



# CONSUMER NEWS

## SAN DIEGO CITY ATTORNEY'S OFFICE

### Dietary Supplements

September 2011

Many people are choosing to supplement their diets with vitamins, minerals, herbs, or other substances that they've heard are beneficial from the internet, television, radio, or word of mouth. Dietary supplements may provide health benefits, but under certain circumstances, the products may be unnecessary or they may cause unexpected and serious health consequences.

This newsletter provides information about the laws that govern the sale of dietary supplements.

#### *WHAT IS A DIETARY SUPPLEMENT?*

Congress defines "dietary supplement" as a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The ingredient may include vitamins, minerals, herbs or other botanicals, amino acids and substances like enzymes, organ tissues, and metabolites. Supplements may take the form of a pill, liquid, or powder.

#### *SAFETY CONCERNS:*

Consumers may take dietary supplements without adequately investigating the product or consulting a doctor. It is not safe to assume that even if a dietary supplement does not work in the way the label suggests, consuming the supplement "can't hurt." Some supplements contain products that can be harmful to your health.

Consumers should be extra cautious when taking dietary supplements if they are currently taking other medications or have medical procedures planned for the future. Taking a combination of supplements and medications, both prescription and over-the-counter, may produce adverse and potentially life-threatening results. It is important to tell your doctor about the supplements you are taking.

#### *DIETARY SUPPLEMENT REGULATIONS:*

Dietary supplements are treated like food under the law. The manufacturing plants must be operated in a sanitary way and

employees must practice good hygiene. Labels must list all ingredients.

Because dietary supplements are not defined as drugs, the people who sell them are not required to prove they are safe and effective for the purpose for which they are sold.

The Food and Drug Administration (FDA), which requires drug companies to prove their products are safe and do what is promised in tests that are scientifically sound, does not regulate dietary supplements. Thus, sellers of dietary supplements make health claims about their products that are not substantiated and they do have to establish that the products are safe before selling them.

Under the Dietary Supplement Health and Education Act of 1994, the FDA is unable to restrict the use of a dietary supplement or remove it from the marketplace if the FDA can establish the supplement is unsafe. Thus, a consumer who uses a dietary supplement does not have the

safeguards in place that he/she would have if using a drug.

Manufacturers are required to record, investigate and forward to the FDA reports they receive of any adverse experiences linked to their products. The FDA evaluates these manufacturers' reports along with any other information provided by healthcare providers or consumers in order to identify safety risks.

#### *LABELING REQUIREMENTS:*

The FDA requires manufacturers to include certain information on product labels. This information includes a descriptive name of the product indicating that it is a supplement, the name and place of business of the manufacturer, packer, or distributor, a complete list of ingredients, and the net contents of the product. Nearly all dietary supplements must have nutrition labeling in the form of a "supplement facts" panel which identifies each dietary ingredient contained in the product. All ingredients must be declared on the product label.

A dietary supplement seller may not legally promote on the supplement's label that it treats, prevents, or cures a specific disease or condition because only sellers of drugs can legally make such claims. If a person makes curative claims about the supplement, then he/she may be prosecuted for selling an unapproved drug.

Sellers of supplements may include a representation of the role of a nutrient or dietary ingredient intended to affect the structure or function of the body, but it must be followed by the disclaimer: "THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE."

When consumers see this disclaimer, they need to assess for themselves if they wish to buy the product knowing the advertising for the product has not been reviewed by a government agency and may in fact be false or misleading.

#### *TIPS FOR CONSUMERS:*

- Just because the packaging on the dietary supplement does not list warnings does not make the product safe. Remember, the FDA does not approve dietary supplements before they reach the marketplace.
- The word "natural" or "herbal" does not always mean safe. Those terms are not well-defined and are often used to imply unsubstantiated health benefits or safety. Many dangerous products are natural, e.g. arsenic.
- Always talk to your doctor, nurse, or pharmacist before you take any dietary supplement.
- Dietary supplements may be harmful when taken in conjunction with other supplements or medications.
- Investigate any dietary supplement by speaking to your health care provider, or contacting the manufacturer directly.
- When visiting a website with information on dietary supplements, identify who runs the website, where they get their information, whether the information is up to date, and if the intent of the website is to sell the supplement or simply provide information.

- Do not take supplements instead of eating healthy food.
- Dietary supplements are not a substitute for prescription medicine.
- If a seller of supplements suggests that you should replace your prescription medicine with supplements, you should consult your doctor and not take the word of a salesman who has no medical license.

#### *COMPLAINTS ABOUT DIETARY SUPPLEMENTS:*

If you believe you have suffered illness or a serious harmful effect from a dietary supplement, you should contact your health care provider immediately. You and your health care provider are encouraged to report the problem to the FDA by calling 1-800-FDA-1088. Reports may also be faxed or submitted online. The FDA urges consumers to report potential harmful products, even if you are not sure the product was the cause and even if you did not visit a health care provider.

If you have a general complaint or concern about a dietary supplement, you may call the consumer complaint coordinator at the local FDA District Office at (949) 608-3530.

#### *CITY ATTORNEY'S ROLE:*

The Consumer & Environmental Protection Unit of the San Diego City Attorney's Office has prosecuted several cases against individuals selling dietary supplements who represented they cured or mitigated medical illness.

In one case, a doctor and an unlicensed individual sold a product called "immunostim" to be injected into the veins. When the

product was tested, it was found to be similar to Drano. Many of the people who took this supplement died of severe pre-existing illnesses.

If you observe someone doing business within the City of San Diego who sells dietary supplements and claims they are able to cure medical illnesses, please call the City Attorney's Consumer hotline number below.

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**San Diego  
City Attorney's Office  
Consumer and Environmental  
Protection Unit  
(619) 533-5600**

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