



## ***SOUTH CAROLINA FAMILY AND COMMUNITY LEADERS***

Affiliated with National Volunteer Outreach Network, Country Women's Council, U.S.A., Associated Country Women of the World and in partnership with Clemson University Cooperative Extension Service  
SCFCL website: <http://www.scfcl.com>

### **Leader Training Guide**

#### **Use Caution with Dietary Supplements**

**Objectives:** At the end of the lesson participants will:

1. Understand how dietary supplements are regulated.
2. Know the questions to ask to evaluate the safety and need for a dietary supplement.
3. Know resources to help evaluate potential dietary supplements

**Lesson Overview/Introduction:** Dietary supplements sales in the United States were 37 billion dollars in 2014<sup>1,2</sup>. Until 1994, dietary supplements followed the same regulations as foods and sales were about 4 billion dollars a year<sup>1</sup>. After passage of the Dietary Supplement Health and Safety Act (DSHEA) of 1994, dietary supplements no longer needed approval from the Food & Drug Administration (FDA) before being available for sale to consumers. Now the product manufacturer holds the responsibility for: 1) determining the safety of the products it manufactures or distributes and 2) having enough evidence to prove any statements or claims made about the product is not false or misleading<sup>3</sup>. Investigations into various supplements by the United States Department of Agriculture (USDA) and the New York State Attorney General's Office, in 2015, have revealed products that contained illegal or prescription substances or those that did not contain any of the ingredients listed on the label<sup>1</sup>. Being an educated consumer is extremely important when buying and using dietary supplements.

#### **Lesson:**

##### **What Are Dietary Supplements?**

- The vitamin pill is the most recognized form of dietary supplement. About 1/3 of the population takes vitamins and minerals in the form of a multivitamin/mineral pill.
- Herbal supplements, amino acids, enzymes, extracts, metabolites, energy boosters, weight loss aids, and specialized products like those for menopause are also dietary supplements<sup>3</sup>.
- Dietary supplements can be a pill, capsule, powder, gel, or liquid, and may be added to a ready-to-eat food and/or drink product<sup>3</sup>.

One way to distinguish a dietary supplement food or beverage product from a conventional food is to check the nutrition labeling of the product. Conventional foods must have a "Nutrition Facts" panel on their labels, but dietary supplements must have a "Supplement Facts" panel<sup>7</sup> (pg. 3.)

##### **How are Dietary Supplements Regulated or Overseen?**

- Since 1994, there is no premarket regulation of dietary supplements. The FDA's role with dietary supplements begins after the product has entered the market place<sup>5</sup>.
- Federal law does not require that, before going to market, the supplements are proven safe, and that label claims of product benefit are true and accurate (for most claims made<sup>5</sup>.)
- The manufacturer or distributor of the products must notify the FDA when use of a New Dietary Ingredient is planned. New Dietary Ingredients are those introduced to the market after 1994 and are subject to a premarket review by the FDA for safety and other information<sup>3</sup>.

- Supplement manufacturers and distributors must record, investigate, and forward to FDA any reports they receive of serious adverse events associated with the use of their products that are reported to them directly <sup>3</sup>.
- Adverse event reporting may also be completed by health care providers, public health officials, and by other professionals, as well as consumers and concerned citizens <sup>3</sup>.
- Dietary supplement products may not be marketed as a treatment or cure for specific diseases, or to alleviate symptoms of disease <sup>5</sup>.

### **What are the Product Label Requirements?** <sup>3</sup>

- The product must be labeled with the term “dietary supplement” or a similar term that provides clarification such as “calcium supplement” or “herbal supplement.”
- Additionally all ingredients must be listed on the label, along with the weight of the product, name and address of manufacturer, packer or distributor.

### **Should I take a dietary supplement?** (See the list of questions on page 3)

Dietary supplements might provide you with nutrients missing from your diet. As we age our nutritional needs change but eating a variety of healthy foods is the best and safest way to get the nutrients you need <sup>4</sup>. Vitamins B12, B6 & D, and Folate are vitamin supplements that people over 50 may consider to ensure needs are being met.

- Take into consideration your age, health conditions, and the prescription medicines you take when considering a dietary supplement to add to your diet. <sup>4</sup>
- Evaluate your diet for fortified foods that may already be providing 100% of the daily recommended intake of a vitamin or mineral. Breakfast cereals and other foods may be fortified with Folate, Calcium, and other nutrients. Consuming too much of certain nutrients can lead to adverse reactions. <sup>6</sup>

### **Are Dietary Supplements Safe?** <sup>5</sup>

Many dietary supplements have been on the market for a long time, are well understood, and have a safe history of use. Newer dietary supplements may be available for purchase but there may be an insufficient amount of scientific information available about its effects on health. Unfortunately, there are sometimes unscrupulous businesses selling fraudulent products. If they are reported to the FDA, there may be recalls on dietary supplements for these and other reasons.

- Use extreme caution with the categories of Weight loss, muscle building, and sexual enhancement. The FDA has identified over 300 fraudulent products. <sup>8</sup>

**Always tell your physician, dietitian, or pharmacist about any dietary supplements you are taking. There might be serious adverse health risk at stake.**

### **How Do I Spot False Claims?** <sup>4</sup>

The old adage “Buyer Beware” (Caveat Emptor) applies to dietary supplements.

- Be on the lookout for extreme claims like “quick and effective,” “cure-all,” or “totally safe.”
- Be skeptical about anecdotal information from personal “testimonials” about incredible benefits or results obtained from using a product.
- Be leery of jargon like “hunger stimulation point” or “thermogenesis” and overly impressive statements “A scientific breakthrough formulated by using proven principles of natural health-based medical science.”
- Sales people trying to pressure you into making a decision is always a warning sign.

## Be Supplement Savvy - Key Points to Ponder

- If using a dietary supplement look for products with the voluntary USP or NSF International, or Consumer Lab seals on the label. This indicates that the product manufacturer followed standards set by an independent, third-party certification body. Fraudulent product producers rarely go to this trouble and cost.
- Realize that the use of the term “natural” on any product is no guarantee that the product is safe. Hemlock, for example, is natural but not safe.

## Questions to Ask When Considering a Dietary Supplement:

- Why do I think I may need a dietary supplement?
- What foods or food groups am I not eating, or not eating enough of?
- Is there a way to increase these food(s) or food group(s)?
- What is the dietary supplement product for?
- What are the product’s intended benefits?
- How, when, and for how long should I take it?
- Are there precautions or warnings I should know about (like not taking over a certain amount)?
- What foods do I eat that are already fortified with vitamins, minerals and/or extracts?
- Are there any known side effects (like nausea, headaches, etc.)? Do they apply to me?
- Are there any foods, medicines (prescription or over-the counter), or other supplements I should avoid while taking this product?
- If scheduled for surgery, should I be concerned about the dietary supplements I am taking?
- Do the product claims seem too good to be true?
- Can I afford this product?

Dietary Supplement Products have a Supplement Facts Panel  
pictured here →.  
Conventional Foods will have a Nutrition Facts Panel

| <b>Supplement Facts</b> |         |               |
|-------------------------|---------|---------------|
| Serving Size 1 Capsule  |         |               |
| Amount Per Capsule      |         | % Daily Value |
| Calories                | 20      |               |
| Calories from Fat 20    |         |               |
| Total Fat               | 2 g     | 3%*           |
| Saturated Fat           | 0.5 g   | 3%*           |
| Polyunsaturated Fat     | 1 g     | †             |
| Monounsaturated Fat     | 0.5 g   | †             |
| Vitamin A               | 4250 IU | 85%           |
| Vitamin D               | 425 IU  | 106%          |
| Omega-3 fatty acids     | 0.5 g   | †             |

\* Percent Daily Values are based on a 2,000 calorie diet.  
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

### Resources for Research

FDA Information on Dietary Supplements for Consumers

<http://www.fda.gov/food/dietarysupplements/usingdietarysupplements/>

FDA Tips for Older Consumers

<http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110493.htm#fraud>

National Institutes of Health Fact Sheets on Dietary Supplements

Vitamin & Mineral <https://ods.od.nih.gov/factsheets/list-VitaminsMinerals/>

Herbal <https://nccih.nih.gov/health/herbsataglance.htm>

**Lesson Summary:** People have been searching for the fountain of youth and quick fixes to health problems for centuries. The Dietary Supplement industry is loosely regulated and includes products that may not be effective and may even cause harm. Individuals that are considering a dietary supplement should do their homework by determining if a supplement is really needed, researching the product, and manufacturer of interest. Look for products that have a third party seal and question those who sell and promote dietary supplements. Report any instances of adverse reactions to your doctor and to the manufacturer. Most importantly follow the old adages “Buyer Beware” and “If it seems too good to be true it probably is!”

**Suggested Activities:**

- Bring in various magazines and critically examine dietary supplement ads against the questions on page 3. Health related and ladies magazines often are rich with these ads.
- If the technology is available show the FDA video: Fortify Your Knowledge About Vitamins <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm118079.htm>
- Review a fact sheet from the National Institutes of Health (See suggested materials)

**Suggested Materials:**

- Page 3 is the handout.
- Magazines that have dietary supplement ads.
- Order the free pamphlet “Dietary Supplements” from the Age Page of the National Institute on Aging. Order on line at <https://order.nia.nih.gov/health/publication/order/AP012> or call 1-800-222-2225 Monday through Friday, 8:30 a.m. – 5:00 p.m.
- Duplicate the fact sheet on Aloe Vera from the NIH. This plant historically has a topical use and is now being sold as something to ingest. See what the recommendation is. Link: <https://nccih.nih.gov/health/aloevera>

**Lesson Prepared by:** Katherine Shavo, MS, RD, LDN, Regional Food Safety & Nutrition Extension Agent, Clemson Cooperative Extension Service

**Lesson Review by:** Michelle Parisi, PhD, RD, Director of Nutrition and Health Extension Programs, Food Safety and Nutrition Team – Cooperative Extension Service

**Sources/References:**

- 1) Weeks, J. (2015, October 30). Dietary supplements. *CQ Researcher*, 25, 913-936. Retrieved from <http://library.cqpress.com/>
- 2) <https://ods.od.nih.gov/factsheets/MVMS-HealthProfessional/>
- 3) [http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.htm#FDA\\_role](http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.htm#FDA_role)
- 4) <http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110493.htm> accessed 7-5-2016
- 5) <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm050803.htm#HowAreSupplementsRegulated>
- 6) [https://ods.od.nih.gov/HealthInformation/DS\\_WhatYouNeedToKnow.aspx](https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx)
- 7) <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194357.htm>
- 8) <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246744.htm>