

Assignment 4

The Safety and Effectiveness of Dietary Supplements

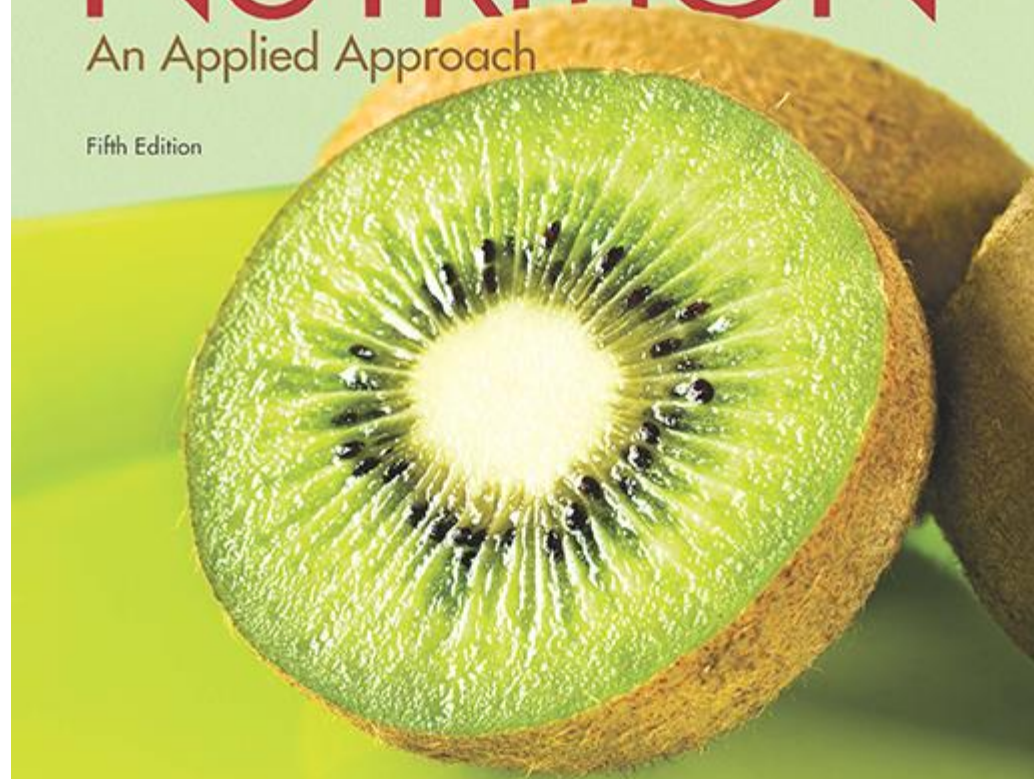
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NUTRITION

An Applied Approach

Fifth Edition



 Pearson

In Depth: Supplements

- **Supplements**, according to the FDA, are a product containing ingredients like vitamins, minerals, herbs, amino acids, or enzymes
- In 2014 sales of dietary supplements reached nearly \$37 billion
- Dietary supplements are defined by the FDA as products taken by mouth containing a "dietary ingredient" intended to supplement the diet

In Depth: Dietary Supplements

May contain:

- Vitamins
- Minerals
- Herbs or other botanicals
- Amino acids
- Enzymes
- Tissues from animal organs or glands
- Concentrate, metabolite, constituent, or extract

In Depth: Supplements (cont.)

- Are supplements safe?
 - In 2015, 14 U.S. Attorneys General signed a letter to congress requesting for an investigation of the dietary supplement industry
 - This comes after an audit for DNA testing of ingredients found they did not contain ingredients listed, but did contain heavy metals

In Depth: Dietary Supplements

Categorized generally as foods, not drugs

Regulation is less rigorous than for drugs

FDA regulation of supplements marketing is currently in flux

In Depth: Dietary Supplements

What you should know:

- FDA approval is not needed for marketing
- Manufacturers are solely responsible for safety
- Sellers are not required to show evidence of safety
- There are no federal guidelines to ensure purity, quality, safety, or composition
- No rules limit serving sizes
- Once a supplement is marketed, the FDA must prove it is unsafe for it to be removed from stores

In Depth: Supplements (cont.)



Vita-Wow

Multivitamin/multimineral supplement with Ginseng*
100 Tablets

* "Helps promote optimal energy."
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.

Directions: Adults: One tablet daily, with food.

Supplement Facts
Serving Size: One tablet

	Amount Per serving	% Daily Value
Vitamin A	2500 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamin	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin	10 mg	50%
Vitamin B ₆	2 mg	100%
Magnesium	50 mg	12%
Iron	18 mg	100%
Zinc	15 mg	100%
American Ginseng Standardized Extract	200 mg	++

++No Daily Value established for Ginseng.

Other ingredients: Cellulose, Dextrin, Gelatin, Starch, Dextrose, FD&C Yellow #6, FD&C Blue #2

Made in U.S.A.
Distributed by:
Supervitamin Corporation
P.O. Box XYZ
Energized, CA 00000

1 Statement of identity

2 Net quantity of contents

3 Directions

4 Supplement facts panel

5 Other ingredients in descending order by weight and using common name

6 Name and place of business, manufacturer, packer, or distributor; the address for more information

In Depth: Supplements (cont.)

- The FDA does not have the authority to review safety and efficacy of supplements
- It is the responsibility of the manufacturer to prove the safety of supplements
- Manufacturers do not have to tell the FDA they have added an ingredient
- The FDA does not regulate practices to ensure the purity

In Depth: Supplements (cont.)

- Herbal supplements
 - The plant or part of the plant that is used to flavor, scent, and/or potential health-related properties
 - The National Center for Complimentary and Integrative Health (NCCIH)
 - Consult a healthcare provider before beginning a supplement

In Depth: Dietary Supplements

Precautions for herbal supplements:

- An **herb** (or botanical) is a plant or plant part used for its scent, flavor, and/or therapeutic properties
- Consult your healthcare provider before using herbal supplements
- Herbs may cause serious medical problems if used in large amounts
- Avoid using herbs when pregnant or nursing unless you have consulted a doctor
- Active ingredients in many herbs and herbal supplements are not known

In Depth: Dietary Supplements

Should you take a dietary supplement?

- Many people do not need supplements
- Supplements are not substitutes for whole foods
- Some individuals who may benefit from supplements include:
 - Vegans
 - Athletes
 - Infants and children
 - Pregnant teens and pregnant women
 - Elderly people
 - Convalescents

In Depth: Supplements (cont.)

TABLE 1 Potentially Harmful Herbal Supplements

Herb	Potential Risks
Bitter orange	Increased blood pressure and heart rate; heart attack; stroke
Ephedra (also known as <i>ma huang</i> , Chinese ephedra, and epitonin)	High blood pressure, irregular heartbeat, nerve damage, insomnia, tremors, headaches, seizures, heart attack, stroke, possible death
Kava (also known as <i>kava kava</i>)	Liver damage; death
Licorice root	High blood pressure, fluid retention, hypokalemia
Noni	Liver damage
Thunder god vine	Diarrhea, nausea, skin rash, headache, hair loss, menstrual changes, male infertility; can be fatal if improperly extracted
Willow bark	Reye's syndrome (a potentially fatal reaction that may occur when children take aspirin), allergic reaction in adults
Yohimbe	High blood pressure, increased heart rate, headache, anxiety, dizziness, nausea, vomiting, tremors, insomnia

Source: Data from National Center for Complementary and Integrative Health (NCCIH). 2016. *Herbs at a Glance*. <https://nccih.nih.gov/health/herbsataglance.htm>

Risks Associated with Supplements

TABLE 2 Supplement Ingredients Associated with Illnesses and Injuries

Ingredient	Potential Risks
Herbal Ingredients	
Chaparral	Liver disease
Kava (also known as <i>kava kava</i>)	Severe liver toxicity
Comfrey	Obstruction of blood flow to liver, possible death
Slimming/dieter's teas	Nausea, diarrhea, vomiting, stomach cramps, constipation, fainting, possible death
Ephedra (also known as <i>ma huang</i> , Chinese ephedra, and epitonin)	High blood pressure, irregular heartbeat, nerve damage, insomnia, tremors, headaches, seizures, heart attack, stroke, possible death
Germander	Liver disease, possible death
Lobelia	Breathing problems, excessive sweating, rapid heartbeat, low blood pressure, coma, possible death
Magnolia-Stephania preparation	Kidney disease, can lead to permanent kidney failure
Willow bark	Reye's syndrome (a potentially fatal disease that may occur when children take aspirin), allergic reaction in adults
Wormwood	Numbness of legs and arms, loss of intellectual processing, delirium, paralysis
Vitamins and Essential Minerals	
Vitamin A (when taking 25,000 IU or more per day)	Birth defects, bone abnormalities, severe liver disease
Vitamin B ₆ (when taking more than 100 mg per day)	Loss of balance, injuries to nerves that alter our touch sensation
Niacin (when taking slow-release doses of 500 mg or more per day, or when taking immediate-release doses of 750 mg or more per day)	Stomach pain; nausea; vomiting; bloating; cramping; diarrhea; liver disease; damage to the muscles, eye, and heart
Selenium (when taking 800 to 1,000 µg per day)	Tissue damage
Other Ingredients	
Germanium (a nonessential mineral)	Kidney damage
L-tryptophan (an amino acid)	Eosinophilia-myalgia syndrome (a potentially fatal blood disorder that causes high fever)

Data from: U.S. Food and Drug Administration. 2007. *Dietary supplements. Warnings and safety information.*

In Depth: Supplements (cont.)

- Surveys show that 67% of Americans use a vitamin or mineral supplement
 - 35% use “specialty” supplements
 - 23% use botanicals
 - 17% use sports supplements

In Depth: Supplements (cont.)

TABLE 2 Individuals Who May Benefit from Micronutrient Supplementation

Type of Individual	Specific Supplements That May Help
Newborns	Routinely given a single dose of vitamin K at birth
Infants	Depends on age and nutrition; may need iron, vitamin D, or other nutrients
Children not drinking fluoridated water	Fluoride supplements
Children with poor eating habits or overweight children on an energy-restricted diet	Multivitamin and multimineral supplement that does not exceed the RDA for the nutrients it contains
Pregnant teenagers	Iron and folic acid; other nutrients may be necessary if diet is very poor
Women who may become pregnant	Multivitamin or multivitamin and multimineral supplement that contains 0.4 mg of folic acid
Pregnant or lactating women	Multivitamin and multimineral supplement that contains iron, folic acid, zinc, copper, calcium, vitamin B ₆ , vitamin C, and vitamin D
People on prolonged or highly calorically restrictive weight-reduction diets	Multivitamin and multimineral supplement
People recovering from serious illness or surgery	Multivitamin and multimineral supplement
People with HIV/AIDS or other wasting diseases; people addicted to drugs or alcohol	Multivitamin and multimineral supplement or single-nutrient supplements
People who do not consume adequate calcium	Calcium should be consumed in whole foods and beverages; however, for some populations, supplements may be prescribed
People with low exposure to sunlight	Vitamin D
People eating a vegan diet	Vitamin B ₁₂ , riboflavin, calcium, vitamin D, iron, and zinc
People who have had portions of their intestinal tract removed; people who have a malabsorptive disease	Depends on the exact condition; may include various fat-soluble and/or water-soluble vitamins and other nutrients
Elderly people	Multivitamin and multimineral supplement, vitamin B ₁₂

Assignment 4:

- *Please provide your answer in a thought-out, coherent essay and use complete sentences.*
- Basketball player Michael's weight averages about 190 pounds during basketball season. He never thought he needed to take a multivitamin and mineral supplement since he is healthy and eats a variety of foods. Michael just took a nutrition course about vitamins and minerals and what they do for the body. He is considering taking a supplement just for the insurance. He uses up a lot of energy working out and playing basketball. He thinks that he will be able to keep his weight up if he takes a pill every day.
- A) Should Michael take a multivitamin and mineral supplement "just for the insurance"? Why or why not?
- B) Would taking a supplement be likely to effect Michael's weight? Explain.
- C) When choosing a supplement, what must Michael consider? Explain.