in the gut by about 25%.<sup>39</sup> Studies have shown modest weight loss with these products but, clinically speaking, it's significantly greater than with placebo. The use of alli resulted in 4.4-kg (9.7-lb) vs. 2.1-kg (4.6-lb) weight loss with placebo over six months.

Despite experiencing weight-loss benefits, at least 10% of those taking orlistat reported adverse effects, including oily spotting, flatus with discharge, fecal urgency, fatty oily stool, oily evacuation, flatulence, and soft stools. A smaller percentage reported abdominal pain, fecal incontinence, increased defecation, and liquid stools. These effects were more likely when individuals consumed a higher-fat meal. Because orlistat also affects the absorption of fat-soluble vitamins, dietitians will need to discuss its use and address this problem with any clients using the product.

Phentermine is the oldest FDA-approved weight-loss medication on the market and is approved for short-term use in patients who are obese.<sup>40</sup> It's a stimulant medication similar to amphetamine and acts as an anorectic by reducing appetite. Short-term studies show modest effects when used as monotherapy. However, longer-term studies show the body eventually adapts, and the drug loses its effect.<sup>41</sup>

Phentermine generally is more successful for achieving significant weight loss when combined with other agents. In the 1990s, its popularity increased as one-half of the drug combination known as Fen-Phen. In 1997, fenfluramine, the "fen" part of the combination, a metabolism booster, was removed from the market following 24 reported cases of heart valve problems.<sup>42</sup> Despite its continued FDA approval, phentermine has known side effects and is contraindicated for individuals with cardiovascular disease.

The newly approved weight-loss medication Qsymia contains a combination of phentermine and the anticonvulsant drug topiramate (Topamax). The initial clinical trials used to prove the combination's efficacy found the new drug led to a mean weight loss of at least 10% of baseline weight, which was sustained for up to two years in more than 50% of subjects.<sup>43</sup> Phentermine and topiramate extended release is contraindicated in individuals with hypothyroid and glaucoma, and should be used with caution in those with cardiovascular risk factors, as it may increase heart rate.

Along with phentermine and topiramate extended release, lorcaserin was approved by the FDA in 2012 for short-term weight loss.<sup>44</sup> It activates the serotonin 2C receptor in the brain, which induces a feeling of satiety. According to the FDA's report, approximately 50% of subjects in clinical trials lost up to 5% of their body weight in 12 weeks. Side effects included issues with attention, headache, nausea, fatigue, and constipation.

Sibutramine (Meridia) was approved until 2010 when the FDA removed it from the market because of safety concerns.<sup>45</sup> A literature review suggested that sibutramine increased heart rate and blood pressure, thus increasing the risk of cardiovascular events. Ceasing production of the drug was controversial because it was effective for modest weight loss, leading to improvements in insulin resistance, glucose metabolism, and dyslipidemia.

### **Supplement Contamination or Mislabeled**

While concerns about the safety of the known ingredients should cause most individuals to question the use of weight-loss supplements, a more recent issue regarding the contamination of supplements with prescription medications should be of even greater concern.

A 2013 study analyzed the composition of nine supplements. The researchers found that three contained the now banned weight-loss drug sibutramine, three contained caffeine, and three contained both caffeine and the anti-anxiety medication temazepam (Restoril). These products were marketed as all natural and purely herbal, and these ingredients weren't declared on the label.<sup>46</sup>

A 2009 study analyzed the active ingredients of a diet supplement purchased over the Internet that led to the death of a woman in her mid-40s. In addition to prescription weight-loss medications, the supplement contained prescription diuretics, antiseizure medications, and antidepressants. Some of the ingredients included phentermine, acetaminophenol, phenobarbital, chlorpheniramine, sibutramine, diazepam (Valium), mazindol, hydrochlorothiazide, fluoxetine (Prozac), and furosemide (Lasix).<sup>47</sup> While these medications can benefit certain individuals, consumers must be aware of what ingredients dietary supplements contain, and their use of these products must be monitored by a physician.

### **In Conclusion**

Given the rise of obesity, many individuals may experiment with dietary weight-loss supplements for a quick, easy fix yet are unaware of the associated risks. Unlike medications, weight-loss supplements are regulated as dietary supplements, a process that doesn't require clinical trials to assess their efficacy or safety before marketing. The FDA can remove weight-loss supplements after marketing only when they're proven harmful to consumers.

While most dietary weight-loss supplements don't offer impressive weight-loss benefits, many can cause harmful side effects, and those most at risk of experiencing adverse effects may be those who are most inclined to try them based on their desire to achieve the weight-loss benefits promoted by the product.

Supplements' weight-loss benefits generally are equal to or less effective than prescription medications and, unlike medications, supplements are poorly monitored by regulatory agencies for purity and consistency of ingredients, making them more dangerous to consumers.

Given the known side effects of supplements and FDA-approved weight-loss medications, supervision is essential to protect consumers, as many who take dietary weight-loss supplements likely aren't being monitored by the appropriate medical professional. Dietitians should work to ensure their clients and patients understand the risks associated with dietary weight-loss supplements.

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[Click here](#) for the patient handout "Information for Using a Nonprescription Weight-Loss Supplement."

[Click here](#) for a screening form for individuals using weight-loss supplements.

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## Examination

**1. A patient assumes that dietary weight-loss supplements, such as green coffee bean extract, and over-the-counter medications, including acetaminophen and pseudoephedrine, are regulated in the same manner. As an RD, how would you explain the current regulation of supplements?**

- A. Supplements must go through rigorous animal and human trials before they're marketed.
- B. It's the manufacturer's responsibility to apply for FDA approval before marketing.
- C. The FDA has the power to remove products after marketing only if the agency can prove the products have caused serious adverse events.
- D. The FDA can remove products after marketing if the agency can prove the products provide no benefit to the consumer.

**2. The FDA requires which of the following types of information to be printed on weight-loss supplement labels?**

- A. A list of active and inactive ingredients as well as the manufacturer's name and address
- B. Risks and side effects associated with using the supplement
- C. Date of FDA approval
- D. A description of the proper use of the supplement

**3. Members of which of the following groups of people tend to use weight-loss supplements most often?**

- A. Men
- B. Older adults
- C. College-educated adults
- D. Blacks

**4. Weight-loss supplements use different mechanisms of action in the body to elicit weight loss. Among the different types, which is the most common class of ingredients in weight-loss supplements?**

- A. Stimulants
- B. Nutrient metabolism changers
- C. Appetite suppressants
- D. Diuretics

**5. Certain stimulants, such as ephedra, have been removed from the market because of health concerns. What is the major concern associated with this class of ingredients?**

- A. Dehydration
- B. Cardiovascular events
- C. Vitamin deficiency
- D. Nausea or vomiting



**6. Weight-loss supplement ingredients can be classified based on their functional mechanism. How would you classify conjugated linoleic acid?**

- A. Stimulant
- B. Nutrient metabolism changer
- C. Appetite suppressant
- D. Diuretic

**7. An overweight patient with a soy allergy seeks advice about using Sensa, a well-known weight-loss supplement intended to suppress appetite. As an RD, how would you advise this patient?**

- A. Start using it. Studies show that individuals lost weight even without altering their lifestyles.
- B. Sensa is made with milk and soy, so people with these allergies should avoid using it.
- C. It's safe. Although there are no published trials to date, there's no evidence regarding adverse reactions.
- D. Start using the supplement but monitor whether you experience any negative side effects.

**8. How would you advise a patient looking to take weight-loss supplements containing caffeine?**

- A. People drink caffeine every day, so these supplements are safe to use.
- B. The FDA sets limits on the amount of caffeine added to supplements to ensure safety.
- C. There's extensive research on caffeine's long-term benefits and safety for weight loss.
- D. High levels of caffeine combined with other ingredients can cause adverse effects.

**9. A patient asks you whether it's safe to take a supplement found on the Internet that claims to be all natural. How would you advise this patient?**

- A. The FDA strictly regulates the use of the term "all natural," so the product is safe.
- B. Prescription medications and other undeclared ingredients sometimes have been found in certain all-natural products.
- C. The FDA strictly regulates products sold on the Internet, so the product is safe.
- D. Take the supplement but be alert to negative side effects.

**10. Which of the following is the only FDA-approved weight-loss medication approved for long-term use (more than six months)?**

- A. Phentermine
- B. Xenical (Orlistat)
- C. Phentermine and topiramate extended release (Qsymia)
- D. Lorcaserin (Belviq)