How are Dietary Supplements Regulated?

Under the Dietary Supplement Health and Education Act (DSHEA), companies are responsible for ensuring that the dietary supplements they sell are safe and properly labeled. Unlike drugs, FDA does not have the authority to approve dietary supplements or their labeling before they are sold to the public. In fact, companies can often introduce a dietary supplement to the market without notifying FDA. FDA’s role in regulating dietary supplements primarily begins after products enter the marketplace. If a product is found to be unsafe or not otherwise in compliance with the law, FDA can work with the company to bring the product into compliance or possibly remove it from the market.

How are Dietary Supplements Labeled?

Dietary Supplements are required to have a Supplement Facts label that lists the serving size, the number of servings per container, each dietary ingredient in the product, and the amount of certain ingredients per serving. They are also required to have a statement on the front of the product identifying it as a “dietary supplement” or similar term (for example, “vitamin supplement”).

What are Dietary Supplements?

Dietary supplements are products that are ingested and are intended to add to or “supplement” the diet. Supplements can come in a variety of forms, including tablets, capsules, softgels, gel caps, liquids, gummies, powders, and bars.

Common dietary supplements include:

- Vitamins (such as multivitamins or individual vitamins like vitamin D and biotin)
- Minerals (such as calcium, magnesium, and iron)
- Botanicals or herbs (such as echinacea and ginger)
- Botanical compounds (such as caffeine and curcumin)
- Amino acids (such as tryptophan and glutamine)
- Live microbials (commonly referred to as “probiotics”)
How Can You Be an Informed Consumer?

Read product labels, be cautious, and always talk to your healthcare professional—doctor, nurse, registered dietitian, or pharmacist—before purchasing or taking any dietary supplement. They can help you decide which supplements, if any, might be right for you.

What Should You Do if You Experience an Adverse Event?

If you think that a dietary supplement may have caused you to experience an adverse event, you should:

1: STOP taking the supplement immediately
2: SEEK medical care
3: REPORT the adverse event to FDA
   - Online via the Safety Reporting Portal at www.safetyreporting.hhs.gov.
   - Call an FDA Consumer Complaint Coordinator. Contact information for your local Consumer Complaint Coordinator can be found at www.fda.gov/consumer-complaint-coordinators or by calling FDA’s SAFEFOOD Information Line at 1-888-SAFEFOOD (1-888-723-3366).

Any information you provide can help FDA identify unsafe products on the market and take action to protect the public.

Are There Any Risks in Taking Dietary Supplements?

Dietary supplements may contain ingredients that can have strong effects in the body, so always be alert to the possibility of a bad reaction or side effect (also known as an adverse event). Problems can occur especially if you:

- Take too much of some supplements
- Combine supplements
- Use supplements with medications (prescription or over-the-counter)
- Take supplements instead of medications

Adverse events can range from less serious to life-threatening and can include rash, fatigue, severe and persistent vomiting or diarrhea, difficulty urinating, severe joint and muscle pain, chest pain, or stroke. For more possible reactions, see www.fda.gov/dietarysupplements.

What are the Benefits of Dietary Supplements?

Dietary supplements can help you improve or maintain your overall health, and some supplements can also help you meet your daily requirements of essential nutrients. For example, calcium and vitamin D can help build strong bones. Even though dietary supplements can be beneficial, they should not take the place of the variety of foods that are important for a healthy diet.