FDA 101: Dietary Supplements

The law defines dietary supplements in part as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.

Dietary supplements come in many forms, including tablets, capsules, powders, energy bars, and liquids. These products are available in stores throughout the United States, as well as on the Internet. They are labeled as dietary supplements and include among others

- vitamin and mineral products
- "botanical" or herbal products—These come in many forms and may include plant materials, algae, macroscopic fungi, or a combination of these materials.
- amino acid products—Amino acids are known as the building blocks of proteins and play a role in metabolism.
- enzyme supplements—Enzymes are complex proteins that speed up biochemical reactions.

People use dietary supplements for a wide assortment of reasons. Some seek to compensate for diets, medical conditions, or eating habits that limit the intake of essential vitamins and nutrients. Other people look to them to boost energy or to get a good night's sleep. Postmenopausal women consider using them to counter a sudden drop in estrogen levels.

Talk with a Health Care Professional

The Food and Drug Administration (FDA) suggests that you consult with a health care professional before using any dietary supplement. Many supplements contain ingredients that have strong biological effects, and such products may not be safe in all people.

If you have certain health conditions and take these products, you may be putting yourself at risk. Your health care professional can discuss with you whether it is safe for you to take a particular product and whether the product is appropriate for your needs. Here is some general advice:

- **Dietary supplements are not intended to treat, diagnose, cure, or alleviate the effects of diseases.** They cannot completely prevent

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Photo Illustration: FDA/Michael Ermarth

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diseases, as some vaccines can. However, some supplements are useful in reducing the risk of certain diseases and are authorized to make label claims about these uses. For example, folic acid supplements may make a claim about reducing the risk of birth defects of the brain and spinal cord.

- **Using supplements improperly can be harmful.** Taking a combination of supplements, using these products together with medicine, or substituting them in place of prescribed medicines could lead to harmful, even life-threatening, results.
- **Some supplements can have unwanted effects before, during, or after surgery.** For example, bleeding is a potential side effect risk of garlic, ginkgo biloba, ginseng, and Vitamin E. In addition, kava and valerian act as sedatives and can increase the effects of anesthetics and other medications used during surgery. Before surgery, you should inform your health care professional about all the supplements you use.

How Are Supplements Regulated?

You should know the following if you are considering using a dietary supplement.

- Federal law requires that every dietary supplement be labeled as such, either with the term "dietary supplement" or with a term that substitutes a description of the product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or "calcium supplement").
- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or truthful before it appears on the product.
- In general, FDA's role with a dietary supplement product begins after the product enters the marketplace. That is usually the agency's first opportunity to take action against a product that presents a significant or unreasonable risk of illness or injury, or that is otherwise adulterated or misbranded.
- Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the Federal Trade Commission.
- Once a dietary supplement is on the market, FDA has certain safety monitoring responsibilities. These include monitoring mandatory reporting of serious adverse events by dietary supplement firms and voluntary adverse event reporting by consumers and health care professionals. As its resources permit, FDA also reviews product labels and other product information, such as package inserts, accompanying literature, and Internet promotion.
- Dietary supplement firms must report to FDA any serious adverse events that are reported to them by consumers or health care professionals.
- Dietary supplement manufacturers do not have to get the agency's approval before producing or selling these products.
- It is not legal to market a dietary supplement product as a treatment or cure for a specific disease, or to alleviate the symptoms of a disease.
- There are limitations to FDA oversight of claims in dietary supplement labeling. For example, FDA reviews substantiation for claims as resources permit.

Are Supplements Safe?

Many dietary supplements have clean safety histories. For example, millions of Americans responsibly consume multi-vitamins and experience no ill effects.

Some dietary supplements have been shown to be beneficial for certain health conditions. For example, the use of folic acid supplements by women of childbearing age who may become pregnant reduces the risk of some birth defects.

Another example is the crystalline form of vitamin B12, which is beneficial in people over age 50 who often have a reduced ability to absorb naturally occurring vitamin B12. But further study is needed for some other

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dietary supplements.

Some supplements have had to be recalled because of proven or potential harmful effects. Reasons for these recalls include

- microbiological, pesticide, and heavy metal contamination
- absence of a dietary ingredient claimed to be in the product
- the presence of more or less than the amount of the dietary ingredient claimed on the label

In addition, unscrupulous manufacturers have tried to sell bogus products that should not be on the market at all.

Before taking a dietary supplement, make sure that the supplement is safe for you and appropriate for the intended purpose.

Be a Safe and Informed Consumer

- Let your health care professional advise you on sorting reliable information from questionable information.
- Contact the manufacturer for information about the product you intend to use.
- Be aware that some supplement ingredients, including nutrients and plant components, can be toxic. Also, some ingredients and products can be harmful when consumed in high amounts, when taken for a long time, or when used in combination with certain other drugs, substances, or foods.
- Do not self-diagnose any health condition. Work with health care professionals to determine how best to achieve optimal health.
- Do not substitute a dietary supplement for a prescription medicine or therapy, or for the variety of foods important to a healthful diet.
- Do not assume that the term "natural" in relation to a product ensures that the product is wholesome or safe.
- Be wary of hype and headlines. Sound health advice is generally based upon research over time, not a single study.
- Learn to spot false claims. If something sounds too good to be true, it probably is.

Report Problems

Adverse effects with dietary supplements should be reported to FDA as soon as possible. If you experience such an adverse effect, contact or see your health care professional immediately. Both of you are then encouraged to report this problem to FDA. For information on how to do this, go to *www.cfsan.fda.gov/~dms/ds-rept.html*.

Adverse effects can also be reported to the product's manufacturer or distributor through the address or phone number listed on the product's label. Dietary supplement firms are required to forward reports they receive about serious adverse effects to FDA within 15 days.

For a general, nonserious complaint or concern about dietary supplements, contact your local FDA District Office (*www.cfsan.fda.gov/~dms/district.html*).

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

For More Information

Protect Your Health
Joint FDA/WebMD resource
www.webmd.com/fda

Fortify Your Knowledge About Vitamins
www.fda.gov/consumer/updates/vitamins111907.html

Tips for the Savvy Supplement User: Making Informed Decisions
www.fda.gov/fdac/features/2002/202_supp.html

Overview of Dietary Supplements
www.cfsan.fda.gov/~dms/ds-oview.html#what

Food Labeling and Nutrition
www.cfsan.fda.gov/label.html

Final Rule Promotes Safe Use of Dietary Supplements
www.fda.gov/consumer/updates/dietarysupps062207.html