

Choosing for Quality: Dietary Supplements

Information for pharmacists advising consumers on quality considerations

Many consumers take dietary supplements without advice from a healthcare professional, meaning they may not be considering quality factors that healthcare professionals would prioritize in choosing a product. A U.S. consumer survey conducted annually from 2018-2022 found that a large majority (>70%) of adults report using dietary supplements.¹⁻⁵ A peer-reviewed 2022 paper reported that dietary supplement use increased in the U.S. from 2007-2018, based on the Center for Disease Control and Prevention's ongoing National Health and Nutrition Evaluation Survey (NHANES).⁶ While many report purchasing such products in pharmacies,⁷ a minority (40%) of consumers discuss dietary supplements with a healthcare professional,⁸ and 75% report using at least one dietary supplement without a recommendation from a physician.⁹ Of those who do seek advice from a healthcare professional, 40% report that they changed their behaviors after such a consultation.^{1,10}

Pharmacists are in a unique position to share their knowledge about dietary supplements with consumers, including the importance of choosing for quality. As a pharmacist, you are their most

accessible healthcare expert,^{11,12} and any of your direct interactions provide you with opportunities to build upon consumers' trust in pharmacists.¹³⁻¹⁵ You are both an expert on the importance of quality products to delivering safe care, and how to educate consumers.^{16,17} As appropriate, when speaking with physicians and pharmacy technicians, remind them to direct consumers to a pharmacist to answer questions about dietary supplement use.

This resource, “Choosing for Quality: Dietary Supplements”, a publication of the USP Convention[‡], provides pharmacists with useful information regarding quality considerations for dietary supplements that you can pass along to consumers. Several references are included, both in Further Reading and as citations, should you seek additional information.

Note that USP quality standards provide comprehensive information to help ensure quality, but do not indicate efficacy, serving size, or nutritional value; USP also does not recommend specific brands or products.

USP – over 200 years of standards for quality: Providing guidelines for quality medications, dietary supplements, and food ingredients, the U.S. Pharmacopeia (USP) prioritizes patient and consumer safety. USP is an independent, scientific nonprofit organization that builds trust through developing quality standards that help manufacturers deliver quality and safe medicines, dietary supplements and food ingredients to billions of people worldwide. Specifically for dietary ingredients and dietary supplements, USP:

- Publishes the *Dietary Supplements Compendium*, a comprehensive resource, which includes +1100 publicly vetted science-based quality standards for manufacturers and dietary ingredient suppliers.^{18, 19}
- Provides voluntary quality verification services for dietary supplement manufacturers through its Dietary Supplements Verification Program.²⁰



Key takeaways: choosing for quality

- **Ask consumers if they have questions about dietary supplements, and help them understand how quality is defined and why it matters.**
- **Encourage consumers to ask healthcare professionals about dietary supplements, especially if they are taking prescription or over-the-counter medicines.**
- **The U.S. Food and Drug Administration (FDA) regulates dietary supplements differently from medicines; regulatory approval is not required prior to releasing a product to the marketplace.**
- **Price and label features, such as serving sizes, are not necessarily indicators of quality.**
- **Certain dietary supplement product categories have a higher potential to be adulterated and/or illegally labeled, and may cause harm. For example, products targeting athletic performance, sexual enhancement, or weight loss have more reports of such problems.**
- **Look for trusted third party quality verification indicators, such as USP Verified, noting such services are voluntary and not required by FDA.**





Defining quality in dietary supplements

USP establishes quality specifications for dietary ingredients including identity, purity, composition/strength, and performance (e.g., dissolution). These are the same attributes USP uses to measure quality for a medicine or a conventional food ingredient:¹⁸⁻²⁰

Identity: does the bottle contain what the label says it does? Inappropriately present materials might include mis-identified or substituted ingredients, such as different botanical species mistakenly included (i.e., collected by accident) or ingredients from another formulation.

Impurity and contaminant controls: what is the product purity? Limits are placed on substances that could be harmful, such as contaminants from cultivation and/or manufacturing, (e.g., heavy metals, pesticides, or mold).

Composition or Strength (commonly referred to as **Potency**): is the labeled amount actually present? Dietary supplements must have at least 100% of their labeled amount present at any shelf-life expiration date (noting that the expiration date is not required labeling).

Performance: does the formulation materially behave as intended? For example, when swallowed, does a solid dose, such as a tablet, disintegrate or dissolve in the stomach as expected? Additional performance criteria, such as weight variation, disintegration or dissolution requirements are included for finished formulations.



Some products may be tainted with illegal and/or harmful ingredients.

By definition, dietary supplements are products that are intended to supplement the diet.²¹ Dietary supplements generally cannot include active pharmaceutical ingredients (APIs) used in medicines. Suspicious products often include one or all of the below:

- Label claims that read too good to be true (e.g., claiming to treat a disease or cure a condition)
- Labeled as a 'legal' alternative to something disallowed (e.g., anabolic steroids²²)
- Do not meet the FDA definition of dietary supplements (see below).

Products promoted for athletic performance/muscle building, sexual enhancement, and dieting/weight loss tend to have a higher rate of FDA warning letters, recalls, or withdrawals due, in many instances, to detection of undeclared and/or illegal ingredients,²³ sometimes referred to as being “spiked.”⁸ Since the FDA does not conduct pre-market approval for dietary supplements in the U.S. (unlike for prescription medicines), these tainted products might be found on shelves unbeknownst to the FDA, healthcare practitioners, or consumers until adverse reactions are reported.¹¹



Dietary supplements are regulated in the U.S. commercial market, but differently than medicines.

While the attributes listed above are scientific parameters that inform quality assurance / quality control, akin to those used for medicines, the FDA regulates dietary supplements differently. Most notably, dietary supplements are a sub-category of foods under U.S. regulatory law.²¹ Thus, like most foods, dietary supplements do not have pre-market approval (new dietary ingredients generally need a 75-day pre-market notification to FDA), whereas prescription medicines have extensive pre-market approval requirements.²⁴

In 2019, FDA reported that the dietary supplement market has “more than 50,000— and possibly as many as 80,000 or even more” individual products.²⁵ For a sense of the dietary supplement market diversity, the National Institutes of Health Office of Dietary Supplements (NIH ODS) provides extensive information on various products and a listing of tens of thousands of labels for pharmacists and consumers to compare to what they find on shelves.^{26, 27} With so many products in a market that does not require pre-approval, knowing what to watch out for is important to choosing a quality dietary supplement. Healthcare professionals can monitor FDA warning letters, recall trends, and information in the resources below to get a general sense of risk profiles by product type and/or claims (e.g., multivitamins, claims for bone health, claims for immune support, etc.).

Specific requirements for dietary supplements include:

- Manufacturers must adhere to current good manufacturing practices (CGMP) for dietary supplements, with FDA conducting inspections
- Mandatory serious adverse event reporting
- Adherence to a specific public quality standard is voluntary, but if one is cited, FDA considers the product misbranded if it does not meet the quality standard
 - E.g., the *USP National Formulary (USP-NF)* contains formulation-specific monographs that guide manufacturers on what tests to conduct to ensure the quality parameters noted above. Thus, if a product claims adherence to USP, the product is considered misbranded if it is not found to meet *USP-NF* standards. Conversely, generic medicines are generally required to meet *USP-NF* standards whether they are claimed or not.

The FDA has strict label requirements for dietary supplements,²⁸ which are summarized for consumers elsewhere (see “Health in Hand” and “Be Label Wise” in the Further Reading section below).^{29, 30}

Some products go through **voluntary** third-party quality testing/verification, with the label indicating that such an additional assessment of quality has been performed beyond that by the manufacturer. USP’s Dietary Supplement Verification Program is one such service that indicates quality.²⁰ **Note that there are differences between these voluntary third-party programs and the quality testing protocols used by those third parties.** (see Further Reading, for example the NIH ODS online resources, for more information).





Dietary supplements may interact with prescription and over-the-counter medications.

Anyone who is taking prescription or over-the-counter medications should check with a healthcare professional before taking any dietary supplement. Even a quality dietary supplement could cause an adverse effect with certain medications. References listed in this fact sheet provide many more specific examples, and there are extensive entries in the peer-reviewed literature, particularly in fields of nutrition/dietetics and pharmacology.

FDA collects information about reported adverse effects for dietary supplements via its Safety Reporting Portal.

[\(https://www.safetyreporting.hhs.gov/\)](https://www.safetyreporting.hhs.gov/)

Learn more:

www.usp.org/about/convention-membership



Convention





Endnotes:

* Top reasons that patients report not revealing their dietary supplement use to healthcare professionals include: fear of disapproval, not being asked, not seen as important to disclose, not believing the healthcare professional has relevant information, lack of time, and/or previous negative experiences upon disclosure.⁸

† How the behavior is changed was not indicated (start/stop/change).

‡ In 1820, 11 physicians gathered to form the first meeting of the U.S. Pharmacopeial Convention to establish standards for drugs to help ensure that the medicines prescribed were the medicines taken, regardless of where a patient lived. As one of USP's governing bodies, the Convention contributes valuable perspectives that help guide USP's areas of impact. In addition to collaborating on critical healthcare and science matters, every five years, Convention Members adopt USP Resolutions and elect USP's Council of Experts, who lead USP's scientifically anchored public standards-setting Expert Committees, and also elect the USP Board of Trustees.

§ Recent examples of products marketed as dietary supplements that have been found to be "spiked" with illegal and/or undeclared ingredients (a form of adulteration):

Athletic performance / muscle building

- E.g. containing anabolic steroids

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hardcore-formulations-issues-voluntary-nationwide-recall-ultra-sten-and-d-zinc-capsules-due-labeling>

Sexual enhancement

- E.g. containing sildenafil and/or tadalafil

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nana-collection-llc-issues-voluntary-nationwide-recall-premierzen-platinum-5000-triple-supremezen>

Dieting / weight loss

- E.g. containing sibutramine

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bella-all-natural-issues-voluntary-nationwide-recall-diet-capsules-labeled-bella-due-presence>

- and/or also phenolphthaleine, sildenafil, and diclofenac

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mynicnaxs-llc-issues-voluntary-nationwide-recall-various-dietary-supplements-due-undeclared-active>

- E.g. containing ephedra

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kingsway-trading-inc-recalls-xanthium-siler-combo-bi-yan-pian-dietary-supplement-because-it-contains>



Useful further reading:

- U.S. Pharmacopeia Dietary Supplements Compendium (USP-DSC)
<https://www.usp.org/products/dietary-supplements-compedium>

The following additional sources are USP Convention members. However, the views therein are their own and not necessarily endorsed by USP.

Industry- and regulatory-focused content:

- Academy of Nutrition and Dietetics (AND) – professionals’ site <https://www.eatrightpro.org/> noting *Journal of the AND*
[https://www.jandonline.org/article/S2212-2672\(20\)30453-6/fulltext](https://www.jandonline.org/article/S2212-2672(20)30453-6/fulltext)
- American Botanical Council (ABC) – Botanical Adulterants Prevention Program
<http://herbalgram.org/resources/botanical-adulterants-prevention-program/>
- American Herbal Products Association (AHPA) – Botanical Safety Handbook
https://www.ahpa.org/store_category.asp?id=11
- American Pharmacists Association (APhA) Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 20th ed (2020); <https://pharmacylibrary.com/doi/10.21019/9781582123172>
- FDA – American Medical Association (AMA) Continuing Education resources
<https://www.fda.gov/food/healthcare-professionals/dietary-supplement-continuing-medical-education-program>
- National Institutes of Health’s Office of Dietary Supplements <https://ods.od.nih.gov/HealthInformation/healthprofessional.aspx>

Consumer/patient-facing content

- AARP <https://www.aarp.org/health/drugs-supplements/supplements-vitamins/>
- AND – consumer-facing site
<https://www.eatright.org/health/essential-nutrients/supplements>
- Consumer Healthcare Products Association (CHPA) “Health in Hand” (includes dietary supplement information) <https://www.healthinhand.org/resources/dietary-supplement-faq>
- Council for Responsible Nutrition (CRN) “Be Label Wise”
<https://belabelwise.org/>
- National Center for Complementary and Integrative Health (NCCIH) <https://www.nccih.nih.gov/health/using-dietary-supplements-wisely>
- National Institutes of Health Office of Dietary Supplements (NIH ODS) for consumers
<https://ods.od.nih.gov/factsheets/WYNTK-Consumer/>



Citations (all webpages accessed in June 2023)

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