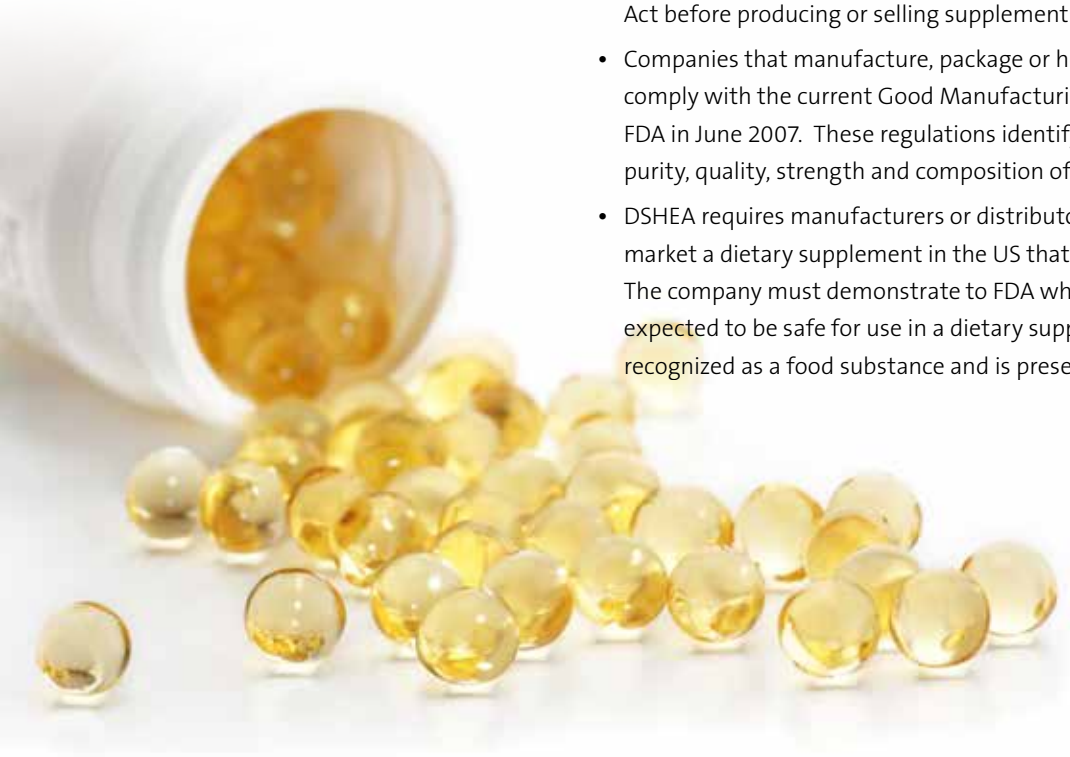
Dietary Supplements

PRODUCT QUALITY AND FDA COMPLIANCE

Nearly half of all Americans take at least one dietary supplement each day. In some cases, the products are marketed or used in a way that classifies them as "drugs" by the US Food and Drug Administration (FDA). Other products, such as food replacements or beverages, are included in FDA's "food" category. In either case, most dietary supplements fall under the jurisdiction, regulations and compliance requirements of the FDA.



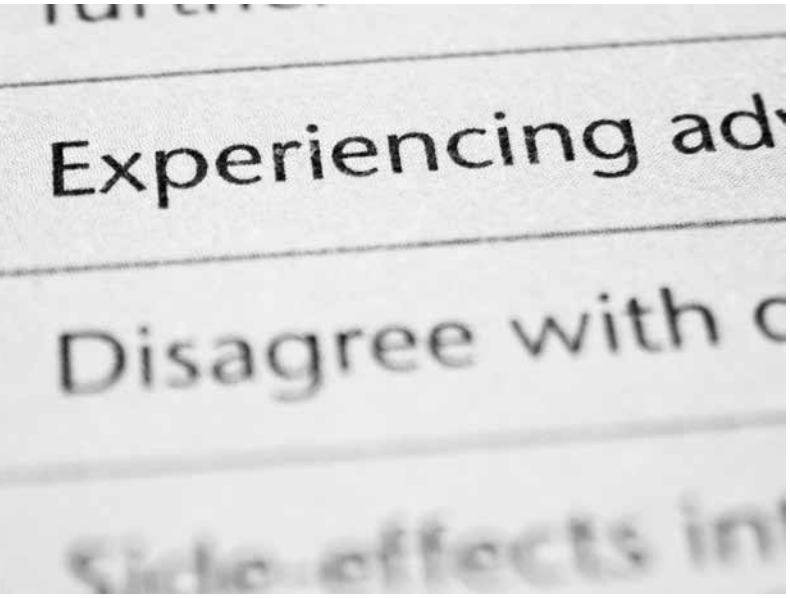
Regulatory Background

Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary supplements are in a special category under the general umbrella of "foods," not drugs. DSHEA defined dietary supplements as a product taken orally that contains a "dietary ingredient" intended to supplement the diet. Ingredients in these products may include, but are not limited to, vitamins, minerals, herbs, amino acids, enzymes, organ tissues, glandular derivatives and metabolites.

Because of their unique status, dietary ingredients are regulated in a way that is different than food or drugs. Most important, a company is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are not false or misleading. Companies do not have to provide FDA with evidence that the supplements are safe or effective before or after marketing the products, but there are specific requirements that do apply to dietary supplements. Among the requirements established by DSHEA:

- Manufacturers must register themselves with FDA pursuant to the Bioterrorism Act before producing or selling supplements;
- Companies that manufacture, package or hold dietary supplements must comply with the current Good Manufacturing Practices (cGMP) published by FDA in June 2007. These regulations identify practices that ensure the identity, purity, quality, strength and composition of dietary supplements;
- DSHEA requires manufacturers or distributors to notify FDA if they intend to market a dietary supplement in the US that contains a "new dietary ingredient." The company must demonstrate to FDA why the ingredient is reasonably expected to be safe for use in a dietary supplement unless it has been recognized as a food substance and is present in the food supply;

- Certain information must appear on dietary supplement labels, including a descriptive name of the product stating that it is a "supplement;" the name and place of the business of the manufacturer, packer or distributor; a complete list of ingredients; and the net contents of the product. Dietary supplements must also have nutrition labeling in the form of a "supplement facts" panel that identifies each ingredient contained in the product;
- Any dietary supplement that is promoted on its label or in labeling as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved drug – and would, therefore, be illegal.



Safety and Compliance

A recent study found that dietary supplements accounted for more than half of all FDA Class I drug recalls between 2004 and 2012. Class I recalls are those reserved for products that contain ingredients that are likely to cause serious adverse health consequences or death. According to the Government Accountability Office (GAO), the FDA received 6,307 reports of health problems (adverse event reports) for dietary supplements between 2008 and 2011. In 2013, mandatory adverse event reports submitted to FDA numbered more than 3,200.

The GAO also reports that many Adverse Events (AEs) may not be reported to FDA. Instead, consumers may be contacting poison centers to report adverse events. Between 2008 and 2010, these poison centers received over 1,000 more AEs linked to dietary supplements than the FDA for the same period.

Several factors are colliding to create heightened compliance and safety challenges for individual manufacturers and the industry as a whole:

- The use of dietary supplements by Americans is rising rapidly, at the same time that the number of individuals taking prescription drugs is also rising, increasing the potential of interactions between supplements and prescription drugs;
- The globalization of dietary supplement manufacturing and ingredient sourcing is escalating rapidly, putting manufacturers that sell products in the US and many other countries under heightened responsibility for ensuring that their products are safe;
- Highly publicized recalls have put the industry under scrutiny, leading to calls in Congress, social media and public advocacy groups for greater regulation of the industry;
- The FDA is intensifying its scrutiny of the industry, increasing the number of inspections it conducts of dietary supplement manufacturing facilities for compliance with cGMPS and adverse event reporting requirements.

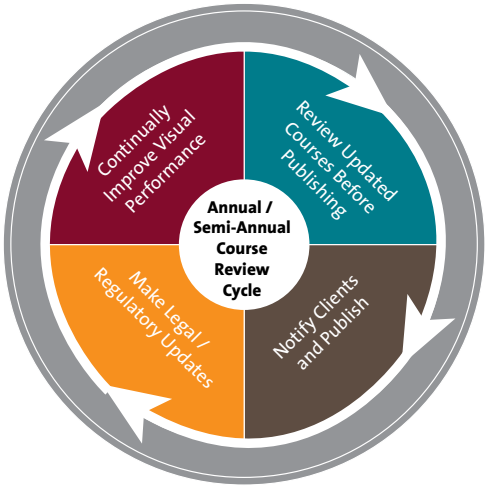
Leading the Industry

Dietary Supplement industry leaders distinguish themselves by their dedicated compliance with FDA's compliance requirements for cGMPs, adverse event reporting, labeling and promotion. As a result, Warning Letters from FDA during the first quarter of 2014 have declined when compared to the same period in 2013. Although a number of violations relate to false claims and misleading labels, others can be traced to inadequate quality and cGMP compliance. As with other FDA-regulated products, cGMPs are designed to ensure product quality, strength, purity and identity. Specific provisions aim to prevent product contamination, ensure control over the production process, establish and follow Standard Operating Procedures (SOPs), ensure that personnel are trained to perform their job responsibilities, document any adverse events, and ensure that corrective actions in response to problems have been properly conducted.

Industry leaders recognize the value of working with FDA and FDA-respected organizations in creating, maintaining and monitoring the programs necessary to ensure product quality and regulatory compliance. UL EduNeering's Cooperative Research and Development Agreement (CRADA) with the FDA has provided the knowledge and management resources needed by FDA to train its own inspectors as well as those of state agencies and counterparts in other countries. These same resources are available under the CRADA exclusively to UL EduNeering's clients as well as additional FDA co-authored or reviewed courses. In fact, more than 250 companies in FDA-regulated industries are currently training 1 million employees and suppliers in topics such as cGMPs, quality systems, adverse event reporting, FDA expectations and inspection protocol. The CRADA was recently extended through 2019 and expanded to include new technologies and services to other government agencies.

Course Updates and Our Content Quality Management Process

Regulatory agencies and related information sources are continually monitored, analyzed and incorporated into course updates or new courses. UL continues to update these courses when new dietary supplement guidelines are enacted as part of our Content Quality Management System (CQMS).



The CQMS provides our customers the assurance that every course in our catalog is kept up-to-date with current legal and regulatory requirements and is instructionally fresh. Our specific commitment is that every catalog course be reviewed at least once per year by a highly-qualified Subject Matter Expert (SME), whose identity and expertise is available for our customers' review.

The UL EduNeering Platform

The GMP Dietary Supplements Library can be delivered via the UL Platform, a web-based LMS that offers a streamlined, convenient method for deploying high-quality training. The UL Platform provides hundreds of features which include:

Automated Training Management:

- Make initial, one-time assignments
- Set up refresher training
- Define training groups
- E-mail reminders
- Individual training transcript for each user
- Add historical assignments
- Supports multiple versions
- SCORM/Aviation Industry Computer-Based Training Committee (AICC) compliant

Reporting:

- 20+ standard reports
- E-mail to managers
- CSV/PDF/Online formats
- Audit-ready
- Ad hoc reports via query tool
- Schedule regular reports
- View training completions
- View qualification status

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL EduNeering has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university.

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