Topics of Professional Interest

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Quality Certification Programs for Dietary Supplements



N 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

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http://dx.doi.org/10.1016/j.jand.2015.11.003 Available online 13 January 2016 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.

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

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PRACTICE APPLICATIONS

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	ldentify 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. ^aGMP=Good Manufacturing Practice.

the 2007 National Health and 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

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