

MARKET RESEARCH REPORT



NUTRACEUTICAL SUPPLEMENTS TARGETED for the LBGT DEMOGRAPHIC

Report created by:



BOTANICAL SCIENCE FOR HEALTHY LIVING

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About NutriCellula, Inc.

NutriCellula, Inc. is a nutraceutical development and marketing company whose mission is to build partnerships with scientists, researchers, formulators, manufacturers, and professionals in the nutritional and supplement industry to benefit the global community and distribute quality products that deliver genuine health-enhancing benefits.

Nutraceuticals help maintain and support good health, good body function and a healthy lifestyle. The global nutraceuticals product market is primarily categorized on the basis of functional food, functional beverages and dietary supplements.

NutriCellula sources its botanical supplements from all over the world. It utilizes two manufacturing facilities in the US and one research facility in Italy.

Nutraceutical Definition

Nutraceutical, a portmanteau of the words “nutrition” and “pharmaceutical”, is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of disease. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.

Nutraceuticals provide health benefits and help in healing and prevention of diseases. The global nutraceuticals product market is primarily categorized on the basis of functional food, functional beverages and dietary supplements. The global nutraceutical market is growing quickly on account of growth in dietary supplement segment. North America has the highest market share for nutraceutical product market, which is primarily supported by the U.S. health conscious consumers segment.

U.S. Dietary Food Supplement Industry

The U.S. Dietary Food Supplement industry posted 4.4% growth in 2010 to reach \$28.1 billion in consumer sales according to Nutritional Business Journal estimates. According to the Transparency Market Research report, "Nutraceuticals Product Market: Global Market Size, Segment and Country Analysis & Forecasts (2007-2017)", the global nutraceutical product market reached USD 142.1 billion in 2011 and is expected to reach USD 204.8 billion by 2017, growing at the compound annual growth rate (CAGR) of 6.3% from 2012 to 2017.

LGBT Niche Market

Market Segment Opportunity

Decades after invisibility and reaching critical mass, a breakthrough July 1991 article in the conservative Wall Street Journal called the lesbian and gay community "*a dream market.*" Today, the American market is estimated to be valued at \$845 billion.

Witeck-Combs and Packaged Facts estimated the American gay, lesbian and bisexual market size at 16 million people (benchmarked at 7% of the adult U.S. population, 16 million individuals over the age of 18), with the buying power of \$845 billion. Not counting the statistical overlap of race and sexuality, that makes the lesbian and gay group larger than the Asian-American population of 12 million (\$344 billion in buying power), but smaller than the African-American population of 36 million (\$688 billion), and the Hispanic population of 41 million (\$653 billion). The data for African-American, Hispanic and Asian-American populations are based on U.S. Census data as well as analysis released recently by the University of Georgia's Selig Center. Witeck-Combs/Packaged Facts found that average income for gay and lesbian individuals is \$46,000, and discretionary income is \$40,000 (86% of total).

There is no question that LGBT segment skews both affluent and influential. In addition, many of its number are early adopters – 26% of gays and lesbians claim to be the first to know about new products and services (compared to 18% of the general population). They are influencers – 60% say others often ask them for advice (vs. 34% of the public).

Yet, while LGBT consumers are vital contributors to the economy and society, they are often overlooked when it comes to advertising.

Like all consumers, gays and lesbians gravitate toward products and brands that advertise directly to them. Recent studies have shown that they tend to seek out companies and products that reflect their concerns, and are much more likely to remain loyal to these advertisers than their straight counterparts. As a result, smart marketers choose to make them a priority. A study by the Harris partnership found GLBT consumers were more likely to make a purchasing decision based on their awareness of the company's diversity policies (47% GLBT versus 18% heterosexual).

Snapshot of the LBGT Community

It is important to remember that the so-called "gay community" or "gay market" are not monolithic -- it is more of a confederation of individuals with identities as diverse as the general population. Gay men's buying habits have little to do with gay women's. Transgender and bisexual people may or may not identify as "gay."

Gay men may live in Chelsea, Fort Lauderdale or West Hollywood/WeHo, they may be nomadic truckers, own a home in the suburbs with a partner and child, they may be in a retirement home, or they could be struggling in the ghetto. Lesbians may own a vegetarian restaurant in Northampton, they may run a major media company, own a home in the suburbs with a partner and child, or they could be working at a discount store.

Gays and lesbians are also Hispanic, African-American, Asian, American-Indian, Caucasian, Jewish, Hindu, Muslim, Christian, Mormon, war veterans, retired, teenagers, Republican, Democrat, rural, suburban, and many other layers of identities. Like everyone else, they face issues of race, class, ethnicity, nationality, age, religion, health, and wealth -- mirroring that of the general population.

Research often lumps lesbians in with gay men, without offering breakout information. Lesbians certainly have different demographics and buying habits than gay men. If gay men have the attention of marketers by benefiting from stereotypes about them (they earn more money than the general population, have expensive tastes, enjoy fashion, theater, home decorating, dance music, art, design, gourmet goods, etc. -- many important ad categories), then lesbians suffer from the stereotypes about them: they don't like fashion, makeup, or shopping in general because they are political-minded feminists who don't subscribe to consumerism. The truth is, women in general, earn less than men.

Further, gay women can be difficult to target even if an advertiser wants to target their niche. Dedicated lesbian publications suffer from low circulation, while mixed audience publications don't attract substantial numbers of women, just about 25% for The Advocate. There are also far fewer lesbian businesses and places where they specifically congregate, though the Dinah Shore Golf Tournament is considered the largest lesbian event, despite its general audience.

Gay women also have children more often than gay men (roughly a third, compared to a fifth for male couples), lowering their disposable incomes.

Marketers should consider gay women separately from gay men, and be certain to include sizable numbers of both for meaningful breakout information. Subaru is a pioneer in reaching out to gay women, starting in 1995. Olivia Cruises is a highly successful lesbian-owned vacation operator that has also done well targeting gay women exclusively.

The gay market is sometimes referred to as DINKs -- double income, no kids -- who have the freedom to travel more often and higher "disposable incomes" to buy luxury items. However, this is changing as more gay families with children are emerging, from 1-in-5 men to 1-in-3 women having kids inside the household through previous opposite-sex marriages, adoption or natural childbirth. Analysis of the US Census also indicates that 57% of same-sex couples have both partners of a household working, compared to 48% of opposite-sex couples.

Gays are not all spring chickens. Witeck-Combs/Packaged Facts also estimates that 2 million gays are approaching or have already reached retirement age, and that by 2020, some 5.7 million, or 25 percent of the gay community, will be 50 or older.

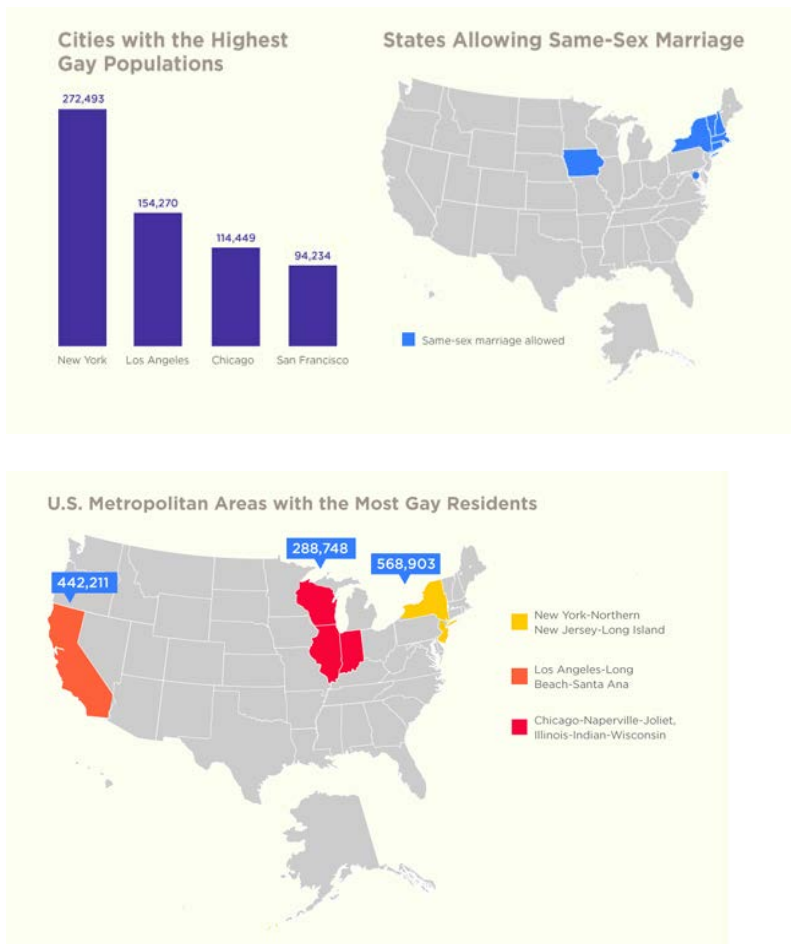
LGBT Community Footprint

A study from the Brookings Institution by Richard Florida and Gary Gates found a relationship between high-tech cities and those with large gay populations. According to the study the top high tech and gay populated cities were San Francisco, Boston, Seattle and Washington, DC.

As for where they live, gay male couples largely prefer urban environments (45%) to suburbs (41.3%) and lesbian couples settle more often in suburban locales (46%) than city centers (38.2%). That compares to opposite-sex partners in the city of 35% and suburbs of 45.9%. Among rural couples, lesbians (15.8%) edged out gay men (13.7%) but predictably not opposite sex partners (19.1%). Interestingly, the South carried the largest number of same-sex couples counted (209,742), followed by the West (159,653), Northeast (119,246) and Midwest (105,705).

Top states for female couples: California, New York, Texas, Florida, Illinois, Pennsylvania and Ohio. Top states for male pairs varied slightly: California, New York, Florida, Texas, Illinois, Pennsylvania and Georgia.

Figure 1.1 LGBT Footprint/ Demographics



Nationally, 33% of female same-sex households had children, the South representing the highest percentage (34%), compared to 22% of male couple households. States representing the highest percent of same-sex couple households with children were Mississippi, South Dakota and Utah.

According to another report of the census data by the HRC and Gates, of 9,328 same-sex couples, 26% of male couples included a stay-at-home parent, versus 25% of heterosexual couples, and 22% of lesbian couples. (The 2000 U.S. Census reported 60,000 male-couple households with children, or about 20% of gay male households. That compares to 96,000 female-couple households with kids, or one third of all lesbian households.)

Mixed race couples occurred in 15.3% of male couples (15% for opposite sex partners) and 12.6% of female pairs.

In more than 10% of same-sex couples, one partner is at least 65 years old, and in nearly 10% of gay couples both adults are over 65. However, senior gay couples earn 4.3% less in combined retirement income than married heterosexual couples.

About 8% of lesbian pairs said they had prior military service, compared with 1% of women who are married or who are in unmarried partnerships. About 14% of gay men had served in the military, about the same as for men in unmarried partnerships but half the rate of married men.

An October 2004 groundbreaking report titled "Black Same-Sex Households in the United States: A Report from the 2000 Census" by the National Gay and Lesbian Task Force Policy Institute and the National Black Justice Coalition, written by Alain Dang and Somjen Frazer, provided the first-ever analysis of African-American lesbians and gays. The report found that black lesbian couples are raising children at almost the same rate as black married couples, and that black same-sex couples raise children at twice the rate of white same-sex couples. Black same-sex couples are 14% of all same-sex couples in the U.S.

Impact of Rising Gay Marriage Rates

With the debate of civil unions and gay marriage comes the idea of spending power on ceremonies and honeymoons. Forbes estimated a \$16.8 billion value to gay weddings across several years in the \$70 billion-per-year U.S. wedding industry. (Here's their math: The average cost of a wedding has climbed steadily in the last decade to reach \$22,000 in 2004, according to The Knot. The U.S. Census found roughly 92% of heterosexual couples living together in 2000 were married. Forbes assumed the same percentage for the 594,000 same-sex couples living together in 2000, concluding roughly 546,000 couples would wed if they could. Because not all couples hold a reception (about 15% of newlyweds pass) Forbes concluded 464,000 gay couples would likely have one. They then multiplied that figure by the amount the average heterosexual couples currently spend on engagement rings, banquet halls, wedding dresses and honeymoons. The magazine did not estimate how many years it would take for the current gay population to wed and achieve the spending figure.)

LGBT Impact on the Travel Industry

Travel is already a particularly strong spending area for many in the gay and lesbian community, honeymoon or none. According to Community Marketing, Inc. the American gay and lesbian community represents a \$54.1 billion travel market, or an estimated 10% of the U.S. travel industry. Study of the gay market indicates 97% took vacations in the past 12 months (national average is 64%), 82% spent 5+ nights in hotels, 72% rented cars, 18% with 15+ days of car rental, and 20% took at least one cruise (national average is about 2%).

LGBT Specific Events - Huge Economic Impact

In 1993, an estimated one million people marched on Washington D.C. to demand equal rights for lesbians and gays. Their presence brought in \$177 million to city businesses. In 1994, the 25th anniversary of the Stonewall riots and Gay Games IV brought in hundreds of thousands of visitors to New York City, and an estimated \$200 million with them.

Gay Pride events occur in every major city with an estimated 15 million people participating in U.S. Pride events alone, according to InterPride. For a list of Pride events, please refer to http://en.wikipedia.org/wiki/List_of_LGBT_events.

Examples of Pride Events & Their Economic Impact

- An economic impact survey calculated that Sydney Gay & Lesbian Mardi Gras attracts 500,000 spectators and contributes AU\$100 million to the Australian economy each year.
- Estimates for the economic boost to the city and county of San Francisco for its Gay & Lesbian Pride parade are at \$100 million, Southern Decadence in New Orleans is \$72 million, and Montreal's Black and Blue Ball generates C\$34 million and attracts about 80,000 people.
- Toronto Pride Parade is Canada's most attended single-day event, with an estimated crowd of more than a million people, and Pride Week festivities bring about C\$60 million to the city's economy.
- Montreal Pride Week, called Divers/Cité, brings in C\$40 million with about 850,000 attendees, while Vancouver's Pride brings in about C\$23 million.

There are a number of major non-Pride related events as well. The still-unofficial "Gay Days" at DisneyWorld, begun in 1991, now attracts 150,000 to events citywide and has competing activity organizers, including One Mighty Weekend. The events pump an estimated \$100 million into the Orlando economy, according to organizers. A smaller version now also appears in Anaheim, Calif. too. Aspen Gay Ski Week, one of several popular ski events, brings in a reported \$12 million to the resort town.

The Gay Games events were founded in 1982 and now attract more athletes than the Olympics, 14,000 every four years. In 1994, it provided an estimated \$300 million to New York City, 125 million Dutch guilders (\$55 million) in Amsterdam in 1998, and Gay Games VI in 2002 generated roughly AU\$100 million (US\$60 million) for Sydney, Australia. The next Gay Games will be in 2014 in Cleveland, Ohio. They are anticipating 30,000 people to attend the events and festivities.

Across the U.S. are also a number of sporting organizations that have regional and national competitions, among the largest are the International Gay Rodeo Association with 20 member associations, the International Gay Bowling Association with roughly 20,000 bowlers in 200 leagues, and the North American Gay Amateur Athletic Alliance with 51 chapters of gay and lesbian softball leagues in 35 cities.

The Folsom Street Fair in San Francisco attracts 300,000 interested in leather annually, and International Mr. Leather competition has been a major event for thousands since 1979 in Chicago, where there is also the Leather Archives & Museum.

Most major cities have popular annual gay film festivals as well, many of them over 10 years old, including Outfest in Los Angeles and The New Fest in New York City.

The largest national gay women's event of any kind is the Dinah Shore Golf Tournament. No lesbian attendance figures are available, though some industry analysts estimate 40% of the 80,000 spectators attending the games are lesbian, and there are many event-related activities, including The Dinah Weekend. Other big women's events include the Michigan Womyn's Music Festival, Women's Week in Provincetown, Mass., and new circuit parties for women, including Aqua Girl in Miami Beach, and Girls in Wonderland, in Orlando.

Gay & lesbian film festivals also are a major draw in many large and small cities internationally, some that have celebrated a decade or more of existence and attract over 15,000 attendees during the run.

Gay business, entertainment, travel and marriage/wedding expositions are also becoming an option for corporations to reach thousands of consumers and small business owners in New York City and a handful of other major cities.

Additionally, major national GLBT organizations such as the Human Rights Campaign, Gay & Lesbian Alliance Against Defamation, National Gay & lesbian Task Force, Lambda Legal and major state GLBT rights groups have numerous national and regional events that attract thousands of supporters and top-level sponsors.

LGBT & Advertising

For more and more advertisers today, "gay" isn't lavender, pink or rainbow-colored -- it's green. While television is about reaching mass audiences with a general message, print ads can be much more targeted. When an ad appears in gay media, it is meant to speak directly to the gay community.

Commercial Closet Association follows noteworthy gay-themed ads from major advertisers in gay publications and some relevant ones from mainstream media. For now, the bulk of the content in the archive is from two American magazines – The Advocate (2006 audited circulation of 155,755) and OUT, (2006 audited circulation of 148,422). There is also some representation by international titles including Australia's BLUE, France's Tetu, the UK's Gay Times, Attitude, Diva, and Belgium's GUS. The Advocate and OUT were formerly competing publications (founded in 1969 and 1992 respectively) were the premiere places for gay marketing for most advertisers through the end of the 20th century. Print had long been the most developed medium to reach gay Americans, despite a handful of radio and local access cable programs.

Gay-themed print advertising has evolved parallel to the growing inclusion of gays in TV advertising in the US. A substantial increase in gay-themed print ads began in 1996 as advertisers, particularly in the alcohol industry, sought to distinguish themselves in an increasingly crowded category. Alcohol and tobacco, both known as "sin" products, developed early because they were much less concerned about boycotts from religious conservatives than other corporate marketers

The nexus between marketers that include gays in their TV commercials and also have gay-specific print ads remains very small. When polled about what types of ads corporations should run, the opinions of visitors to CommercialCloset.org varied. About 21% of 1,000 polled said that ads should feature gay-specific pictures, while 17.9% thought mainstream ads would work --so long as they didn't picture heterosexual couples. But a majority, 52.8%, said that ads should be a mix of both.

The most developed ad categories targeting gay audiences include Alcohol (140+ ads), Fashion (140+), Travel (50+), Financial Services (40+), Automotive (35+) and Media (35+), among others. Meanwhile, other categories remain largely missing, such as Telecom, Fast Food, Snack Foods, Packaged Goods, Electronics, Personal Products, Household Goods, Healthcare, Home, Office, Remodeling, Retirement and many others.

LGBT Online

Up to an additional \$27 million is now spent annually in online advertising (\$26.5 million with dominant player PlanetOut), and an estimated \$20 million on LOGO, for a total of \$270 million in gay media alone. (In late 2005, LPI Media, which publishes The Advocate and OUT, were acquired by PlanetOut Inc. which owns gay.com.) According to CCA's Corporate Sponsorship Report, another \$6 million is spent on sponsorships of major national GLBT organizations and events, totaling \$276 million spent on reaching the market.

Social is the future. Gay consumers – especially younger gay men – are leading the charge toward the intersection of social networking and brand interaction with mobile applications like Grindr. Emerging advertising platforms such as mobile applications and QR tags are gaining noticeable traction and will only become more important.

70% of gay men and 60% of gay women own a smartphone. Gay men under 45 (over 80%) are most likely to have a smartphone and over 40% of them utilize an iPhone. Over 80% of gay men and women utilize their smartphones to send email, text and search the internet. Over 60% of gay men and women utilize their smartphones to access social networking sites. Gay men are clearly more likely to be using their smartphones to meet people, use 'check-in' applications like Four Square™ and make purchases. Younger gay men and women are much heavier users of technology for socializing with their networks. They send nearly twice as many texts per day as age 30+ and about a third spend at least an hour per day on Facebook. 69% of gay men and 61% of gay women visit mainstream internet sites weekly. In comparison, 61% of gay men and 63% of gay women visit LGBT websites weekly. Everyone uses Facebook

primarily to facilitate connections, but younger gay men (62%) and women (57%) are more likely to also see it as a source of 'entertainment'. Younger gay men are the most likely to use Facebook for online dating. When it comes to finding out about the things that matter, the ubiquity of Facebook is apparent – especially in the lives of gay and lesbian consumers under 30 (over 70% of young gay men and women utilize Facebook to obtain their daily news). Twitter is particularly strong among these groups as well. Facebook advertising is rivaling traditional website banner ads among all LGBT consumer groups. Among younger gay men, emerging ad platforms such as 'QR codes/tags' and mobile apps are gaining traction.

Diversity within LGBT: Differences by Ethnic Segments

Gay Asian men tend to be the most 'tech---forward' audience – they are much more likely to be smartphone users (84% vs. 68% on average) and over 1 in 4 have already purchased a tablet computer. They are also the most likely to use their smartphones for activities such as navigation (74%) and playing games (66%). When it comes to media usage, readership of regional/local LGBT print publications tends to be slightly higher among African Americans, while Asian gay men and women are somewhat more likely to read LGBT blogs.

Dietary Supplement Health and Education Act

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), a dietary supplement is defined as a product intended to supplement the diet and contains any of a number of ingredients such as: vitamins, minerals, herbs or other botanicals or amino acids. Dietary supplements are meant to be taken orally and are come in pill, capsule, tablet, powder or liquid form. They are most often used to fuel metabolism, immunity, growth, organ function, weight management and energy levels. Dietary supplements are regulated by the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN).

Recognizing that dietary supplements play a valuable role in promoting improved health and well-being, in 1994 the Congress enacted a comprehensive new law changing the way in which vitamins, minerals, herbs and specialty supplements are regulated by the federal government. Called the Dietary Supplement Health and Education Act (DSHEA), this law gives considerable power to the federal government to ensure the safety of supplements and the accuracy of health claims. At the same time, DSHEA recognized the importance of funding additional scientific studies on the relationship between supplements and disease prevention and created the Office of Dietary Supplements within the National Institutes of Health to coordinate this research.

We founded the DSIB to ensure that the goals of the Dietary Supplement Health and Education Act (DSHEA) are met by providing meaningful information about the health benefits and responsible use of dietary supplements to all Americans.

Because DSHEA set up a new framework for regulating dietary supplements, questions persist about how these products are regulated at the federal level. Accordingly, what follows is a review of the regulations now in place to ensure that only safe, beneficial, and quality supplements are marketed to the American public.

Dietary Supplements: Establishing a Formal Definition

In passing DSHEA, Congress recognized that consumers would benefit from having expanded and well-informed access to properly regulated vitamins, minerals, amino acids, herbs and other substances. For this reason, DSHEA defines a "dietary supplement" as a product that:

- Contains 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 combination of these ingredients
- Is intended for ingestion in pill, capsule, tablet or liquid form, unless...
- It is not represented for use as a conventional food or as the sole item of a meal or diet
- It is labeled as a "dietary supplement"

An Emphasis on Safety

Before DSHEA, there was considerable confusion over how to regulate dietary supplements. Specifically, the U.S. Food and Drug Administration (FDA) regulated these products either as foods or as drugs, depending on their intended use, or sometimes as food additives like artificial colors. To resolve these inconsistencies, Congress determined that the FDA should regulate supplements with the same safety requirements that the agency applies when regulating commonly used foods. This means that like most other foods, it is the manufacturer's responsibility to ensure that the company's products are safe and properly labeled prior to marketing.

Just as the FDA doesn't require pre-market approval for foods with a very long history of safe use, the new law applies the same principle to dietary supplements that do not contain new dietary ingredients. For products containing a new ingredient (one not marketed in the U.S. before 1994), DSHEA requires manufacturers to submit data to the FDA demonstrating that the new ingredient does not present a safety risk under the conditions of use. Another option is for manufacturers to petition the FDA, asking the agency to establish the conditions under which the new dietary ingredient would reasonably be expected to be safe.

In addition, the FDA has considerable enforcement authority over dietary supplements that are on the market. Specifically, the FDA has the power to:

- Stop any company from selling a dietary supplement that is "adulterated" or misbranded
- Stop the sale of a dietary supplement that makes false or unsubstantiated claims
- Take action against any dietary supplement that poses "a significant or unreasonable risk of illness or injury"
- Stop any company making a claim that a product cures or treats a disease
- Require dietary supplements to meet strict manufacturing standards, including potency, cleanliness and stability

Comprehensive Labeling Requirements

Like foods, dietary supplements are required to carry ingredient labeling. This information must include the name and the net quantity of contents on the principle display panel. The label must also list all ingredients that do not appear in the supplement facts information panel in the order of their amount in the product.

But unlike foods, the law spells out a number of labeling requirements for dietary supplements that are unique. Specifically, these rules call for:

- Inclusion of the term "dietary supplement" (or similar terms such as "herbal supplement") as part of the statement of identity
- Stating the quantity of each dietary ingredient or for combination products, the total quantity of all dietary ingredients in the blend

Most importantly for consumers, the new law requires that dietary supplements provide nutritional labeling. This labeling, called a "Supplement Facts" information panel, lists the amount of calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins, and minerals. The Supplement Facts panel must also include the quantity per serving for each dietary ingredient (or blend) and may describe the source of a dietary ingredient (for example, "calcium from Calcium gluconate").

Regulating Health Benefit Claims

To help consumers make informed decisions about using dietary supplements, the law sets out very stringent requirements for when manufacturers can make claims about the health benefits of their products. Based upon DSHEA and specific food labeling laws, FDA has issued regulations that allow dietary supplement manufacturers to make three types of claims: 1) nutrient-content claims, 2) health claims, and 3) structure-function claims.

With nutrient-content claims, the regulations are straightforward: based on FDA's requirements, when a supplement contains a high enough level of a nutrient, the product can carry a claim such as "high in calcium" or "an excellent source of vitamin C." FDA also authorizes health-related claims for foods and dietary supplements when there is a documented link between a food/dietary supplement and a health-related condition. Here, FDA has by regulation established approved health-related claims based on a review of the scientific evidence for significant scientific agreement, or based upon an authoritative statement from a scientific body like the National Academy of Sciences. The following six claims apply to dietary supplements:

- Folic acid and a decreased risk of birth defects
- Calcium and a lower risk of osteoporosis
- Potassium and the reduced risk of high blood pressure and stroke
- Psyllium seed husk (as part of a diet low in cholesterol and saturated fat) and a reduced risk of coronary heart disease
- Soy protein and the reduced risk of coronary heart disease
- Plant sterol/stanol esters and the reduced risk of coronary heart disease

Finally, the law allows information describing the supplement's effect on the body's structure or function, such as Vitamin E supports a healthy heart, or fiber maintains bowel regularity. To use these claims, manufacturers must have scientific data to substantiate the statement and the product label must bear this notice: "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." In addition, FDA requires marketers to inform the agency of the use of the claim no later than 30 days after the product is first marketed and to certify that they can substantiate the claim, if challenged. Knowingly filing a false certification is a crime.

While DSHEA permits manufacturers that qualify to make structure-function claims, the law specifically prohibits disease claims for dietary supplements. For this reason, FDA has developed regulations that distinguish between a structure-function claim and a disease claim. Under these regulations, for example, a product cannot carry the claim "cures cancer" or "treats arthritis" or make statements that the product is a substitute for an approved therapy.

Regulating Advertising

While FDA has primary responsibility for regulating the safety and labeling of dietary supplements, the Federal Trade Commission (FTC) has authority over claims in advertising, infomercials, catalogs, web sites, and direct marketing materials. Accordingly, FTC issued "Dietary Supplements: An Advertising Guide for Industry" in which the agency states that both strong scientific substantiation and a careful presentation of the facts are the criteria that FTC relies on in regulating the advertising and Internet marketing of dietary supplements.




- When FTC determines that the claim is unfounded, the agency has the power to:
- Challenge and stop advertising that is not adequately substantiated
- Investigate complaints or questionable trade practices. Here, the agency has the power to require a company to produce documents, give testimony, and provide answers to written questions
- Negotiate a consent order or work through the administrative and/or federal courts to obtain a cease and desist order, which can be very broad in scope
- Seek preliminary or permanent injunctions to stop false advertisements or other marketing practices
- Seek civil penalties from violators

As this description makes clear, the dietary supplement industry is subject to extensive laws and regulations at the federal level, all of which are designed to ensure that safe, beneficial and quality supplements are available for health promotion and disease management. When viewed in this manner, the public can have confidence that the regulatory

framework now in place gives consumers greater access to a wide range of dietary supplements while making sure that products that don't meet government requirements are removed from the market.

Competitive Product Research

- Competitor Product Name
- Company Name & Information
- Competitor Product Branding
- Pricing

Product	Company Name	Branding/Logo	Pricing
Orexis	Urban Nutrition https://www.urbannutritioninc.com/urbaninc/?w=orexis.com &af=&orpa=gay.php&pid=		\$144.96 for a 4 month supply \$49.99 for a one month supply
Perfomaxx	Qisxara Global Resources http://www.perfomaxxformen.com		1 Box (10 capsules)-\$47.40 (includes shipping) 2 Boxes (20 capsules)-\$75.81 4 Boxes (40 capsules)-\$143.64
Instamaxx Sex Pill	Instamaxx for Men http://instamaxxformen.com/gay-issues.html		1 Pack-\$51.95 2 Packs-\$86.90 Value Pack - Buy 5 free 1 pack. \$186.80

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