

SEPTEMBER 2022

Feedback on FDA's 'Supplement Your Knowledge' and more

FDA Launches New Dietary Supplement Education Initiative

FDA U.S. FOOD & DRUG ADMINISTRATION

Supplement Your Knowledge

Dietary Supplement Education Initiative




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What Physicians Should Know – Part 1

Dietary supplements are defined, regulated, and labeled, including...



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SCIENCE AND OUR FOOD SUPPLY

Examining Dietary Supplements

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% all trans-retinyl)	500 IU	100%
Vitamin C (as ascorbic acid)	250 mg	50%
Vitamin E (as d-alpha-tocopherol)	15 mg	30%
Vitamin K (as menaquinone)	1.2 mg	24%
Iron (as ferrous fumarate)	18 mg	36%
Vitamin B1 (as thiamine hydrochloride)	1.2 mg	24%
Vitamin B2 (as riboflavin)	1.7 mg	34%
Vitamin B3 (as niacin)	18 mg	36%
Vitamin B6 (as pyridoxine hydrochloride)	1.8 mg	36%
Vitamin B12 (as cyanocobalamin)	600 mcg	120%
Folate (as folic acid)	400 mcg	80%
Vitamin D3 (as cholecalciferol)	2000 IU	400%
Vitamin D2 (as ergocalciferol)	2000 IU	400%
Vitamin D4 (as calciferol)	2000 IU	400%

Teacher!

CRN examined:

- FDA's consumer education materials, ***Supplement Your Knowledge***
- FDA's ***Dietary Supplement Continuing Medical Education Program*** (developed in collaboration with the AMA)
- FDA's new curriculum for high school science classes, ***Science and Our Food Supply: Examining Dietary Supplements***
- FDA's general treatment and descriptions of dietary supplements and dietary supplement regulation on its website

CRN's recommendations address ways that FDA's content:

- Overstates the potential risks of taking supplements, while downplaying their benefits.
- Fails to convey the robust regulatory framework that gives the agency authority over dietary supplements—downplays areas of existing authority and draws attention to ways FDA lacks authority.
- Misses opportunities to address public health issues like nutrition gaps, shortfalls in nutrient of concern, and nutritional needs of specific populations.
- Could be enhanced by collaboration with the dietary supplement industry.

Overall tone

Cosmetics

VS

Supplements

From FDA's "[Cosmetic Products](#)" page:

“Under U.S. law, cosmetic products and ingredients **do not need FDA approval before they go on the market.** The one exception is color additives (other than coloring materials used in coal-tar hair dyes), which must be approved for their intended use. Companies and individuals who market cosmetics have a legal responsibility to ensure the safety of their products. In order to take action for safety reasons against a cosmetic on the market, we need reliable information showing that it is unsafe when consumers use it according to the directions in the labeling or in the customary or expected way.”

The "[Information for Consumers on Using Dietary Supplements](#)" page

“The Dietary Supplement Health and Education Act (DSHEA) of 1994, which amended the Federal Food, Drug, and Cosmetic Act, transformed FDA’s authority to regulate dietary supplements. Under DSHEA, **FDA is not authorized to approve dietary supplements for safety and effectiveness before they are marketed.** In fact, in many cases, firms can lawfully introduce dietary supplements to the market without even notifying FDA. Since DSHEA was enacted, the dietary supplement market has grown significantly. For example, the number of products has expanded nearly twenty times since 1994.”

Overall tone

From FDA's "[Cosmetic Products](#)" page:

"Under U.S. law, cosmetic products and ingredients do not need FDA approval

Note that cosmetics "do not need FDA approval" but "FDA is not authorized to approve" dietary supplements. Other FDA regulated categories are portrayed as appropriately regulated, while dietary supplements are depicted as insufficiently regulated.

(other than those approved for their safety and efficacy) have a legal right to market their products without FDA action for approval. For more information, see the FDA's directions in the

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1994, which gave FDA's authority to regulate dietary supplements. **not**

authorized to approve dietary supplements for safety and effectiveness before they are marketed. In fact, in many cases, firms can lawfully introduce dietary supplements to the market without even notifying FDA. Since DSHEA was enacted, the dietary supplement market has grown significantly. For example, the number of products has expanded nearly twenty times since 1994."

Overall tone

Over-emphasis of risk compared with other FDA-regulated products



Dietary Supplements: What Physicians Should Know

Patients may take dietary supplements, whether recommended by you or on their own, for a variety of reasons. Some supplements can help patients meet the daily requirements for essential nutrients or can help improve and maintain their overall health. **But dietary supplements may also come with health risks that your patients may not know about.**

What are the Risks of Taking Dietary Supplements?

Dietary supplements may contain ingredients that can have strong effects in the body. Patients may experience harmful and...

Stay Safe While Taking Dietary Supplements

- Read the product labels
- Be cautious
- Know the facts
- Always talk to your doctor or healthcare professional

FDA strongly encourages you to talk to your patients about dietary supplements during your review of their medical health history.

- Ask your patients about what

FDA U.S. FOOD & DRUG ADMINISTRATION

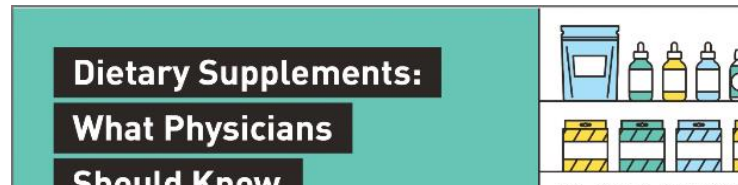
Supplement Your Knowledge

Dietary Supplement Education Initiative

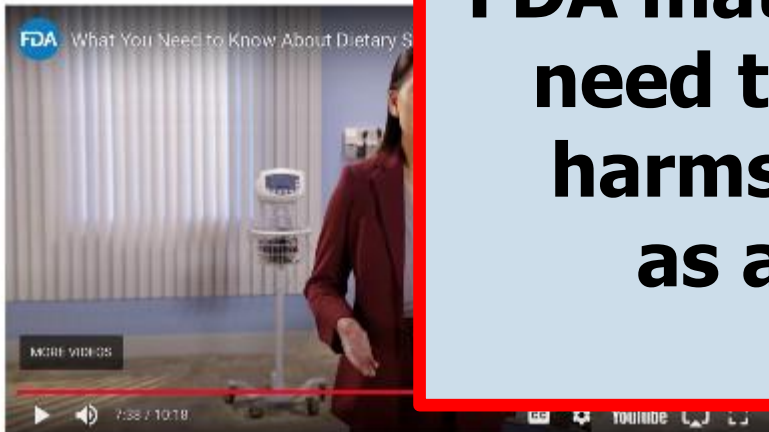
Dietary supplements can help people improve or maintain their overall health. But they may also come with health risks. Whether you're a consumer of dietary supplements or it's your job to inform and educate, it's important to know the facts before deciding to take any dietary supplement.

Overall tone

Over-emphasis of risk
compared with other
FDA-regulated products



FDA materials emphasize "health risk," the need to "stay safe," and other potential harms from supplements. Staying safe as a supplement user is portrayed as a "challenge."



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• Ask your patients about what

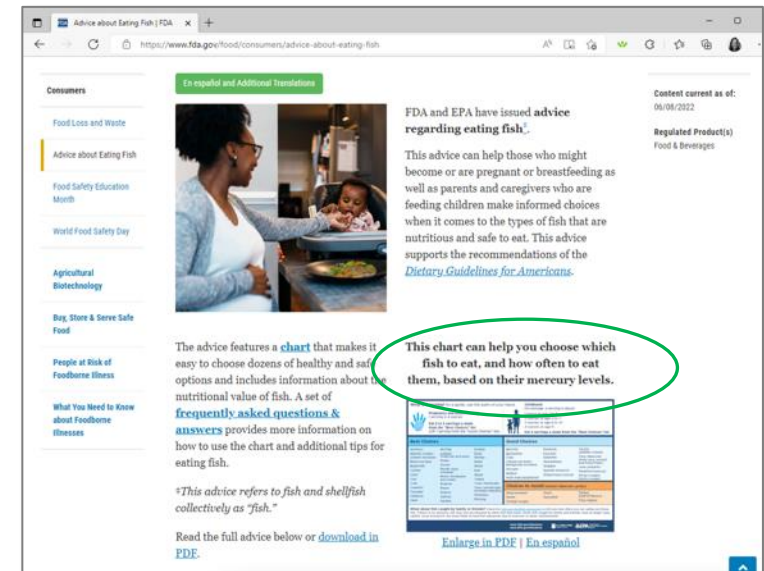
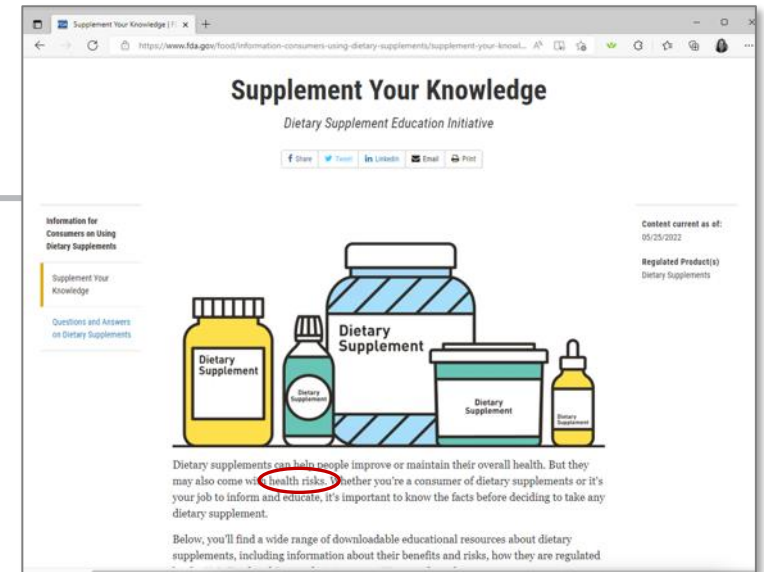
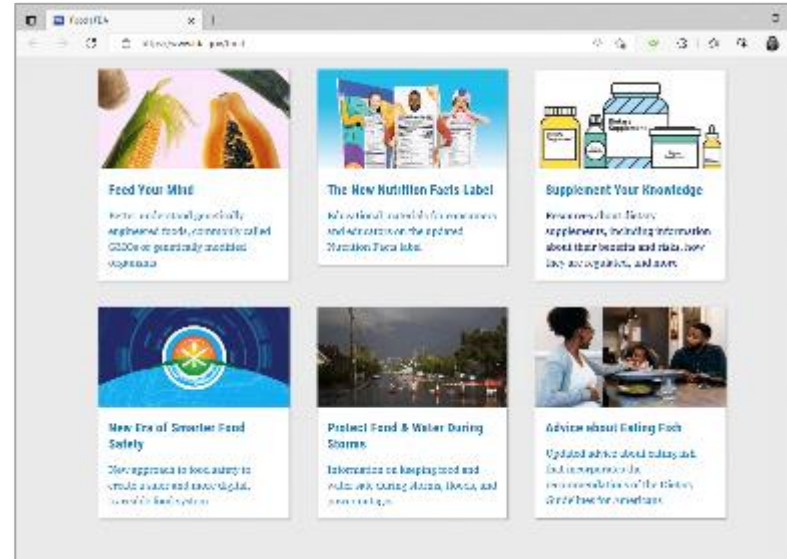
RESPONDING TO FDA'S CHARACTERIZATION OF SUPPLEMENTS

Overall tone

Supplements

VS

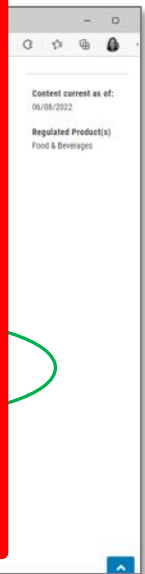
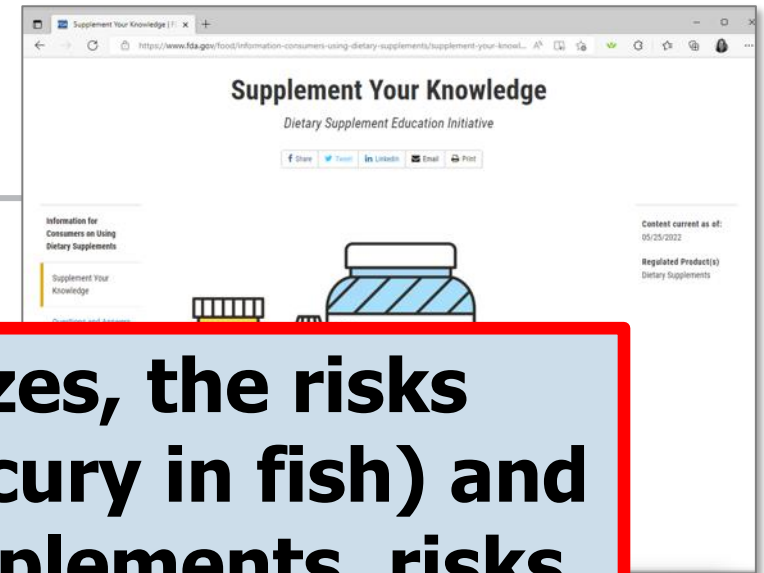
Other foods



Overall tone

FDA acknowledges, but minimizes, the risks associated with food (such as mercury in fish) and gives tips to reduce risk. With supplements, risks are highlighted; FDA's solution is don't use them.

Note also that omega-3 supplements are highly purified and provide this essential nutrient without risks from heavy metals. Yet supplements are not even mentioned as an alternate source of omega-3s for pregnant women.



Overall tone



The DGA also mention nutrient shortfalls and the need for supplementation in some populations—but these facts are not addressed in FDA's content about dietary supplements. This is a missed opportunity to provide important information about the prevalence of nutrient shortfalls.

Americans fall short in many key nutrients.¹ The 2020 – 2025 Dietary Guidelines for Americans (DGAs) identified that under-consumption of calcium, potassium, dietary fiber, and vitamin D is of public health concern for the general U.S. population because low intakes are associated with particular health concerns.² Iron was also identified to be of public health concern in adolescent girls and women of reproductive age, as well as in breastfed infants ages 6 through 11 months.^{3,4} In pregnant women, under-consumption of folic acid (in the first trimester), iron, and iodine is also of public health concern.^{5,6} The DGAs also state that adolescent females have low dietary intakes of protein, folate, vitamin B6, vitamin B12, choline, and magnesium, and that dietary protein and vitamin B12 are more likely to be under-consumed in older adults (60+).

¹ The 2020 Dietary Guidelines Advisory Committee (DGAC). Scientific report of the 2020 Dietary Guidelines Advisory Committee. Washington (DC): USDA, Agricultural Research Service; 2020.

² U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (HHS). Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

³ DGAC. Scientific report of the 2020 Dietary Guidelines Advisory Committee. Washington (DC): USDA, Agricultural Research Service; 2020.

⁴ USDA and HHS. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

⁵ DGAC. Scientific report of the 2020 Dietary Guidelines Advisory Committee. Washington (DC): USDA, Agricultural Research Service; 2020.

⁶ UUSDA and HHS. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

Overall tone



FDA materials do not acknowledge that the *2020–2025 Dietary Guidelines for Americans* identifies numerous nutrients where low intakes are associated with particular health concerns, and supplements could help offset under-consumption of these essential nutrients.

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* UUSDA and HHS. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov.

Regulation as a category of food



**Dietary Supplements:
How FDA Helps Keep You Safe**



The Law

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defined dietary supplements and set out FDA's authority regarding these products. Under DSHEA:

- **FDA does not have the authority to approve dietary supplements for safety and effectiveness or their labeling before they are sold in stores or online.**
- Dietary supplement companies are responsible for ensuring that their products are safe and label claims are truthful and substantiated.
- Dietary supplement companies can introduce new dietary supplements to the market without receiving approval from FDA. In fact, they often can introduce dietary supplements to the market without even notifying FDA.

Suggested rephrasing

Dietary supplements are regulated by FDA in many respects, but they do not require FDA approval for safety or effectiveness before they are sold in stores or online.

Dietary supplements include vitamins, minerals, herbs, amino acids, whey protein, and creatine. **FDA does not approve dietary supplements before they are sold to the public.** Therefore, it is particularly important for consumers, healthcare professionals, and industry members to report health-related reactions or illnesses (also known as adverse events) to FDA, so we can evaluate the marketplace and take action to protect the public from possibly unsafe products.*

Regulation as a category of food



FDA materials do not identify ways that dietary supplements are more regulated than food: separate Good Manufacturing Practices, adverse event reporting, separate labeling requirements, NDI notifications for new ingredients, etc.

Suggested rephrasing
Dietary supplements are regulated products, but they require approval from FDA before they are sold online.

herbs, amino acids, when dietary supplements before particularly important for consumers to report health-related reactions or illnesses (also known as adverse events) to FDA, so we can evaluate the marketplace and take action to protect the public from possibly unsafe products."

- their labeling before they are sold in stores or online.
- Dietary supplement companies are responsible for ensuring that their products are safe and label claims are truthful and substantiated.
 - Dietary supplement companies can introduce new dietary supplements to the market without receiving approval from FDA. In fact, they often can introduce dietary supplements to the market without even notifying FDA.

Regulation as a category of food

Stakeholders need to know that, when compared to other foods, dietary supplements are in many respects *more* regulated.

- **As with foods, FDA has inspection authority** over dietary supplement facilities.
- **Plus, dietary supplements have their own GMP requirements** under Part 111 that in many respects are more stringent than those for other foods in Part 110 and Part 117.
- **Dietary supplements must submit their structure-function claims** to FDA, whereas foods do not.
- **The serious adverse event reporting** requirement is another example of a regulation specific to supplements and not other foods.

Serious adverse event reports

- Portrays adverse events are much more common than they are.
- Examples presented are very frightening—and unlikely.
- **FDA should present information** on how to report serious adverse events without leading consumers to assume these products pose a higher level of risk.
- **The number of serious adverse events** associated with dietary supplements—relatively few—should be included to put the risk in context.

By contrast, FDA gets it right in the high school curriculum

Dietary supplements comprise only a small portion of total FDA recalls: just 2% of more than 800 recalls initiated in 2019 involved dietary supplement products.

Manufacturers usually voluntarily recall products of concern.

MODULE 1 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=-Y1Ln9UjVs>

Drugs vs. Supplements (1:18)
<https://www.webmd.com/medications-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 Pro and Pre and Probiotics (3:14)
<https://www.youtube.com/watch?v=U1p4YMUSWk>

Vitamins and Minerals – Nutrition Fundamentals (6:58)

Content for educators

15 mentions of “benefit”

VS

65 mentions of “risk”

MODULE 2: DIETARY SUPPLEMENTS: RISKS, REALITIES, AND REPORTING

BACKGROUND INFORMATION

What is a Steroid?


The term “steroid” refers to a type of compound that has a specific molecular structure. Generally speaking, steroids mimic hormones that are produced by glands in the human body. But there are different types of steroids. Some are used to treat health problems—but others can be dangerous.

To learn more about bodybuilding products and FDA's warnings about them, visit: <https://www.fda.gov/consumers/consumer-updates/caution-bodybuilding-products-can-be-risky>

Corticosteroids: These are common steroids that are taken—usually for a short time—for a variety of health issues. Corticosteroids are similar to the hormones that your adrenal glands make to fight stress associated with illnesses

Steroid- Related Risk Prevention Efforts

1990 Congress passed the **Anabolic Steroid Act of 1990**



Content for educators

15 mentions of "benefit"

VS

65 mentions of "risk"

FDA materials overemphasize risks of dietary supplements and minimize potential health benefits.

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Social media

- The suggested messages for posting are more balanced than other FDA content.
- However, the lead-in language on the toolkit page keeps with the theme of overemphasizing risk.
- And, of course, the content it links to has its issues, as we've shown.



Dietary supplements can be beneficial to your health, but they can also involve health risks. When you take too much of a dietary supplement or take supplements with prescription or over-the-counter medicines, you can have a bad reaction—also called an adverse event. And, if you take dietary supplements instead of prescribed medicines, the results potentially could be life-threatening.

Facebook and Twitter Posts



How are dietary supplements regulated? What are the benefits? Risks? If you want to know more, FDA has the answers.
<https://go.usa.gov/xuAGK>

Always talk with your doctor or other healthcare professional about any supplements you are taking or considering...and do your research. You can find important facts about dietary supplements on FDA's website.
<https://go.usa.gov/xuAGK>

Content for health care professionals



Did you know that dietary supplements are not approved by FDA?



...that's concerning

Content for health care professionals

Did you know that

FDA-AMA continuing education videos are examples of what NOT to do:

- Overly alarm the patient.
- Raise potential risks unrelated to the specific supplement at hand.
- Dismiss or minimize the health benefits.
- Discourage open communication by the patient.
- Reduce likelihood of candor in the future about supplement usage.

cerning

Content for health care professionals

- Why AMA collaboration but no supplement experts?
- Warnings about ingesting nutrients above 100% Daily Value demonstrates complete lack of appreciation for the appropriate uses of DVs as contrasted with Tolerable Upper Intake Levels (ULs).
- The illustrated doctor-patient consultation is likely to reduce future conversations with the patient about supplements and discourage candor about actual usage.

Why it matters

In addition to educating the core 3 audiences to support public health...

- **Journalists and policymakers** may access the content for background so it is critical that the fact that FDA regulates dietary supplements is clearly stated.
- **There's a difference between** encouraging constituents to be smart consumers of safe and beneficial products and painting an entire industry and CPG category as deserving of skepticism.
- **CRN seeks to open a more active dialogue** as a trusted resource for factual, science-backed as updates are made to educational content or new content is developed in the future.