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Is My Patient Taking an Unsafe Dietary Supplement?

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Abstract

Dietary supplements do not require premarket approval by the US Food and Drug Administration (FDA), yet they can have side effects; interact with medications, food, or other supplements; or be unsafe, so it is important for clinicians to discuss dietary supplement use with patients. This article provides an overview of dietary supplement requirements related to safety, manufacturing, labeling, advertising, and adverse event reporting; discusses tainted supplements and the FDA's and Federal Trade Commission's enforcement actions against dietary supplements; and offers recommendations to clinicians on matters of key clinical and ethical importance during clinical encounters.

Helping Clinicians Help Patients

Nearly three-quarters of Americans take dietary supplements¹ as tablets, capsules, powders, softgels, or liquids.² With 80 000 products currently on the market,³ clinicians should help patients safely choose and use these products. This article aims to further that cause; we discuss the US Food and Drug Administration's (FDA's) regulation of dietary supplements and the Federal Trade Commission's (FTC's) oversight of dietary supplement advertising and offer recommendations to help **guide clinicians' discussions** with patients.

Regulating Dietary Supplements

Dietary supplements are regulated under the Dietary Supplement Health and Education Act (DSHEA) of 1994,⁴ which defines a dietary supplement as a non-tobacco product taken by mouth that contains an ingredient intended to supplement the diet. Dietary ingredients in supplements can include vitamins, minerals, herbs, botanicals, amino acids, enzymes, or metabolites.⁵ Many incorrectly assume that dietary supplements are tested by the FDA for safety and effectiveness. While manufacturers must ensure their products are safe and that all labeling claims are substantiated by adequate evidence,⁶ dietary supplements do not require FDA approval before they are marketed.⁶ The FDA can only act against misbranded, unsafe, or adulterated supplements after they are on the market.⁷

Adverse events. Manufacturers must notify the FDA of serious adverse events (SAEs) associated with their supplements.⁸ Clinicians and patients may also report SAEs to the FDA through the agency's Safety Reporting Portal⁹ or by calling 1-800-FDA-1088.¹⁰ In addition to ensuring safety, manufacturers are required to register their production facilities with the FDA¹¹ and to adhere to current good manufacturing practices.¹²

Labeling requirements. The FDA requires dietary supplement labels to include the following:

- A descriptive name of the product stating that it is a "supplement"¹³
- The name and address of the manufacturer, packer, or distributor¹⁴
- A complete list of ingredients¹⁵
- The quantity of each ingredient or the total quantity of all ingredients in a proprietary blend¹⁵

Each dietary supplement must have a "Supplement Facts" panel¹⁶ that includes the following¹⁷:

- Serving size and amount per serving
- Names and quantities of each ingredient for which daily values have been established: total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron (when present in measurable amounts)
- Dietary ingredients with no daily value must be listed by common name
- Percent daily value (% DV) for each dietary ingredient

Although each ingredient must be listed, the FDA does not regulate serving sizes or nutrient amounts.⁶

Dietary supplement claims. Three types of claims can be made about dietary supplements: health, structure/function, and nutrient content claims. Health claims describe relationships between a nutrient or food substance and reduced risk of a disease or health-related condition. There are 3 ways in which the FDA oversees health claims: (1) by authorizing regulations; (2) through sufficient notification that a health claim is based on an authoritative statement of the National Academy of Sciences or a scientific body of the US government that has responsibilities in nutrition research or public health protection; and (3) by issuing a letter of enforcement discretion for credible, nonmisleading, qualified health claims.¹⁸ Some dietary supplements' packaging might claim that a nutrient or ingredient is intended to affect the body's structure or function. The FDA does not authorize structure/function claims, but the DSHEA requires the supplement label to bear the disclaimer, "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."¹⁹ Nutrient content claims describe a nutrient's "level" beyond amounts listed on a label's "Supplement Facts" panel and must be authorized by the FDA. For example, "high protein," "low fat," or "100% whole grains" are common¹⁸ and must comply with information found in Appendices A and B of the FDA's food labeling guide.²⁰

Adulteration. The FDA bears the burden of proof that a supplement is adulterated.²¹ Under the DSHEA, a dietary supplement is deemed adulterated if any of the following 4 conditions hold:

1. It “presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”²²
2. It “is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”²³
3. It “pose[s] an imminent hazard to public health or safety.”²⁴
4. It meets a conventional food adulteration standard in the Federal Food, Drug, and Cosmetic Act “under the conditions of use recommended or suggested in the labeling of such dietary supplement.”²⁵

Enforcement. If the FDA finds that a dietary supplement is unsafe, contains false or misleading labeling, or is adulterated, the agency can issue a warning letter or require the product’s removal from the market.²⁶ The FTC may prohibit **false or misleading** dietary supplement advertising as “an unfair or deceptive act or practice.”²⁷ Violations of the FTC Act may result in issuance of an injunction or an administrative cease and desist order.²⁸ Manufacturers making deceptive claims about treatment, cure, prevention, or mitigation of disease can be subject to civil penalty up to \$43 792 per violation and be required to refund consumers or provide other relief.²⁹ Since 2010, the FTC has challenged more than 100 dietary supplement health claims.³⁰ Clinicians and patients can report false and misleading advertising claims at ReportFraud.ftc.gov.³¹

Dietary supplements of particular concern. Tainted supplements containing undeclared ingredients can pose serious risks. To date, the FDA has found over 1060 tainted products marketed as dietary supplements,³² including products for bodybuilding, sexual enhancement, weight loss, arthritis or pain, and insomnia.³³ The FDA has taken action against products sold on the internet that claimed to be, but were not, legally marketed dietary supplements.³⁴ The FDA notes that it is “unable to test and identify all products marketed as dietary supplements on the market that have potentially harmful hidden ingredients” and urges consumer caution.³⁵

Three Upshots

1. *Dietary supplements can have side effects; interact with medications, food, or other supplements; or be unsafe.* These harms result due to the supplement’s being contaminated, tainted with at least one drug ingredient, or containing more than a labeled amount of ingredients.³⁶ For these reasons, clinicians should specifically ask whether patients use dietary supplements, which ones, at which dose(s), and counsel them appropriately.
2. *Clinicians may recommend products tested by independent labs.* The United States Pharmacopeia (USP), ConsumerLab.com, NSF International, and the Natural Products Association, for example, can verify product ingredients and amounts. The USP Verified Mark indicates that a dietary supplement meets its evaluation criteria.³⁷

3. *Counsel patients about claims that seem too good to be true.* Clinicians should counsel patients not to use dietary supplements with exaggerated or unrealistic advertising, such as those claiming to be magical, cure-alls, quick fixes, or scientific breakthroughs.³⁸ Simply put, if a claim seems too good to be true, it probably is!

Most Americans take dietary supplements in some form, and it is important for clinicians to help consumers understand that their safety and efficacy are not established by the FDA. Supplements' quality varies, so clinicians should cultivate adequate knowledge prior to recommending a dietary supplement, specifically ask patients about their use of dietary supplements, and counsel patients appropriately.

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