PRACTICE APPLICATIONS
Topics of Professional Interest

Quality Certification Programs for Dietary Supplements

IN THE UNITED STATES IN 2014, dietary supplements were a $36.7 billion industry.[1] The public has easy access to dietary supplements without prescription, and most consume them without their health care provider's advice or knowledge.[2] Thus, while there is extensive use of dietary supplements, there is little quality standardization of these products, and it is difficult for health care professionals and consumers alike to discern their safety and quality.

However, quality certification programs do exist. In the United States, three certification programs independently assess dietary supplement quality and evaluate purity, potency, composition, and other criteria. They also have a seal of approval or "mark" that supplement manufacturers can license to use on their product packaging and in promotional materials to communicate to the public and health professionals which of their products meet established standards. The certifying organizations are ConsumerLab.com, NSF International, and the US Pharmacopeial Convention (USP). Details on each organization are presented in Figure 1. This article describes the regulatory framework for dietary supplements, these third-party organizations, the standards they follow, and the mechanics of their certification programs.

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DEFINITION OF DIETARY SUPPLEMENTS

The Dietary Supplement Health and Education Act (DSHEA) of 1994 set the regulatory framework for dietary supplements, defining them as products other than tobacco that are intended to supplement the diet and that contain one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used to supplement the diet by increasing the total daily intake; or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. Dietary supplements are intended for ingestion in capsule, tablet, powder, liquid, or other form; they are not represented for use as a conventional food or as the sole item of a meal or diet; they are labeled as a dietary supplement and bear a Supplement Facts panel, not a Nutrition Facts label, as found on foods.[3] In 2014, dietary supplement sales by product category were 32% for vitamins, 7% for minerals, 18% for herbs/botanicals, 13% for sports nutrition, 12% for meal replacements, and 18% for other specialty supplements.[1]

DIETARY SUPPLEMENT USAGE

Supplement use in the United States has been monitored by the National Health and Nutrition Examination Survey since the 1970s[2,4] (see Table). Overall, women are three times more likely than men to use one or more supplements.[5] Between 1970 and 2006, dietary supplement use increased from 38% to 54% among females older than 1 year of age and from 28% to 43% among males older than 1 year of age.

The 2003-2006 National Health and Nutrition Examination Survey showed that more than half (54%) of adults were taking at least one supplement, a 25% increase since the turn of the millennium. The majority of adults took a multivitamin/mineral supplement daily; 20% reported taking a supplement with at least one botanical ingredient (eg, echinacea), and 10% reported taking more than five dietary supplements. Use increased with age: 65% of males and females aged 51 to 70 years reported taking at least one supplement, and this increased to 71% for adults aged 71 years and older. Dietary supplement use was greater among non-Hispanic whites than other racial groups, and among individuals with more than a high school education.[4] The 2007 National Health Interview Survey conducted by the National Center for Health Statistics reported that 37% of children in the United Stated younger than 18 years of age took dietary supplements, and most of them consumed a multivitamin/mineral or multivitamin product. Only about 15% of children using supplements were doing so on the recommendation of a doctor or other health care professional.[6,7] Clearly, there is considerable use of dietary supplements in the United States.

Consumers use dietary supplements for diverse reasons, including supplementing a poor diet and improving or maintaining general health. Older adults take supplements to support organ-specific health, such as calcium for skeletal health (women) and n-3 fish oil for heart health (men). Younger adults tend to take supplements for shorter-term benefits, such as increasing energy or boosting immunity. Among supplement users surveyed in the 2007 National Health and

Name of third-party organization	ConsumerLab.com	NSF International	US Pharmacopeial Convention
Company characteristics	Private	Private	Private
	For profit	Not for profit	Not for profit
	Informational and quality certification	Standard setting and quality certification	Standard setting and quality verification
	United States, Canada, and China	International	International
Company mission	Identify the best-quality health and nutritional products through independent testing.	Protect and improve public health by providing safety-based risk-management solutions to companies, governments, and consumers around the world.	To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.
Program funding	Individual and institutional membership fees enable access to product reviews; participating companies pay fees for certification services.	Participating companies pay fees for certification services.	Participating companies pay fees for verification services.
Services provided	Product reviews Quality Certification Program	NSF Product Certification NSF Certified for Sport Facility GMP[a] audit registration	Dietary Supplement Verification Program
Website for additional program information	www.consumerlab.com	www.nsf.org www.nsfsport.com/sport_app.asp	www.usp.org www.uspverified.org
Type of information available on website	Test methods and standards. Members have access to product reviews and ConsumerLab.com—approved products (including ingredient and price comparisons); information on dietary supplement recalls and warnings; clinical information; an annual survey of vitamin and supplement users; and other resources.	List of NSF International—certified dietary supplements and certified for sport supplements and where they can be purchased; list of NSF International—Registered GMP audited facilities; dietary, nutritional and sports supplements tips and other resources; available training courses on GMPs, testing, etc.	List of US Pharmacopeial Convention—verified products by brand and where they can be purchased; dietary supplement education program and other resources.

Figure 1. Overview of third-party dietary supplement certification organizations and services. [a]GMP=Good Manufacturing Practice.

Nutrition Examination Survey, only 23% were taking supplements on the advice of their health care professional.[2]

STANDARDIZATION AND QUALITY ISSUES

There is little standardization of dietary supplements. Unlike prescription and over-the-counter medication, the Food and Drug Administration does not establish standards for the contents of dietary supplements. For example, what constitutes an extract of a botanical supplement or the minimum and/or maximum amounts of nutrients in a multivitamin/mineral supplement is not regulated.[8] Therefore, while multivitamin/mineral supplement use is common, the amount and composition of ingredients in these multivitamin/mineral supplements varies. Calcium, fish oil, protein powders, and vitamin E are some of the more common single dietary ingredient supplements, and similarly, the serving size, form, source, and delivery (eg, liquid, chewable, or capsule) vary.

Consumers have easy access to products in the marketplace. They

Table. Dietary Supplement Use in the United States[a]

	Males	Females
	←——%——→	
NHANES[b] I[c] (1971-1974)	28	38
NHANES II[d] (1976-1980)	32	43
NHANES III[e] (1988-1994)	35	43
NHANES 2007-2010[d]	43	54

[a]Source: Bailey and colleagues.[2,4]
[b]National Health and Nutrition Examination Survey.
[c]Age-adjusted adults.
[d]Adults age 20 y and older.
[e]Adults age 2 mo and older.

also have easy access to web-based information, but the quality of information available ranges from promotional to academic, and it is often difficult for the reader to discern the difference. The plethora of information about dietary supplements at point of purchase and in the media is also often unclear, unreliable, and conflicting.[9]

There are many reasons for the lack of clarity and agreement about the potential health benefits of dietary supplements and concerns about the quality and safety of these products. These include the limited amount of existing scientific evidence; the lack of financial incentive for industry to fund clinical research; the fact that clinical efficacy and safety is not mandated by the DSHEA; the fact that independent product validation is not required, as it is for drugs; and the limited formal education about dietary supplements that health care professionals receive.

REGULATORY OVERSIGHT OF DIETARY SUPPLEMENTS

The Food and Drug Administration (FDA) regulates dietary supplement manufacturing and labeling, such as package inserts and accompanying literature, and the Federal Trade Commission (FTC) regulates dietary supplement advertising.

FDA

Dietary supplements fall under a set of regulations that differ from those covering conventional food and drug products. Dietary supplements (both finished products and ingredients) are regulated under the DSHEA as a special category of foods overseen by the programs in the FDA's Center for Food Safety and Nutrition.

Under DSHEA, supplement manufacturers and distributors are responsible for substantiating the safety of the dietary ingredients they use in manufacturing their products. They are also responsible for ensuring that product labeling (eg, Supplement Facts panel, ingredients) meets all the requirements of the DSHEA and other FDA labeling regulations before going to market. However, dietary supplement manufacturers are not required to get FDA approval before producing or selling dietary supplements, nor are they required to demonstrate clinical efficacy. Manufacturers and distributors are required to ensure that any representations or claims made about their products are substantiated, truthful, and not misleading. They are also prohibited from marketing products that are adulterated or misbranded, but the DSHEA places the burden of proof on the FDA to demonstrate that a dietary supplement is adulterated or misbranded or that it presents a significant or unreasonable risk of illness or injury before the supplement can be removed from the market.

The FDA has limited resources for analyzing the composition of dietary supplements on the market; instead, the agency focuses its resources first on public health emergencies and products that may have caused injury or illness, and then on products thought to be unsafe or fraudulent or in violation of the DSHEA.[10]

Finally, in accordance with the Dietary Supplement and Nonprescription Drug Consumer Protection Act, serious adverse events associated with use of a dietary supplement in the United States are required to be submitted to the FDA by the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States.

Good Manufacturing Practices

As part of the DSHEA, Congress gave the Secretary of Health and Human Services and the FDA the authority to issue regulations establishing current Good Manufacturing Practice (GMP) requirements for dietary supplements. FDA GMPs are codified in the Code of Federal Regulations (CFR) in 21 CFR Part 111 *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*. The final GMP rule, issued in June 2007, has been mandatory for all supplement manufacturing companies since 2010.[11] This GMP rule establishes the minimum requirements necessary for activities related to manufacturing, packaging, labeling, and holding of dietary supplements to ensure product quality.

FTC

The FTC prevents business practices that are anticompetitive, deceptive, or unfair to consumers. The FTC regulates dietary supplement advertising; it has the primary responsibility for monitoring claims in advertising, including print and broadcast advertisement, infomercials, the Internet, catalogs, and similar direct marketing materials.[12] In contrast, the FDA has responsibility for claims on product labeling, packaging, inserts, and promotional materials distributed at the point of sale. Because the FTC and FDA have shared jurisdiction for advertising claims, they often work together on enforcement activities.

THIRD-PARTY CERTIFICATION AND INDUSTRY ACCEPTANCE

More than 55,000 dietary supplements are currently marketed in the United States, with new products and dietary ingredients being continuously introduced into the marketplace.[13,14] Given the size and diversity of the products and ingredients, the rapid pace with which new dietary supplements are introduced into the market, and the fact that FDA approval is not required before products are introduced to the market, independent third-party certification programs offer quality assurance for dietary supplements in the marketplace. It is important to note that there is no direct or indirect ownership or control of these certification programs by companies involved in the manufacture or sale of dietary supplements.

Third-party certification/verification programs are not universally used by the dietary supplement industry; they

Name of third-party organization	ConsumerLab.com	NSF International	US Pharmacopeial Convention
Program mark or seal			
Use of mark or seal	CL[a] Seal of Approval can be licensed and used on product labels, packaging, advertising, and marketing with preapproval.	NSF Contents Tested and Certified Mark can be used on product packaging and in promotional materials. NSF Certified for Sport Mark can only be used directly on the product label of the specific lot of product and in promotional marketing materials. NSF GMP[b] Registered Mark can be used on facility promotions but not product packaging or in product marketing materials.	USP[c] Verified Mark can be licensed for use on product labels, packaging, advertising, websites, infomercials, and promotional products and materials with preapproval. The mark cannot be used in conjunction with the seal or mark of another organization.
Enforcement of program mark	CL seal is a US registered certification mark. Unauthorized use is illegal and proper use is enforced.	The NSF Mark is a US and international registered certification mark. Unauthorized use is illegal and proper use is enforced.	The USP Verified Mark is a US registered certification mark. Unauthorized use is illegal and proper use is enforced.

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Figure 2. Use and meaning of dietary supplement certification program mark or seal.

are fee-based programs and participation is voluntary. The cost of participating can be an obstacle for small companies, whereas larger companies, some of whom are divisions of pharmaceutical companies, believe they can self-affirm the quality of their products. Larger companies are also likely to have a well-established marketing campaign to promote their brand and may see no market advantage in participating in a third-party certification program.

THIRD-PARTY QUALITY ORGANIZATIONS

ConsumerLab.com, NSF International, and USP each have quality certification programs: ConsumerLab.com Quality Certification Program, NSF International Product Certification Program, and USP Dietary Supplement Verification Program. These organizations test dietary supplements as finished products, that is, pills, powders, liquids, drinks, and sport and energy products. Products are tested for identity, ingredient quality, strength (quantity), purity, and, as applicable, freshness (eg, liquid oils) and disintegration (eg, tablets) (see Figure 2). For example, products must meet acceptable limits for suspected contaminants such as heavy metals, pesticides, dioxins, furans, polychlorinated biphenyls, and microbes. In addition, quality certification ensures that supplements do not contain harmful levels of toxic botanical species, or greater or lesser amounts

Name of third-party organization		ConsumerLab.com	NSF International	US Pharmacopeial Convention
Meaning of program mark or seal	Quality	The product has passed the specific test(s) performed and contains the key ingredients listed on the label in the declared potency and amounts; it does not contain harmful levels of specified contaminants.	The product contains the ingredients listed on the label in the declared potency and amounts; it does not contain harmful levels of specified contaminants, including >200 athletic banned substances for Certified for Sport products; it has been manufactured according to FDA[d] current GMPs.	The product contains the ingredients listed on the label in the declared potency and amounts; it does not contain harmful levels of specified contaminants; and it has been manufactured according to FDA current GMPs and USP GMPs.
	Safety	Does not contain harmful levels of specified contaminants, using stringent limits, for example, California Proposition 65.	No unsafe level of contaminants and absence of ingredients with known safety risk.	Absence of ingredients with known safety risk; appropriate allergen labeling; meets acceptable levels of specified contaminants, based on toxicologic concerns; testing per California Proposition 65 for labeling purposes.
	Performance	Product disintegrates or dissolves per USP standards; it will break down and release into the body in a specified time.	Product disintegrates; it will break down and release into the body in a specified time.	Product disintegrates or dissolves per USP standards; it will break down and release dietary ingredients into the body in a specified time.
	Claims	The product contains the tested ingredients listed on the label in the declared amounts and of high quality. Products making a claim of health benefit do so in a manner consistent with applicable regulatory requirements.	Product label has an accurate list of ingredients in the stated amounts (ie, ingredients meet quantitative label claims). All claims of fact made for the approved product, either stated or implied, must be accurate, consistent with NSF program requirements, and meaningful in terms of the benefits offered.	Product label has an accurate list of ingredients in the stated amounts (ie, ingredients meet quantitative label claims). All claims of fact, either stated or implied, must be supported by data, consistent with USP program requirements. Products making a claim of health benefit do so in a manner consistent with applicable regulatory requirements.

[a]CL=ConsumerLab.com.

[b]GMP=Good Manufacturing Practice.

[c]USP=US Pharmacopeial Convention.

[d]FDA=US Food and Drug Administration.

Figure 2. *(continued)* Use and meaning of dietary supplement certification program mark or seal.

of active or marker compounds than indicated on the product specification and label.

QUALITY STANDARDS DEVELOPMENT

When the FDA established GMP regulations for dietary supplements, they set minimum requirements but did not specify test methods or quality standards. USP and NSF have developed standard-setting programs.

USP sets public standards for the identity, strength, quality, and purity of medicines, dietary supplements, and food ingredients. USP collaborates with governments, businesses, and academic institutions around the world to set standards based on scientific evidence. USP scientists collect information and perform laboratory testing to produce data that USP volunteer experts use in deciding what the quality standards should be. The expert committee reviews the data, ensures public comment, and approves the standards. These standards include product monographs and general informational chapters (eg, document standards), which are published in one of several USP compendia, such as the *USP Dietary Supplements Compendium*. It also includes associated reference standard materials (eg, vials of chemical and biological materials), which are highly purified and characterized substances used in performing tests for ingredients and finished products.

In the United States, conformity to USP standards is mandatory for pharmaceutical drugs, but voluntary for dietary supplements. A dietary supplement is considered "misbranded" only if it is represented as conforming to USP specifications and fails to so conform. Enforcement is the responsibility of the FDA and relevant governmental authorities worldwide. USP has no role in enforcement.

NSF International is a standards-writing body accredited by the American National Standards Institute (ANSI). A committee of stakeholders composed of state and federal agencies, manufacturers, retailers, trade associations, and consumer groups created the *NSF International American National Standard for Dietary Supplements* (NSF/ANSI Standard 173). NSF/ANSI Standard 173 sets standards for identification and quantification of ingredients stated on the label, toxicology and label review, testing of known contaminants, and on-site facility inspections to audit compliance with current FDA 21 CFR Part 111 GMPs.

THIRD-PARTY CERTIFICATION PROGRAMS

Started in 1999, the ConsumerLab.com Quality Certification Program was the first national third-party verification program for dietary supplements. ConsumerLab.com does not accept products directly from the manufacturer; instead it purchases products from the marketplace and products must comply with FDA labeling requirements, must disclose necessary information about each ingredient (such as the correct plant name and plant part in botanical products), and can only display allowed product claims. ConsumerLab.com identifies test methods and uses validated test methods and standards based on the latest international research; their standards include USP, World Health Organization, and California Proposition 65. These methods and standards, which can be more stringent than those used by industry, are posted on the ConsumerLab.com website at no cost. Although the results of these tests (pass or fail) are proprietary and confidential to the manufacturer, if the product meets test standards, manufacturers can license the use of the ConsumerLab.com seal of approval to use on their product labels, packaging, advertising, and marketing. Continued use of the ConsumerLab.com seal of approval is contingent on annual testing and adherence to licensing requirements.

USP began its Dietary Supplement Verification Program in 2001. This third-party verification program helps manufacturers ensure the quality of their dietary supplements in the marketplace. The requirements of the program include an annual on-site facility audit that verifies compliance with FDA GMPs and with USP's General Chapter <2750> Manufacturing Practices for Dietary Supplements; a review of manufacturing and quality-control documentation; laboratory testing for conformance to dietary supplement standards found in the US Pharmacopeia-National Formulary or for conformance to appropriate manufacturer specifications if a USP standard does not exist; and annual off-the-shelf testing of randomly selected samples to confirm that USP-verified products continue to meet USP's standards. Manufacturers who meet the requirements of the Dietary Supplement Verification Program are able to use the USP Verified Mark on product labels, packaging, and promotional materials. USP performs annual testing for conformance to all product specifications of products bearing the USP Verified Mark, which it purchases from retail stores. In addition, on-site facility GMP audits are conducted annually.

Since 2003, NSF International has been verifying that dietary supplements, ingredients, and functional foods meet the requirements of NSF/ANSI Standard 173 through annual product review and testing and biannual GMP auditing. Products that meet the NSF International Certification Program requirements can carry the NSF International "Content Tested and Certified" mark on product packaging and in promotional materials. Products are retested annually to ensure compliance, and manufacturers must continue to adhere to licensing requirements in order to continue to place the mark on their products.

NSF International also has a Certified for Sport certification that further tests NSF International–certified products on a lot-by-lot basis for >200 banned athletic substances. Lot-by-lot testing means that each lot, or batch, of product is tested. Only lot-specific products that meet these requirements can use the NSF Certified for Sport mark directly on the product label of the specific lot of product. Continued use of the mark requires lot-by-lot testing. NSF International tests for substances banned by the World Anti-Doping Agency, as well as the National Football League and Major League Baseball.

Dietary supplements that are ConsumerLab.com–approved, NSF International–certified, and USP-verified can be found on each company's website (see Figure 1).

GMP REGISTRATION PROGRAM

NSF works confidentially with dietary supplement manufacturers to audit compliance with current FDA GMPs two times per year, ensuring full implementation of corrective actions that

were required for any nonconformance found. Companies that meet GMP requirements can use NSF International's "GMP Registered" mark in promotional materials, but not on product packaging. On-site facility audits are conducted twice per year to ensure adherence.

INDEPENDENT PRODUCT REVIEWS

In addition to its voluntary Quality Certification Program, ConsumerLab.com independently selects and tests products. Results are posted on the ConsumerLab.com website as product reviews, which members can access for a nominal subscription fee. Dietary supplements included in product reviews are purchased in the marketplace; ConsumerLab.com does not accept products from the manufacturer. Product reviews are categorized by nutrient (eg, calcium supplements); testing is repeated periodically and the newest results replace previous results. Products that fail to meet the criteria are retested by a second laboratory before being posted in the product reviews. Products certified in ConsumerLab.com's Quality Certification Program can be included in the product reviews, as they have met the same standards, and they will be identified as having been tested through the Quality Certification Program.

Consumer education, such as cost comparisons, clinical evidence for or against various uses of the supplements, potential side effects, and cautions, are included in the product reviews. ConsumerLab.com also indicates when the recommended serving size for a nutrient exceeds the Tolerable Upper Intake Level established by the Institute of Medicine of the National Academies. For members, the ConsumerLab.com website also provides product recalls, warnings, and educational resources.

MATTERS OF SAFETY

ConsumerLab.com, NSF International, and USP evaluate finished products and ingredients to ensure they do not contain ingredients with known safety risks. However, safety is also influenced by the inherent nature of the ingredients (eg, stimulants, laxatives), potential nutrient/nutrient or nutrient/drug interactions, side effects, and the recommended serving sizes (eg, ingredients present at levels above the Tolerable Upper Intake Level). ConsumerLab.com does identify product recommendations that exceed the Tolerable Upper Intake Level, but assessment of these other safety risks are beyond the scope of third-party quality certification.

SUMMARY

Dietary supplements that are ConsumerLab.com-approved, NSF International–certified, and USP-verified have been independently tested to meet their respective, established program criteria. In all cases, though often by different test methods and standards, dietary supplements that meet these criteria contain the ingredients stated on the label, in the stated amounts, and they meet acceptable limits for suspected or known contaminants, toxins, and/or marker compounds. Meeting the criteria of these programs also ensures that the dietary supplements have the proper performance characteristics (eg, dissolution or disintegration). With the exception of product reviews that are independently assessed and published by ConsumerLab.com, product test results from the three certifiers are proprietary and confidential to each supplement manufacturer.

Dietary supplement manufacturers that engage the services of these certifiers do so voluntarily; it is not required. Meeting quality standards that enable supplement manufacturers to earn and use the respective certification marks on product labels and in promotional material is currently the best resource for assessing product quality among dietary supplements.

Certification of quality is not a product recommendation, nor does it discern the appropriate use of products among the public. Given the widespread use of dietary supplements among the US population, being familiar with these organizations can help prepare registered dietitian nutritionists to direct and manage patients and clients who choose to include dietary supplements in their dietary regime and advise patients and clients who can benefit from their use.

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