FDA U.S. FOOD & DRUG

**SUPPLEMENTS** 



## INTRO TO DIETARY SUPPLEMENTS

The "Intro to Dietary Supplements" module introduces students to the rapidly growing world of dietary supplements, providing a foundational understanding of what they are, how they are regulated, and their potential benefits and risks. This module highlights the importance of making informed decisions when considering supplements, emphasizing the need to read labels carefully and consult reliable sources. A notable aspect of this module is its focus on the differences between dietary supplements and medications, a distinction that is crucial for consumer safety. Developed by educators and FDA experts, this module connects directly to LifeSmarts topics like health, consumer awareness, and safety. With engaging videos, real-world examples, and interactive discussions, teachers will find this module invaluable for helping students navigate the complexities of dietary supplements and prepare for LifeSmarts competitions.



## **DISCUSSION QUESTIONS**

- Why is it important to consult a healthcare provider before taking dietary supplements? Discuss the potential risks of taking supplements without professional guidance.
- Explain the difference between a dietary supplement and a prescription drug. How does the regulation of these two categories differ in terms of safety and efficacy?

## **CHALLENGE QUESTION**

Research a case where a dietary supplement was found to be harmful or ineffective. What actions were taken by the FDA or other regulatory bodies, and what was the outcome?



## See this lesson and more at LifeSmarts U.

This lesson was developed by educators and experts in conjunction with the U.S. Food & Drug Administration

## VOCABULARY

- Dietary Supplement
- Supplement Facts Label
- Probiotics
- Vitamins
- Minerals
- Herbs or Botanicals
- Amino Acids
- Enzymes
- DSHEA (Dietary Supplement Health and Education Act)
- Adverse Reaction

## ACTIVITIES

- Product Categories
- Supplements vs. Food

VIDEOS

\* See reverse side for list





### **VIDEO LINKS**

Dietary Supplements: What You Need to Know (1:43) https://www.youtube.com/watch?v=-tY1Ln9JfVs

Drugs vs. Supplements (1:19) https://www.webmd.com/vitamins-and-supplements/vi deo/drugs-vs-supplements

The Real Story of Snake Oil (1:44) https://www.youtube.com/watch?v=LaDsOJATX3A

Understand Changes to Dietary Supplement Labels (2:02) https://www.youtube.com/watch?v=kLploVqHjBA

Understanding Pre and Probiotics (3:14) https://www.youtube.com/watch?v=U1p4YMU3vWk

Vitamins and Minerals – Nutrition Fundamentals (6:58) https://www.youtube.com/watch?v=qgNURQFWNWM

Dietary Supplement Practicum (5 of 21): Drugs vs. Foods vs. Dietary Supplements https://www.youtube.com/watch?v=3EtmTEHZi0Y

Osmosis.org: Prebiotics & Probiotics https://www.youtube.com/watch?v=0z47wLZ4-O4

### **OTHER WEB LINKS**

MyPlate Plan https://www.myplate.gov/myplate-plan

Dietary Supplement Products & Ingredients https://www.fda.gov/food/dietary-supplements/dietarysupplement-products-ingredients

Dietary Supplement Ingredient Advisory List https://www.fda.gov/food/dietary-supplements/inform ation-select-dietary-supplement-ingredients-and-othe r-substances

FDA Alerts, Advisories & Safety Information http://www.fda.gov/food/recalls-outbreaks-emergencie s/alerts-advisories-safety-information

FDA Consumer Updates – Health Fraud https://www.fda.gov/consumers/health-fraud-scams/co nsumer-updates-health-fraud

How to Read a Supplement Label https://qualitymatters.usp.org/how-read-supplement-l abel

NIH Dietary Supplement Label Database https://dsld.od.nih.gov

## **DISCUSSION QUESTIONS (SAMPLE ANSWERS)**

A: It is important to consult a healthcare provider before taking dietary supplements because supplements can interact with prescription medications, cause side effects, or exacerbate existing health conditions. For example, taking high doses of certain vitamins or minerals can lead to toxicity, and some supplements may interfere with the effectiveness of medications. A healthcare provider can help determine the appropriate dosage and ensure that the supplement is safe to take based on an individual's health status and needs. Without professional guidance, there is a risk of overconsumption, adverse reactions, and potentially harmful interactions, which could compromise a person's health.

A: A dietary supplement is a product intended to supplement the diet and may include vitamins, minerals, herbs, amino acids, and enzymes. In contrast, a prescription drug is a medication prescribed by a healthcare provider to treat, cure, or prevent a specific medical condition. The regulation of these two categories differs significantly: prescription drugs must undergo rigorous testing for safety, efficacy, and quality before they can be approved by the FDA for public use. Dietary supplements, however, do not require FDA approval before being marketed. The responsibility for ensuring the safety of dietary supplements lies with the manufacturers, and the FDA only steps in after a product has been introduced to the market if safety concerns arise. This difference in regulation means that dietary supplements are not held to the same safety and efficacy standards as prescription drugs.

### **CHALLENGE QUESTION (SAMPLE ANSWER)**

An example is the case of ephedra, a popular weight-loss supplement that was found to cause serious health risks.

https://ods.od.nih.gov/factsheets/EphedraandEphedrine-HealthProfessional/

#### **Key Points:**

**Harmful Effects:** Ephedra, a natural stimulant, was widely used for weight loss and athletic performance enhancement. However, it was linked to numerous cases of heart attacks, strokes, and even deaths due to its powerful stimulant effects on the cardiovascular system.

**Regulatory Actions:** In 2004, after reviewing the scientific evidence and numerous adverse event reports, the FDA banned the sale of dietary supplements containing ephedra. The decision was based on the significant health risks posed by the supplement, which outweighed its benefits.

**Outcome:** The ban on ephedra was a landmark decision, as it was the first time the FDA banned a dietary supplement due to safety concerns. This action led to increased awareness about the potential dangers of dietary supplements and reinforced the importance of regulatory oversight in protecting public health.



## **Supplements - Intro to Dietary Supplements**



Serving Size 1 Gelcap Servings Per Container 100	Amount Per Serving	% Da
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100
Vitamin C (as ascorbic acid)	90 mg	100
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100
Thiamin (as thiamin mononitrate)	1.2 mg	100
Riboflavin	1.3 mg	100
Niacin (as niacinamide)	16 mg	100
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	1.7 mg	100
Folate 4 (240 m	00 mcg DFE	100

100%

10%

100%

2.4 mca

3 mcg

5 mg

Vitamin B<sub>12</sub> (as cyanocobalamin)

Pantothenic Acid (as calcium pantothenate)

Biotin



**Teacher's Guide for High School Classrooms 1**<sup>st</sup> Edition



## OVERVIEW OF ACTIVITIES

The activities are written in this easy-to-understand format.



MATERIALS: Includes the items needed to perform the activity.

**ADVANCE PREPARATION:** Indicates what you need to do before conducting the activity.

**INTRODUCTION:** Provides fun, innovative suggestions for introducing the activity. Where provided, suggested teacher dialogue is indicated by *boldface italics*.

MATERIALS    Interret Access  Distary Supplements and Advertising Worksheet  Credible Source Guide  Presentation Rubric	ADVANCE PREPARATION 1. Divide your class into small groups. 2. Secure Internet access 3. Make copies of the Dietary Supplements and the Media worksheet, Credible Source Guide, and Presentation Bubric
INTRODUCTION	V
Then many understrands to be surgified or halfs many many subscription of the surgified or halfs and subscription of the surgified or halfs and subscription of the surgified or halfs and subscription of the surgified or halfs the subscription of the surgified or halfs and subscription of the subscription of the subscription of subscription of subscri	we will avail a darar takke and was dhe two langer data will be an end of a data set of the set of a set of the set of th



STUDENT PROCEDURE: Gives the step-by-step process for the activity.

**REVIEW:** Uses interesting questions to guide students through a review of what they learned in the activity.

SUMMARY: Summarizes key concepts learned in the activity.

**EXTENSIONS:** Suggest activities to help students learn more about the topic.

**RESOURCES:** Provide references to online resources for the activity or for further study.

**UP NEXT:** Gives a preview of the next activity.





## INTRODUCTION TO DIETARY SUPPLEMENTS

## **Definitions, Supplement Facts label, Categories, Claims**

For this module, it is recommended that teachers will have taught the following key concepts: the structure and properties of matter; what happens in chemical reactions; the human body is a system of interacting systems; basic human nutrition needs; metric system

## **BACKGROUND INFORMATION**



What is a Dietary Supplement? introduces dietary supplements as a category of products that are heavily marketed to consumers, and which should only be taken with a healthcare provider's advice.

## ACTIVITY 1



**Product Categories** helps teenagers distinguish characteristics of products that they might use.



Time to Tune In

*Dietary Supplements: What You Need to Know* (1:43) https://www.youtube.com/watch?v=-tY1Ln9JfVs

Drugs vs. Supplements (1:19) https://www.webmd.com/vitamins-and-supplements/video/ drugs-vs-supplements

The Real Story of Snake Oil (1:44) https://www.youtube.com/watch?v=LaDsOJATX3A

## **ACTIVITY 2**



Supplements vs. Food helps teens evaluate and compare nutrients that could be obtained through foods or dietary supplements.



#### Time to Tune In

Understand Changes to Dietary Supplement Labels (2:02) https://www.youtube.com/watch?v=kLploVqHjBA

Understanding Pre and Probiotics (3:14) https://www.youtube.com/watch?v=U1p4YMU3vWk

*Vitamins and Minerals – Nutrition Fundamentals* (6:58) https://www.youtube.com/watch?v=qgNURQFWNWM

### **MODULE 1: INTRODUCTION TO DIETARY SUPPLEMENTS**



**BACKGROUND INFORMATION** 

## What is a Dietary Supplement?

#### **Dietary Supplements: Defined**

A dietary supplement is a product that is used to supplement, or *add to*, a person's diet. But a dietary supplement is *not* intended to be a substitute for an actual food or a meal.

To be categorized as a dietary supplement, a product must be able to be "ingested" – in other words, something you can eat or drink. Something that is intended to be injected or applied topically (like to the skin or hair) would *not* be a dietary supplement.

- Vitamins and minerals are common dietary supplements.
- Other dietary supplements include herbs or botanicals and their extracts and constituents, amino acids, live microbials (commonly referred to as "probiotics"), and enzymes.

Dietary supplements come in a variety of forms such as tablets, capsules, softgels, gelcaps, powders, and liquids. They can provide nutritional benefit by helping you meet daily requirements for the nutrients your body needs to function. But it is important to remember that food should be the primary source of nutrients. A healthy diet starts with eating a variety of foods.

Note: Many foods and dietary supplements contain the same components, but a product is classified as a dietary supplement when that component (e.g., vitamin D) is separate from the food (e.g., milk). Foods that are "fortified" with vitamins/minerals are still considered foods, not dietary supplements.

A dietary supplement might include other ingredients, for example, inactive or "filler" ingredients such as silica, which helps the ingredients bind together during manufacturing. These other ingredients are regulated as food additives.

Dietary Supplements: What They Include					
Dietary Supplement Categories	<i>Example of a Specific Dietary Supplement component in each category</i>	Other Product Classification (not a Dietary Supplement) that might contain the same component	Example of other product not classified as a dietary supplement		
Vitamins	Vitamin C	Cosmetics	Facial serum containing vitamin C		
Minerals	Iron	Drug	Iron injection		
Herbs or Botanicals, Extracts and Constituents	Caffeine (from green tea, for example)	Drugs	Over-the-counter (OTC) stimulant drugs		
Live microbials ("probiotics")	Lactobacillus acidophilus	Food	Yogurt containing lactobacillus acidophilus		
Amino Acids	Lysine	Food	Poultry		
Other (such as fish oil, glucosamine, etc.)	Omega 3 fatty acids	Food	Salmon		

## MODULE 1: INTRODUCTION TO DIETARY SUPPLEMENTS

**BACKGROUND INFORMATION** 



## The Dietary Supplement Health and Education Act (DSHEA)

Unlike prescription medications, under DSHEA, FDA does not have the authority to approve dietary supplement

products. FDA strives to achieve the right balance between preserving consumers' access to lawful supplements, while still upholding the agency's obligation to protect the public from unsafe and unlawful products.

### **Connecting the (Historical) Dots to DSHEA**

- **1906** The **Pure Food and Drug Act**, a law a quartercentury in the making, prohibited interstate and foreign commerce in adulterated and misbranded food and drugs. It also positioned the Bureau of Chemistry (predecessor of FDA) as the first federal agency to focus primarily on consumer protection.
- **1938** The U.S. Congress passed the **Federal Food**, **Drug, and Cosmetic Act** (FD&C Act) to replace the Food and Drugs Act. This important updated legislation enhanced the consumer protections for food and drugs and broadened the scope of products under FDA's oversight to include medical devices and cosmetics.
- **1976** The **Vitamins and Minerals Amendments** (led by Sen. William Proxmire of Wisconsin) prohibited FDA from limiting the potency of vitamins and minerals or classifying those that exceeded a specific potency threshold as drugs. It also prevented FDA from limiting any combination of vitamins or minerals or other food ingredients (except in products used for childhood diseases or by pregnant or lactating women).

**1994** The **Dietary Supplement Health Education Act** (DSHEA) was signed into law. DSHEA created a new

regulatory framework for



the safety and labeling of dietary supplements. It defined a **dietary ingredient** as a vitamin, mineral, herb or botanical, amino acid, or a dietary substance used to supplement the diet by increasing total dietary intake (for example, food substances). A dietary ingredient can also be a concentrate, metabolite, constituent, extract, or combination of these ingredients.

DSHEA enabled FDA to take action against unsafe or otherwise adulterated or misbranded dietary supplements. But unlike the approach taken for drugs, FDA is responsible for demonstrating that a dietary supplement is adulterated prior to taking any enforcement action. Because dietary supplements are under the "umbrella" of foods, FDA's Center for Food Safety and Applied Nutrition (CFSAN) regulates both *finished* dietary supplements and the *individual ingredients* that a supplement might contain. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products.

#### **Responsibility of the Manufacturing Company**

Under DSHEA, it is the companies that manufacture or market dietary supplements that are responsible for ensuring that the products they sell are **safe and otherwise lawful**. So unlike FDA's role in regulating prescription drugs, FDA does *not* have the authority to approve dietary supplements or their labeling. In fact, companies can often introduce new dietary supplement products to market without even notifying FDA. In most cases, FDA's role with a dietary supplement product begins *after* the product enters the marketplace. Specifically, FDA is responsible for taking action against any "adulterated" or "misbranded" dietary supplement. For example, if a product is "adulterated," it might mean that the product contains contaminants or is otherwise unsafe; if a product is "misbranded," it could mean that the labeling is false or misleading. In these cases, FDA can take action to **remove products from the market**.



#### The Nutrients You Need: A Closer Look

Food should always be the **first choice** for getting the nutrients you need. You can learn how much you need from each food group with a personalized **MyPlate Plan**, based on your age, sex, height, weight, and physical activity level. Beneficial vitamins and minerals can be found in nutrient-dense foods such as fruits, vegetables, and whole grains.

You can refer to the Nutrition Facts label on food packages, which is a helpful tool to evaluate nutrients you are getting from food. The label lists key nutrients in a food and how much a particular food contributes to the recommended amount of that nutrient in the daily diet.

Someone might choose to take a dietary supplement to help reach the daily recommended amount of certain nutrients if they are unable to get them from their diet. For example, someone with lactose intolerance might find it challenging to consume the daily recommended amount of calcium, a key nutrient found in dairy products.

Vitamins and minerals help your body to work properly. Vitamins occur naturally in plants and animals and can also be produced synthetically. **Minerals** are inorganic elements that come from the soil and water, and they are absorbed by plants or eaten by people and animals. Your body needs larger amounts of some minerals like calcium. Other minerals are called **trace minerals** because you only need small amounts. Trace minerals include chromium, copper, iodine, iron, selenium, and zinc. FDA's Vitamins and Minerals charts offer a quick way to track down foods that contain the specific nutrients you may want to add to *your* diet.

VITAMIN	WHAT IT DOES	WHERE IT IS FOUND	DAILY VALUE*
Vitamin C	Antioxidant     Collagen and connective     tissue formation     Immune function     Wound healing	<ul> <li>Fruit (e.g., cantaloupe, citrus fruits, kiwifruit, and strawberries)</li> <li>Juices (e.g., oranges, grapefruit, and tomato)</li> <li>Vegetables (e.g., broccoli, Brussels sprouts, peppers, and tomatoes)</li> </ul>	90 mg
Vitamin D Nutrient to get more of	Blood pressure regulation     Bone growth     Calcium blance     Hormone production     Hormone production     Hornore function     Nervous system function	Eggs     Fish (e.g., herring, mackerel, salmon, trout, and tuna)     Fish oil and cod live oil     Fortified diny products     Fortified margarine     Fortified range luide     Portified range luide     Fortified range luide     Portified range luide     Fortified range lu	20 mcg**
Vitamin E	Antioxidant     Formation of blood     vessels     Immune function	Fortified cereals and juices     Green vegetables (e.g., spinach and broccoli)     Nuts and seeds     Peanuts and peanut butter     Vegetable oils	15 mg**
Vitamin K	<ul> <li>Blood clotting</li> <li>Strong bones</li> </ul>	<ul> <li>Green vegetables (e.g., broccoli, kale, spinach, turnip greens, collard greens, Swiss chard, mustard greens)</li> </ul>	120 mcg
The Daily Values are re	ference amounts of nutrients to con	isume or not to exceed each day.	

The National Academies of Sciences, Engineering, and Medicine have created in-depth nutrient charts that offer Recommended Dietary Allowances (RDA) depending on age and life stage. These not only show the amount of nutrients you *do* need, but also "how much is too much."

The nutrient charts are organized by:

1. What You Need	For Vitamins
	For Minerals (Elements)
	For Water and Macronutrients
2. Upper Limits	Tolerable Upper Intake Level for Vitamins
	Tolerable Upper Intake Level for Minerals (Elements)

#### There are two types of vitamins.

- Fat-soluble vitamins A, D, E, and K are dissolved, transported, and stored similar to how fats are used in your body.
- Water-soluble vitamins C and the B-complex vitamins (such as vitamins B6, B12, niacin, riboflavin, and folate) are generally excreted rapidly by the body and most are not as easily stored.

## **BACKGROUND INFORMATION**



#### The Dietary Supplement Facts Label: What It Includes

Dietary supplements must be labeled with a **Supplement Facts** label that is specific for the contents in that dietary supplement.

## pplement Facts

#### Serving Size 1 Gelcap Servings Per Container 100

900 mcg	100%
00 mg	
Song	100%
20 mcg (800 IU)	100%
15 mg	100%
1.2 mg	100%
1.3 mg	100%
16 mg	100%
1.7 mg	100%
mcg DFE	100%
folic acid)	
2.4 mcg	100%
3 mcg	10%
5 mg	100%
stearate, microcryst	alline
	15 mg 15 mg 1.2 mg 1.3 mg 16 mg 1.7 mg mcg DFE folic acid) 2.4 mcg 3 mcg 5 mg Stearate, microcryst preservatives (prop

#### You Can "Overdo" It with Vitamins or Minerals

While vitamins and minerals are part of a healthy diet, it is possible to take too much of a "good thing." If it is necessary for you to consume them because you can't get enough through the foods you eat, it's important to remember that "more" isn't necessarily better.

*Calcium*: The body absorbs calcium from food better than from dietary supplements. Too much calcium can increase the risk of heart attack and stroke and cause muscle pain, constipation, abdominal pain and kidney stones. You can also help calcium do its job by getting your calcium from dairy products, avoiding excess salt, and not smoking.

*Vitamin D*: High levels of vitamin D in the blood can be dangerous. It triggers extra calcium absorption, which in turn can cause the same symptoms as too much calcium.

*Vitamin A*: The body stores excess vitamin A in fat and does not excrete it. The fact that vitamin A is found in many different supplements means it's easy to get too much. Vitamin A toxicity is

#### Group 1

#### Servings

The "Serving Size" and the number of "Servings Per Container." The serving size for dietary supplements that are pills, capsules, tablets, or packets is listed as a quantity (e.g., one capsule), whereas the serving size for dietary supplements that are bulk powders or liquids is listed as a volume (e.g., one teaspoon).

#### - Group 2

#### Nutrients

List of nutrients in this particular product that are required or permitted on the Supplement Facts label. The actual amount in milligrams or micrograms in addition to the % Daily Value (%DV) are listed. Daily values are reference amounts of nutrients to consume or not to exceed and are used to calculate the %DV, based on a 2,000-calorie/day diet. Not all dietary supplement components have a DV.

#### Group 3

Ы

#### Other ingredients

List of additional ingredients in descending order by weight. These ingredients can include fillers, preservatives, sweeteners, flavorings, or colors.

caused by too much preformed vitamin A (retinol); signs include headache and skin rashes. Large amounts of beta-carotene and other provitamin A carotenoids are not associated with major adverse effects.

*Iron*: Iron is a nutrient that supports such functions as growth and development, immunity, and red blood cell formation. But taking high doses of iron supplements (especially on an empty stomach) can cause an upset stomach, constipation, nausea, abdominal pain, vomiting, and fainting. High doses of iron can also decrease zinc absorption; zinc promotes wound healing, immune function, and nervous system function.

Read more in the sources for this information:

- For Calcium, vitamin D and vitamin A: from the Cleveland Clinic
- For Iron: from an NIH factsheet

The **Tolerable Upper Intake Level (UL)** is the term used for the maximum daily intake unlikely to cause adverse health effects.

Always talk to a healthcare professional before starting a vitamin or mineral supplement.

HIGH SCHOOL



## **BACKGROUND INFORMATION**

#### What Are Live Microbials?

A live microbial is a single-celled prokaryotic (e.g., bacteria) or eukaryotic (e.g., yeast) microorganism that is intended to be viable or "active" when consumed. Many dietary supplements that are described as "probiotics" contain live microbial ingredients. "Probiotics" are not defined as a regulatory product category under the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the Public Health Service Act (PHSA), and products that may be considered to be "probiotics" may be foods, drugs, and/or biologics under the FD&C Act and/or PHSA, depending on various factors, such as the intended use of the product. "Probiotics" have been defined in other contexts as live microorganisms that, when consumed in adequate amounts of food, provide the host with a health benefit. While there has been a lot of research on live microbials, it's not clear which are helpful and which are not.

Live microbials are present in some fermented foods and available as dietary supplements. They act mainly in the gastrointestinal (GI) tract, where they can affect your gut microbiome. This microbiome is made up of many microorganisms (mostly bacteria) that live primarily in your large intestine. The goal of taking live microbials is that, when you eat or drink enough, they help protect your GI tract from harmful microorganisms, improve your digestion and gut function, and might provide other health benefits as well.

Commonly consumed live microbials include *Lactobacillus, Bifidobacterium, Saccharomyces, Streptococcus, Enterococcus, Escherichia,* and *Bacillus.* Microorganisms are named by their genus and species, and sometimes by their strain. An example is *Lactobacillus rhamnosus* GG. In this example, *Lactobacillus* is the genus, *rhamnosus* is the species, and GG is the strain.

#### Which foods provide live microbials?

Fermented foods have added microbial cultures. Manufacturers make yogurt, for example, by adding live microorganisms (such as *Lactobacillus* or *Streptococcus*) to milk. But whether the microorganisms provide benefits is inconclusive. Some fermented foods (such as sourdough bread and most pickles) are processed after fermentation, which kills the microorganisms. Microorganisms that are not alive do not provide the same benefits as living microorganisms and are not considered to be live microbials. Other fermented foods contain microorganisms that have not been studied to the same extent, so whether they have any benefits is not known. Examples of these include apple cider vinegar, cheese, kimchi, kombucha, miso, and sauerkraut.

Some unfermented foods have added microorganisms. These foods include some cereals, juices, milks, nutrition bars, and smoothies. Whether these microorganisms provide benefits is not clear.

## What kinds of live microbial dietary supplements are available?

Dietary supplements may contain a wide variety of microorganisms and amounts. The Supplement Facts label on a dietary supplement that contains live microbials lists the total weight of the microorganisms in the product. Many product labels also list the number of colony forming units (CFUs) in a serving. CFUs are a better indicator than total weight of the number of live microorganisms. Examples of CFUs that you might see on a label are  $1 \times 10^9$  (1 billion) CFUs and  $1 \times 10^{10}$  (10 billion) CFUs.

## **Supplement Facts**

Serving Size 1 capsule Servings Per Container 60

Amount Per Serving	% Daily Value**
180 mg	†
0 calorie diet. Your dail your calorie needs.	ly values
	Amount Per Serving 180 mg 0 calorie diet. Your dail your calorie needs.

Other Ingredients: Vegetable cellulose, vegetable magnesium stearate, silica.

## MODULE 1: INTRODUCTION TO DIETARY SUPPLEMENTS BACKGROUND INFORMATION



#### **Dietary Supplement Safety**

FDA oversees dietary supplements under a different set of regulations than those covering drug products and "conventional" foods. Under the Food, Drug & Cosmetics Act, manufacturers and distributors of dietary supplements are prohibited from marketing products in interstate commerce that are adulterated or misbranded. They are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of the FD&C Act and the FDA's regulations. Unlike prescription drugs, dietary supplements are not approved by the government for safety and efficacy. FDA is authorized to take action against any adulterated or misbranded dietary supplement product after it reaches the market.

FDA monitors the compliance of dietary supplement products through a variety of surveillance activities and carefully reviews product complaints and adverse event reports. If FDA determines that a dietary supplement violates the law, the agency takes action, as appropriate. The public can access FDA's resource lists, which are updated with ingredients that are not or do not appear to be lawfully included in products marketed as dietary supplements. Information about ingredients and products that have been the subject of FDA action or advisory statements is shown on these FDA webpages:

- Dietary Supplement Products & Ingredients (https:// www.fda.gov/food/dietary-supplements/dietarysupplement-products-ingredients)
- Dietary Supplement Ingredient Advisory List of ingredients under current evaluation (https://www.fda. gov/food/dietary-supplement-products-ingredients/ dietary-supplement-ingredient-advisory-list)
- Alerts, Advisories & Safety Information (www.fda.gov/ food/recalls-outbreaks-emergencies/alerts-advisoriessafety-information)

### Some Dietary Supplements Have Been Recalled

DID YOU KNOW?



Some dietary supplements are recalled because of potential – or even proven – harmful effects. Reasons for product recalls include:

- microbiological, heavy metal, or other types of contamination
- absence of a dietary ingredient claimed to be in the product
- the presence of unlabeled allergens or ingredients found in drugs

#### "Say What?" It's All About Claims

It is not uncommon for people to mistakenly think that dietary supplements have been proven to have the same benefits as drugs. Legally, products labeled as dietary supplements that bear claims that the products are intended to treat, prevent, or cure diseases are drugs and subject to all requirements that pertain to drugs. An example would be a dietary supplement label that states, or claims, that the product "treats heart disease." Claims like this render the product a drug and can generally *only* be made after FDA has reviewed and approved the drug.

Dietary supplements *are* permitted to make certain claims that describe how the product might affect either the *structure* or the *function* of the body. These are called structure/function claims, and they describe the role a specific nutrient plays in relation to the human body.

#### **Examples of Structure/Function Claims**

Structure and/or function claims can describe the *role* of an ingredient that is intended to affect the normal human body, or the *way* an ingredient acts to maintain such structure or function. For example:

"Calcium builds strong bones." (Structure)

"Fiber maintains bowel regularity." (Function)

These claims can be made if:

- They are truthful and non-misleading
- The manufacturer has proof that the claims are truthful
- The manufacturer notifies FDA of the text of the claim no later than 30 days after marketing the dietary supplement with the claim
- The label includes a disclaimer that says: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

FDA has an informative webpage, **Consumer Updates** – **Health Fraud** (https://www.fda.gov/consumers/health-fraud-scams/consumer-updates-health-fraud), that reviews all types of health claim fraud, including those for dietary supplements.

HIGH SCHOOL



## BACKGROUND INFORMATION

### **Claims Terminology: At a Glance**

Among the claims that are allowed for dietary supplements are health claims, nutrient content claims, structure/function claims, general well-being claims, and nutrient deficiency disease claims. For all such claims, the manufacturer must have substantiation that the claim is truthful and not misleading.

**Health claims:** Health claims are claims that express or imply the role a food or particular ingredient may have in *reducing the risk of a disease or a health-related condition.* FDA has the authority to review health claims before the product about which the claim is made is marketed.

**Nutrient content claims:** These are claims that describe the *level* of a nutrient in a food or dietary supplement. For example, this could be terms such as *free, high,* and *low,* or could compare the level of a nutrient in a food to that of another food, using terms such as *more, reduced,* and *lite.* For example, a product could use the claim "high in antioxidant vitamin C" if it contains 20 percent or more of the daily value for vitamin C.

**Structure/function claims:** These are claims that describe the role of a dietary ingredient intended to affect the normal structure or function of the human body. Structure/function claims may not link the claimed effect of the dietary ingredient to a disease or state of health leading to a disease.

- *General well-being claims:* These are claims that describe general well-being derived from consuming a dietary ingredient.
- Nutrient deficiency disease claims: These are claims that describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy). But interestingly, these are allowed only if they also say how widespread the disease is in the United States.

## Silver Poisoning can make a person turn blue!



#### Think Before You Decide

The potential impact that a dietary supplement can have on overall health, and the fact that dietary supplements are released into the marketplace without FDA approval, underscores the need to **thoroughly research** any dietary supplement you might consider taking.

FDA and the National Institutes of Health offer these tips for consideration:

- Consider your overall diet. Remember: dietary supplements are intended to *supplement* the diet when needed, but not to *replace* a healthy and balanced diet. While you need enough nutrients, too much of some nutrients can cause problems.
- 2. Talk to your healthcare provider before deciding to purchase or use a dietary supplement. Be mindful that some supplements may interact with medicines or other supplements. Also, do not use dietary supplements in place of prescription medications. Many supplements contain active ingredients that have strong biological effects; if you have certain health conditions, using them could place your health at risk.
- **3.** Be aware that some dietary ingredients can be toxic in certain circumstances. 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, dietary supplements, or foods.
- 4. Investigate potential dietary supplement(s) + drug interactions including prescription and over-the-counter (OTC) medicines. For example, certain supplements can be problematic when used with blood thinners or can lessen the effectiveness of prescription medicine. So, be sure to check out potential interactions of any dietary supplement with the prescription or OTC drugs *you* are taking.

#### Combining Dietary Supplements with Drugs Can Cause Problems



increase the potential for internal bleeding.

• St. John's Wort may reduce the effectiveness of prescription drugs for heart disease, depression, seizures, HIV, certain cancers, or oral contraceptives.





- 5. Know the health implications in certain situations, like before a surgical procedure or platelet donation.
  - If you are planning elective surgery: Be aware that some dietary supplements can interact in a harmful way with medications you need to take before, after, or during surgery. Your healthcare professional may ask you to stop taking dietary supplements 2-3 weeks before the procedure to avoid potentially dangerous changes in heart rate, blood pressure, or bleeding risk.
  - If you plan to donate platelets: You must not take a blood-thinning supplement, such as vitamin E, (or aspirin) for at least 48 hours preceding platelet donation.
- 6. Most important of all, be "skeptical"! Be aware that if claims on the label (or in the marketing materials/ website) of a dietary supplement *sound* too good to be true—they probably are. Safety is the most important thing—so always do your research and be sure to consult your healthcare provider before deciding to purchase or use any dietary supplement.

DID YOU KNOW?

Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the Federal Trade Commission (FTC). FDA and FTC work together to regulate dietary supplement marketing.

#### "Natural"?

Do not assume that the term "natural" ensures wholesomeness, or that these food-like substances necessarily have milder effects, than drugs. The term "natural" on labels is not well defined and is sometimes used ambiguously to imply unsubstantiated benefits or safety. For example, many weight-loss products claim to be "natural" or "herbal," but this doesn't necessarily make them safe. Their ingredients may interact with drugs or may be dangerous for people with certain medical conditions.

**Common Sense Tip:** If it sounds too good to be true, it probably is! FDA says that consumers should be suspicious of product claims such as "works better than [a prescription drug]," "totally safe," or has "no side effects."

### **Research Matters!**

When considering whether to take a dietary supplement, it's absolutely critical to do your research. FDA recommends using noncommercial sites instead of depending on information from sellers, which could contain "marketing spin" versus scientific fact.

Credible sites could include:

- FDA Dietary Supplements: https://www.fda.gov/ food/dietary-supplements
- NIH Office of Dietary Supplements: https://ods.od.nih.gov/HealthInformation/DS\_ WhatYouNeedToKnow.aspx/
- NIH Dietary Supplement Label Database: https://dsld.od.nih.gov/dsld/
- USDA National Agricultural Library Dietary Supplements: https://www.nal.usda.gov/topics/ dietary-supplements
- USDA's Dietary Supplement Ingredient Database: https://dietarysupplementdatabase.usda.nih.gov/

#### Quality

FDA has established good manufacturing practices (GMPs) that companies must follow to help ensure the identity, purity, strength, and composition of their dietary supplements. These GMPs can prevent adding the wrong ingredient (or too much or too little of the correct ingredient) and reduce the chance of contamination or improper packaging and labeling of a product. FDA also periodically inspects facilities that manufacture supplements.

Several independent organizations offer quality testing and allow products that pass these tests to display a seal of quality assurance that indicates the product was properly manufactured, contains the ingredients listed on the label, and does not contain harmful levels of contaminants. These seals do not guarantee that a product is safe or effective. Organizations\* that offer quality testing include:

- ConsumerLab.com
- NSF International
- U.S. Pharmacopeia (USP)

\* Listing a specific company, organization, or service does not represent an endorsement by FDA.



### **MODULE 1: INTRODUCTION TO DIETARY SUPPLEMENTS**





TIME One 45-Minute Class Period



### **ACTIVITY AT A GLANCE**

In this activity, students will learn to identify products that are dietary supplements, as opposed to foods, drugs, or cosmetics.



#### **TIME TO TUNE IN**

*Dietary Supplements: What You Need to Know* (1:43) https://www.youtube.com/watch?v=-tY1Ln9JfVs

Drugs vs. Supplements (1:19) https://www.webmd.com/vitamins-and-supplements/video/ drugs-vs-supplements

The Real Story of Snake Oil (1:44) https://www.youtube.com/watch?v=LaDsOJATX3A

### GETTING STARTED

#### **MATERIALS**

- Product Category cards
- Product Category worksheet

#### **ADVANCE PREPARATION**

- Students can work individually or in groups.
- Make a **Product Category** card set for each student or group.
- Make a copy of the **Product Category** worksheet for each student or group.
- Confirm student access to the online student worksheet if teaching in an online setting.

### INTRODUCTION

Explain that dietary supplements are meant to *supplement* the diet and must be *ingested* (taken orally). Discuss a few examples, such as multivitamins.

Ask why people might take dietary supplements, e.g., for possible health benefits or for a desired benefit to their

appearance. Point out that cosmetics are often used to enhance appearance, but they are not ingested.

Explain that dietary supplements are not approved for safety prior to sales to consumers, but that a reporting system exists for people to report adverse reactions to specific dietary supplements.



## PRODUCT CATEGORIES



## STUDENT PROCEDURE

- 1. Work alone or in pairs.
- 2. Examine each **Product Card** and decide which category each one belongs to: food, drug, cosmetic, or dietary supplement.
- 3. Complete the Product Category student worksheet.
- **4.** Watch these three videos that provide an overview about what dietary supplements are and also explain how to understand the Supplement Label.

Dietary Supplements: What You Need to Know (1:43) https://www.youtube.com/watch?v=-tY1Ln9JfVs Drugs vs. Supplements (1:19) https://www.webmd.com/vitamins-and-supplements/ video/drugs-vs-supplements

The Real Story of Snake Oil (1:44) https://www.youtube.com/watch?v=LaDsOJATX3A

- 5. Read FDA's Fact Sheet: Cosmetics Facts https://www.fda.gov/media/93074/download
- 6. Review the answers on your worksheet. Based on the information learned from the videos and the Cosmetics Fact Sheet, check if your initial choices are correct, and if necessary, move items into their correct categories.
- **7.** As a class, discuss the differences among the product categories.

### REVIEW

# *What are some examples of dietary supplements?* Dietary supplements can be vitamins, minerals, live microbials (commonly referred to as "probiotics"), herbs, botanicals, extracts, fish oil, amino acids, or enzymes.

## How do dietary supplements differ from drugs? From foods? From cosmetics?

Dietary supplements are taken **in addition to** food, to supplement the diet, and they must be taken orally (not applied topically). In contrast, drugs are Intended to, among other things, treat or prevent disease.

## EXTENSIONS

Students could do one or more of the following activities:

- 1. Design a poster (for display in class or online) to inform other high school students about different categories of dietary supplements.
- **2.** Create a game for middle school students that will teach them how to recognize what a dietary supplement is.
- **3.** Design a similar card activity using a different set of items with properties similar to those in the original set.

### SUMMARY

Dietary supplements should not replace eating healthy food. You should always talk with your healthcare provider before you consider taking a dietary supplement.

## UP NEXT 🕨 🕨

Now that you can identify a dietary supplement, let's take a closer look at the label that informs people about what is in dietary supplements.

### RESOURCES

U.S. Pharmacopeia https://qualitymatters.usp.org/index.php/topics/dietary-supplements

Dietary Supplement Practicum (5 of 21): Drugs vs. Foods vs. Dietary Supplements https://www.youtube.com/watch?v=3EtmTEHZi0Y

Dietary Supplements: A Framework for Evaluating Safety https://www.ncbi.nlm.nih.gov/books/NBK216048

## STUDENT WORKSHEET **ACTIVITY 1: PRODUCT CATEGORIES**

Name \_\_\_\_\_ Date \_\_\_\_\_ Class/Hour \_\_\_\_\_

Consider each product below and complete the chart. Some products could be in more than one category.

	Product	Food, Drug, Cosmetic, Dietary Supplement, or multiple possible categories?	What evidence did you use to decide on this category?	Safety evaluated before or after sales?
Consectivered LIP BALM	Orange-flavored lip balm			
Daily Wuti- vitamin	Daily multivitamin			
Whitening <u>TootHpaste</u> Hegs Prevent Cavitas	Whitening toothpaste that helps prevent cavities			
Biotin Winnerstein Winnerstein	Biotin pills (100 micrograms each)			
ENERGY	Energy Drink			
WIEY D Protein Powder	Whey protein powder			
Cosmutation	Coconut-scented shampoo			
Vitamin E Di	Vitamin E oil			
Sieep °	Sleep aid liquid			
	Caffeine lozenges			
Yogart Active cultures	Yogurt			
WEIGHT LOSS	Weight loss pill			





### **MODULE 1: INTRODUCTION TO DIETARY SUPPLEMENTS**





TIME One 45-Minute Class Period



### **ACTIVITY AT A GLANCE**

Students will examine a Supplement Facts label for a product containing a multivitamin, or fish oil. They will choose one component shown on the label, and identify food sources to achieve the same daily intake amount.



#### **TIME TO TUNE IN**

Understand Changes to Dietary Supplement Labels (2:02) https://www.youtube.com/watch?v=kLploVqHjBA

Understanding Pre and Probiotics (3:14) https://www.youtube.com/watch?v=U1p4YMU3vWk

Vitamins and Minerals – Nutrition Fundamentals (6:58) https://www.youtube.com/watch?v=qgNURQFWNWM

### GETTING STARTED

#### **MATERIALS**

- Sample Supplement Facts label
- Supplement Facts Label student worksheet
- Credible Source Guide

#### **ADVANCE PREPARATION**

- Students can work individually or in groups.
- Make a copy of the **Supplement Facts Label** student worksheet for each student.
- Confirm internet access for online teaching.

### INTRODUCTION

A balanced diet typically offers all the nutrients people need. If you are considering taking a dietary supplement, how do you think your overall nutrient intake might differ if you consumed the same nutrients through the foods you eat and the beverages you drink?

## SUPPLEMENTS VS. FOOD



## STUDENT PROCEDURE

#### Watch these three videos: Understand Changes to Dietary Supplement Labels (2:02) https://www.youtube.com/watch?v=kLploVqHjBA

Understanding Pre and Probiotics (3:14) https://www.youtube.com/watch?v=U1p4YMU3vWk

Vitamins and Minerals – Nutrition Fundamentals (6:58) https://www.youtube.com/watch?v=qgNURQFWNWM

- 2. Review the instructions on the Supplement Facts Label worksheet and choose a Supplement Facts label to examine. You can use the one provided or choose a different one from the references on the worksheet, from a supplement bottle from home, or from the NIH Dietary Supplement Label Database: https://dsld.od.nih.gov
- **3.** If you choose a different label, make a copy/photo of the label to add to the worksheet.

#### 4. Complete the Supplement Facts Label student worksheet.

- Select one component in the dietary supplement to study further.
- List the dietary supplement component category (e.g., vitamins, minerals).
- How much of that component is in one dose/serving of the supplement?
- Is this component water soluble?
- Identify foods and/or beverages that could be consumed to match the same quantity of your chosen dietary supplement component. Using the Nutrition Facts label (or online nutrition data) to list each food and/or beverage and the amount of this component per serving.
- What are some of the other nutrients (e.g., dietary fiber) provided by consuming the food choices that are not in the dietary supplement?
- 5. When you have completed your worksheet, discuss your answers with the whole class.

## REVIEW

#### What is included on a Supplement Facts label?

This label includes the serving size, servings per container, the amount per serving for many components, and the % Daily Value for some components. The label also lists Other Ingredients such as fillers and preservatives in the supplement.

## EXTENSIONS

Students could do one or more of the following activities:

- 1. Make a poster showing how to read parts of a Supplement Facts label.
- **2.** Identify five nutrients to get more of and create a daily menu that fulfills this goal.

### RESOURCES

How to Read a Supplement Label https://qualitymatters.usp.org/how-read-supplement-label

Osmosis.org: Prebiotics & Probiotics https://www.youtube.com/watch?v=0z47wLZ4-O4

Probiotic Product Labels https://isappscience.org/for-consumers/probiotic-product-labels/

How to Evaluate Health Information on the Internet: Questions and Answers https://ods.od.nih.gov/HealthInformation/How\_To\_Evaluate\_Health\_ Information\_on\_the\_Internet\_Questions\_and\_Answers.aspx

## Why is a Daily Value shown for some dietary supplement components and not shown for others?

Not all nutrients or dietary supplement components have an established Daily Value. For example, omega-3 fatty acids found in fish oil supplements do not have a Daily Value.

### SUMMARY

The same nutrients that are in dietary supplements are also available in foods and beverages. Foods and beverages also usually provide additional nutrients and health benefits not found in dietary supplements.

## UP NEXT 🕨 🕨

Now that you are more familiar with Supplement Facts labels, let's take a closer look at some more dietary supplements issues that might be helpful to know about.



## STUDENT WORKSHEET ACTIVITY 2: SUPPLEMENT FACTS LABEL

Name

Date \_\_\_\_\_ Class/Hour \_\_\_

Use the Supplement Facts label to the right or choose another one that includes multivitamins, live microbials (commonly referred to as "probiotics"), or fish oil. You could use a label from a dietary supplement found in your home, find one online, or choose one from the NIH Dietary Supplement Label Database: https://dsld.od.nih.gov.

Choose one of the key components, such as a specific vitamin or mineral listed on the label of your chosen supplement, to research and answer the following guestions about that component:

- 1. Identify your chosen supplement \_\_\_\_
- 2. Which component of that supplement will you research?
- 3. How much of that component is in one dose/serving?

Supplement Facts Serving Size 1 Gelcap Servings Per Container 100

% Daih

	Per Serving	Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	1.7 mg	100%
Folate 4	00 mcg DFE	100%
(240 m	cg fo <b>l</b> ic acid)	
Vitamin B12 (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

- 4. Is this component water soluble?
- 5. Complete the first line of the chart below with information about your component.
- 6. Research your chosen component to learn about foods/beverages that contain that component; list at least 3 different foods/beverages that contain your chosen component on the chart below.

Use the Nutrition Facts label (or online nutrition data, such as this database https://fdc.nal.usda.gov/index.html) to research each food and/or beverage to complete the chart below. Your completed chart will help you identify food sources that could provide you with the same daily intake amount.

Dietary supplement versus food/beverage consumption					
Dietary Supplement Component	Amount per serving	Number of servings/day	Daily total amount consumed		
Food or beverage	Nutrient amount per serving	Number of servings consumed	Total amount consumed		
Could you get enough of this					

Choose one of the foods or beverages in column 1, and list some of the other nutrients (e.g., protein) that are found in that food that are **not** in the dietary supplement?

### **FROM MODULE1**

## STUDENT WORKSHEET ANSWERS **ACTIVITY 1: PRODUCT CATEGORIES**

Name \_\_\_\_\_

\_\_ Date \_\_\_\_\_\_ Class/Hour \_\_\_\_\_\_

Consider each product below and complete the chart. Some products could be in more than one category.

	Product	Food, Drug, Cosmetic, Dietary Supplement, or multiple possible categories?	What evidence did you use to decide on this category?	Safety evaluated before or after sales?
Competitiveed LIP BALM	Orange-flavored lip balm	Cosmetic	Enhances appearance, applied topically	After sales
Daily Wutt- vitamin	Daily multivitamin	Dietary Supplement	Ingested; has dietary ingredients	After sales
Whitening <u>Toothpaste</u> Helps Preview Cavities	Whitening toothpaste that helps prevent cavities	Cosmetic OTC drug	Enhances appearance, claims to "prevent cavities"	After sales Before sales
Biotin Warst	Biotin pills (100 micrograms each)	Dietary Supplement	Ingested; has dietary ingredients	After sales
EVERGY 44 DRINK	Energy Drink	Food (beverage) or Dietary Supplement	Ingested; has dietary ingredients	After sales
WHEY D Protein Powder	Whey protein powder	Food or Dietary Supplement	Ingested; has dietary ingredients	After sales
Cosmittener	Coconut-scented shampoo	Cosmetic	Enhances appearance, applied topically	After sales
Vitamin E oil	Vitamin E oil	Cosmetic or Dietary Supplement	Enhances appearance; placed on skin Ingested; some products may be taken orally (has dietary ingredients)	After sales
Sleep Ald	Sleep aid liquid	Over the Counter (OTC) drug	Ingested	Before sales
	Caffeine lozenges	Food or Dietary supplement or OTC Drug	Ingested; has dietary ingredients Cough lozenges are OTC drugs, and some can contain caffeine.	After sales Before sales (OTC drugs)
Yogurt Active cultures	Yogurt	Food	Ingested	After sales
WEIGHT LOSS	Weight loss pill	Drug or Dietary Supplement	Ingested; has dietary ingredients Some drug products require a prescription	Before sales (drugs) After sales

## STUDENT WORKSHEET ANSWERS ACTIVITY 2: SUPPLEMENT FACTS LABEL

Name \_\_\_

Date

\_\_\_\_\_Class/Hour \_\_\_

Use the Supplement Facts label to the right or choose another one that includes multivitamins, live microbials (commonly referred to as "probiotics"), or fish oil. You could use a label from a dietary supplement found in your home, find one online, or choose one from the NIH Dietary Supplement Label Database: https://dsld.od.nih.gov.

Choose one of the key components, such as a specific vitamin or mineral listed on the label of your chosen supplement, to research and answer the following questions about that component:

- 1. Identify your chosen supplement <u>Multivitamin 1 Gelcap</u>
- 2. Which component of that supplement will you research? Vitamin D
- How much of that component is in one dose/serving?
   20 mcg

Supplement Facts

Serving Size 1 Gelcap Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE	100%
(240)	ncg fo <b>l</b> ic acid)	
Vitamin B12 (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate	) 5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

- 4. Is this component water soluble? No
- 5. Complete the first line of the chart below with information about your component.
- 6. Research your chosen component to learn about foods/beverages that contain that component; list at least 3 different foods/beverages that contain your chosen component on the chart below.

Use the Nutrition Facts label (or online nutrition data, such as this database https://fdc.nal.usda.gov/index.html) to research each food and/or beverage to complete the chart below. Your completed chart will help you identify food sources that could provide you with the same daily intake amount.

Dietary supplement versus food/beverage consumption			
Dietary Supplement Component	Amount per serving	Number of servings/day	Daily total amount consumed
Vitamin D	20 mcg	1	20 mcg
Food or beverage	Nutrient amount per serving	Number of servings consumed	Total amount consumed
Milk - 1 cup	2.5 mcg	2	5 mcg
Wild caught salmon (3.5 ounce filet)	24.7 mcg	1	24.7 mcg
Canned light tuna - 3.5 oz.	6.7 mcg	1	6.7 mcg
Could you get enough of this component in foods you would eat?			

Choose one of the foods or beverages in column 1, and list some of the other nutrients (e.g., protein) that are found in that food that are **not** in the dietary supplement?

Milk also contains calcium, protein, phosphorus, and fat.



#### Science and Our Food Supply: Examining Dietary Supplements was brought to you by...



Center for Food Safety and Applied Nutrition College Park, MD

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NIH

#### FDA

Office of Dietary Supplements

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