

UNPA ASIA REPORT

*A special section produced by the
United Natural Products Alliance*

Chinese botanicals as U.S. dietary ingredients: Meeting FDA's GMP requirements

Also:

- U.S. herb sales reach \$7.45 billion
- China chamber helps companies build health businesses
- The consumer demand for 'clean-label' supplements

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As your industry partner, UNPA will help you reach your strategic business goals. The United Natural Products Alliance (UNPA) is an international association representing more than 100 leading natural products, dietary supplement, functional food, and scientific and technology and related service companies that work together to create collaborative problem solving and to enhance market opportunities for its members.

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- Market intelligence
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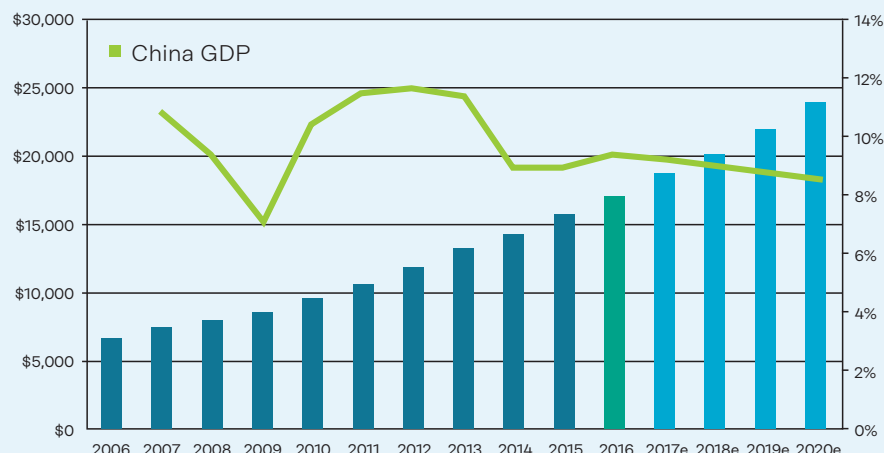
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Supplement sales in China reach \$17.2 billion in 2016

China: Supplements sales and growth, 2006–2020e



The Chinese market for dietary supplements is outpacing the country's GDP growth. Reaching \$17.2 billion in 2016, a 9.3 percent annual increase, the Chinese market is growing at a much faster rate than the global growth rate of 5.7 percent.

Source: Nutrition Business Journal (\$mil., consumer sales)

China not yet meeting population's TCM needs

While China continues to make progress in meeting the demands of its population for Traditional Chinese Medicine (TCM), according to a report released by the State Administration for TCM, it is not yet able to meet this demand.

China is undergoing its fourth pilot program to survey the national resources of TCM. Since 2011, the program has surveyed about half of the country's administrative divisions, including 1,300 counties thus far. In addition, China has established more than 200 seedling nurseries for growing TCM herbs.

Under President Xi Jinping's Healthy China 2030 blueprint, the Chinese are moving forward with plans to build more TCM clinics and hospitals throughout the country.

According to newly published data, approximately 15 percent of Chinese patients were treated at TCM clinics in 2017. Wang Guoqiang, head of the State Administration for TCM, said the administration planned to build at least one TCM clinic or hospital in every county.

—Nutraingredients-asia.com

Probiotics on the verge of exploding in China

Growth in probiotics is outstripping all other categories in the United States, but on the other side of the world, the market is only just beginning to develop.

In a presentation to the China Health Industry Technology & China Microecological Health Conference, George Paraskevatos, executive director of the International Probiotics Association, and Loren Israelsen, president of the United Natural Products Alliance, discussed the burgeoning boom in the probiotic sector in China. While the majority of probiotics are consumed in the form of yogurt and other fermented products, Chinese consumers are beginning to turn to dietary supplements, as well.

"It is crystal clear that probiotics are on the verge of exploding in China," said Israelsen. "The potential market is vast. Currently consumer education is super low and domestic production is inconsistent."

"The need for standards, quality, external support and advice into the China market is wide open, and I think welcome," Israelsen added. —Nutraingredients-usa.com

China's Feihe International acquires Vitamin World

Chinese dairy and infant formula specialist Feihe International has completed its acquisition of U.S. retailer Vitamin World for an undisclosed sum.

Feihe and Vitamin World will begin immediately to expand the 40-year-old brand into the Asian markets. Vitamin World currently has 156 retail stores throughout the United States and its territories in Guam, Puerto Rico and the U.S. Virgin Islands.

"We are extremely fortunate to have such a strategic partner that not only truly understands our industry, but has the vision and ability to help Vitamin World rapidly gain significant global expansion," said Michael Madden, CEO of Vitamin World.

—Nutraingredients.com

Understanding WeChat is critical to success in Chinese e-commerce, says CHPA director

Exporters of dietary supplements into China need to be familiar with that country's dominant social media platform, WeChat, if they want to thrive, according to Jeff Crowther, executive director of the U.S.-China Health Products Association (CHPA).

Just as in the U.S., social media in China is ubiquitous. Many westerners are connected through channels such as Twitter, LinkedIn, Instagram and of course, Facebook. Many use large review sites such as Yelp or Trip

GNC's alliance with Chinese firm to boost brand, market

Harbin Pharmaceutical Group Holding Co., which operates under the name Hayao, has formed a joint venture with GNC to manufacture, market, sell and distribute GNC-branded products in China. The Chinese pharmaceutical company will also invest \$300 million in the struggling retailer and become its largest single shareholder.

GNC is making inroads into the Chinese market via this strategic partnership with one of the leading pharmaceutical firms. Hayao is described as a major Chinese company involved in all facets of pharmaceuticals, from research and development to manufacturing and sales. The board will expand to 11 members, with five members from Hayao and five from GNC, plus returning GNC CEO Ken Martindale. —Pittsburgh Post-Gazette

Advisor and shop online at Amazon. But for all of the reach these sites enjoy, it is nothing compared to the reach WeChat has earned in China, with more than 900 million users per day. WeChat facilitates almost anything a consumer would want to do online in China, Crowther said. For any business wishing to expand its influence and reach in the Chinese market, Crowther asserts, WeChat needs to be a part of the strategy.

—Nutraingredients.com

2018 Trade Shows & Conferences

International Conference on the Science of Botanicals

April 9-12 • Oxford, Miss.

SupplySide East

April 10-11 • Secaucus, N.J.

Medicinal and Health Product Hall Guangzhou Chinese Commodity Import and Export Fair

May 1-5 • Guangzhou, China

Vitafoods Europe

May 15-17 • Geneva, Switzerland

Dietary Supplements Regulatory Summit

May 16 • Washington, D.C.

World Tea Expo

June 11-14 • Las Vegas, Nev.

IADSA 20th Anniversary Week

June 19-21 • London

SupplySide China

June 28-30 • Guangzhou, China

Institute of Food Technologists 2018

July 15-18 • Chicago, Ill.

NBJ Summit

July 16-19 • Rancho Palos Verdes, Calif.

Vitafoods Asia

September 9-11 • Singapore

Natural Products Expo East & All Things Organic

September 12-15 • Baltimore, Md.

China International Import Expo

November 5-10 • Shanghai, China

SupplySide West

November 6-10 • Las Vegas, Nev.

For more information, visit www.unpa.com/events

U.S.-China research partnership on ginseng a sign of new backing for TCM, sources say

The funding of a U.S.-China research partnership focusing on ginseng in healthy aging and immunity is a sign of growing investment behind, and interest in, TCM, according to experts in the field, including from the American Botanical Council (ABC) and the American Herbal Pharmacopoeia (AHP). Both organizations are UNPA Memorandum of Understanding Partners.

Fusheng Pharmaceutical Company Co. LTD, a major pharmaceutical company in Dalian, China, is continuing to fund a research project at Johns Hopkins University studying the effects of the ginsenoside Rg3, a triterpene

saponin that is extracted from Panax ginseng, on aging and immunity. Fusheng, the leading manufacturer of Rg3 in the world, has committed funding through 2019.

"There has been a development happening in the past 10 or 12 years in China to look at the production of modern pharmaceutical drugs from TCM extracts," said ABC founder and Executive Director Mark Blumenthal. "Rg3 is one of many ginsenosides found in Asian ginseng and American ginseng. This could potentially stimulate more research and could push back on other ginseng extracts."

Roy Upton, founder and executive director of AHP, noted that when Chinese researcher Tu Youyou won the 2015 Nobel Prize in Medicine, it convinced the Chinese government to support further research into TCM.

"Unfortunately, in the East, there is a sense that Chinese herbal medicines or the research that goes into them are inferior to Western drugs and so, rightfully or not, there is a desire to conduct Chinese herbal medicine studies according to what they feel reflects the gold standard in medical research," Upton said. —Nutraingredients.usa.com

U.S. 2016 herbal supplement sales increase 7.7 percent

By Stephen DeNorscia

Consumers in the United States spent an estimated 7.7 percent more on herbal dietary supplements in 2016 than in the previous year, according to the recently published *HerbalGram* "Herb Market Report." The report, published by The American Botanical Council (ABC), highlighted the fact that the total sales exceeded \$7 billion for the first time and was the 13th consecutive year of growth in the dietary supplement industry.

The year saw the second-highest growth rate for retail sales of herbal supplements in more than a decade. U.S. consumers spent an estimated \$7.45 billion, an increase of approximately \$530 million from 2015.

In addition to the 7.7 percent increase in total sales of herbal supplements for 2016, retail sales increased for the eighth consecutive year in each of the three primary market channels: mass market, natural and health food retail stores, and direct-to-consumer. Mass-market sales growth is estimated to be 11 percent and totaling \$1.3 billion. Retail sales within natural and health food outlets increased by 6.4 percent, with sales of \$2.5 billion, while direct-to-consumer sales recorded an increase of 7.3 percent, with an estimated sales volume of \$3.6 billion.

The report, which tracks U.S. retail sales data compiled from multiple sources within the natural products industry, also focused on the top-selling herbal supplements within the mass market and natural channels. For the fourth consecutive year, horehound (*Marrubium vulgare*, *Lamiaceae*) was the top-selling herbal supplement in mainstream retail outlets in the United States. Sales of horehound supplements, which include cough drops and lozenges with horehound as the primary ingredient, totaled \$125.5 million in 2016. The category logged a growth rate of approximately 9.3 percent on an estimated sales increase of \$10.7 million.

Wheatgrass (*Triticum aestivum*, *Poaceae*) and barley (*Hordeum vulgare*, *Poaceae*) experienced the strongest mainstream sales growth in 2016, with a 131.9 percent jump in sales from 2015.

Three other ingredients experienced mainstream sales increases of more than 50 percent: boswellia (*Boswellia serrata*, *Burseraceae*—up 118.7 percent), turmeric (*Curcuma longa*, *Zingiberaceae*—up 85.5 percent), and fenugreek (*Trigonella foenum-graecum*, *Fabaceae*—up 52.1 percent). This growth is less pronounced than the sales increases seen in 2015, in

which mainstream sales for each of these herbs more than doubled from 2014.

Within the natural and health food retail channel, turmeric was the top-selling herbal supplement for the fourth consecutive year, with sales of \$47 million in 2016. This represents a 32 percent increase in sales, which was the third-highest increase of any of the 40 top-selling herbs in this channel.

Since 2011, sales growth of combination herbs has outpaced that of single-herb supplements, and this trend continued in 2016. Combination-herb supplement sales in all channels grew 10.1 percent from 2015, and single-herb supplement sales increased by 6.1 percent.

The report suggests that consumers, from casual shoppers in mainstream retail outlets to core consumers of natural products, are continuing to turn to plant- and fungi-based options for their health care and self-care. The shift in sales of specific ingredients points to evolving preferences for more single-herb supplements. ■

To access the full report, visit <http://cms.herbalgram.org/herbalgram/issue115/hg115-herbmarketrpt.html>

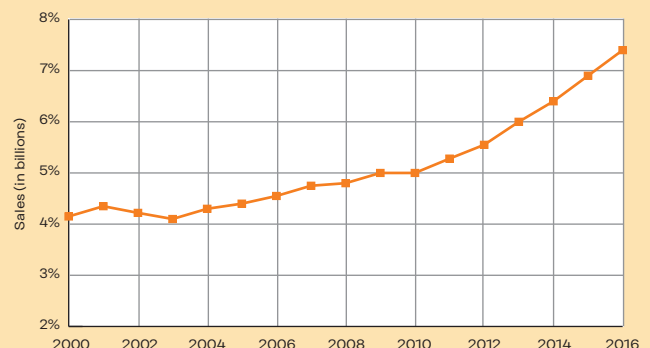


Total U.S. retail sales of herbal supplements

	2014	2015	2016	% change from 2015
Mass market	\$1.116	\$1.204	\$1.336	+11.0%
Natural & health food	\$2.186	\$2.356	\$2.506	+6.4%
Direct sales	\$3.139	\$3.363	\$3.609	+7.3%

The mass-market channel saw the largest growth in herbal supplement sales for 2016, underscoring growing consumer acceptance of herbs for health care and self-care.

Source: *Nutrition Business Journal* (\$bil.)



The "Herb Market Report" shows that 2016 was the 13th consecutive year of growth for herbal supplement sales in the U.S.

Packaging trends to help meet consumers' 'green' expectations

By Brent Anderson

Personal beliefs and a collectivist culture will shape 2018's top packaging trends, as many consumers are becoming more conscious of their own behaviors, according to market research company Mintel.

Because of this, dietary supplement brands are utilizing packaging to help make connections with their consumers, especially when it comes to connecting on a "green" level and conveying a brand message around environmental issues. Why? Mintel's "Global Packaging Trends 2018" report states that consumers are beginning to better "understand the balance between their own health and that of the environment ... demanding greener, healthier life solutions from brands."

Here are two ways for brands to address these trends through their printed packaging.

Eco packaging

Environmental issues have been a focal point in the news media and public consciousness over the past few years, drawing passionate responses on all sides of the discussion. Increasingly, consumers are aware that their daily purchasing decisions impact the macro environment. Remember the checkout question: "Paper or plastic?" That's why packaging's role in sustainability is most apparent in the area of the materials used.

Folding cartons and labels can be produced with post-consumer recycled materials and sourced through sustainable-certified paper suppliers with SFI (Sustainable Forestry Initiative), FSC (Forest Stewardship Council) or PEFC (Programme for the Endorsement of Forest Certification) oversight.

Likewise, plastics can be sourced from suppliers with programs to recover and reuse materials from the ocean. Companies, such as method home and Coca Cola, prominently feature this messaging to tell a story about their brand and mission.

So, what can brands do to further their commitment to eco packaging? Utilizing recycled materials is one option. Another often overlooked option is StretchPak, which provides an alternative to the traditional rigid clamshell or blister plastic. The StretchPak reduces plastic usage by utilizing a thin, PVC-free film paired with a printed card, all while providing product visibility and protection.

Extended copy requirements

For supplement brand holders or copackers, keeping up-to-date with regulatory requirements on packaging can be daunting, especially for brands that are selling internationally. As

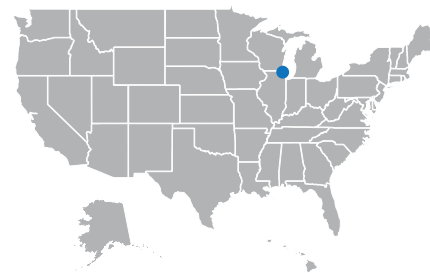
these companies face increasing requirements for information on their packaging and look to reduce the complexity of managing country-specific stock-keeping units, extended-content packaging is growing in application.

Multipanel labels, for example, can extend copy space on primary labels from between 200 and 1,600 percent. This enables primary packaging to

contain all of the necessary regulatory information and/or multiple languages, while utilizing existing manufacturing equipment and label applicators. There are also options for expanding content areas on or within a folding carton, which include fifth- and sixth-panel cartons, as well as combination packaging, such as Nosco's Lit-a-Sure.

Fifth- and sixth-panel cartons extend copy area with a header card that folds over and tucks into itself. The Lit-a-Sure option, on the other hand, offers the ability to pre-attach instruction package inserts to a carton. This eliminates the need to manually insert instructions on the packaging line and allows for automated scanning, verifying the presence and correct item number for each insert and carton combination. ■

Nosco is a printed packaging company offering complete packaging and individual solutions to companies in the dietary supplement market. For more information, contact Natural Health Market Leader Brent Anderson, banderson@nosco.com, 847.504.6409.



Sirio Pharma: On the cusp of global supplement trends

Dietary supplement companies looking to create products and do business internationally face a daunting task to understand not only regional trends and markets, but also all of the regulatory and quality requirements from market to market. Choosing a contract-manufacturing partner is a viable option to help provide some of this market intelligence.

Sirio Pharma is a Shantou, Guangdong, China-based, integrated contract manufacturer for the dietary supplement industry. The company is one of the few that offers global operations with development and manufacturing capabilities spanning all dosage forms, from softgels and nutraceutical gummies to functional beverages. The forward-looking company has 24 years of professional experience in supplement manufacturing, quality management and product R&D.



Rui Yang

In this Q&A with *UNPA Asia Report*, Rui Yang, Sirio's chief science officer and executive vice president, discussed the importance of quality, the global dietary supplements market and staying ahead of innovation, science and market trends.

UNPA Asia Report: Sirio Pharma has a strong quality mission. What are some of the key quality assurances that you have in place?

Rui Yang: For us, quality is a constant motivation, not a destination. Starting as a pharmaceutical business, Sirio appreciates the strict controls needed when it comes to quality management—from the sourcing of raw materials, along the entire supply chain to the end market. Standardized quality assurance of all products, combined with continuous monitoring and optimized processes, is a central component of our quality management. In this way, Sirio guarantees safe, high-quality



products for its customers around the globe.

Additionally, Sirio utilizes effective quality management and monitoring throughout the entire production process to prevent any contamination or deviation from quality standards.

UAR: What are some of the biggest challenges of doing business in many different markets?

Rui Yang: Regulations vary from country to country. We must get familiar with different markets' regulations to support our customers with their global business. In addition, customers from different markets are in need of different products and services. Therefore, we must understand local market trends, maintain close and frequent communication with customers and offer products and services that exceed their expectations.

UAR: Contract manufacturers are often ahead of the curve in product manufacturing trends. What are some of the current trends you see?

Rui Yang: We all see that consumers want personalized products, something new and a more convenient package. Furthermore, they want products supported by nutraceutical science, that are more food-like and not a burden to take. As a contract manufacturer, our aim is to bring something new and attractive to customers to support their growth and



industry development. We continuously invest resources to find out consumers' preferences and utilize our technology to develop new products.

UAR: How can you help U.S. companies that want to manufacture and distribute products in China?

Rui Yang: The Chinese market develops very quickly, and the potential is tremendous. China's cross-border business provides U.S. companies with convenient conditions to enter the Chinese market. However, China's regulations, distribution, consumer structure and product portfolio differ from that in U.S. We understand those issues and have the ability to give U.S. companies advice, help them avoid risk and find advantageous strategies. ■

For more information, visit <http://en.siriopharm.com>.

UNPA announces new China partnership agreement and executive member

Association welcomes CCGB as a new member and CCCMHPIE as its newest MOU partner

By Frank Lampe

In its continuing efforts to create long, lasting relationships with organizations and companies in China, to promote Sino-U.S. trade and to assist in improving the quality of the ingredients and products from China, the United Natural Products Alliance (UNPA) has announced the signing of a memorandum of understanding (MOU) partnership with the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE). (See related article, page 11).

The partnership agreement with CCCMHPIE additionally aims to facilitate the development of the Traditional Chinese Medicine, dietary supplement and natural health products industries in both China and the United States.

The CCCMPHIE agreement joins 14 other MOU partnerships, which allows UNPA to

organize its key objectives and work plans through partnerships that bring expertise, influence and trusted reputations. By laying out its joint objectives via an MOU, UNPA is able to serve the needs of its members and its industry stakeholders with greatest effect and efficiency.

"We are very impressed by the CCCMHPIE professionalism, the speed at which it works and its clear maturity and experience in dealing with foreign governments, trade associations and scientific and technical bodies," said Loren Israelsen, UNPA president.

"It is the working equivalent of the U.S. Chamber of Commerce plus the Department of Commerce interface between government and industry," he added. "We have several specific activities we are working on together, including two big trade shows and one international trade fair sponsored by the Chinese government. This will be a very productive MOU relationship for UNPA and the U.S. dietary supplement industry."

New executive member

Additionally, UNPA is pleased to welcome Lu Chenguang Biotech Group Co. Ltd., based in Quzhou, China, as its newest executive member. The firm operates under the trade name CCGB.

The company, founded in 1998, produces a wide range of ingredients, including

natural colors, natural spice extracts, essential oils and nutritional products, such as lycopene, lutein, green coffee bean, grape seed extract, red yeast rice powder, capsaicin, ginkgetin and astaxanthin, among others. CCGB exports its products to Europe, North and South America, Australia, the Russian Federation, Japan, Korea, India and Southeast Asia.

"We are pleased to welcome CCGB to the UNPA family," said Israelsen. "I have visited CCGB's primary facility—which is impressive—and have gained great respect for its commitment to our industry, to sustainable agriculture practices and its desire to advance as a leader on the global stage." ■



MOU partnerships help UNPA organize its key objectives and work plans.



Meet the UNPA staff: Loren Israelsen



Loren Israelsen

When Loren Israelsen was a young man, he lived in Asia. And while there, everywhere he went, he met people with a reverence for the natural world and respect for their elders and who openly accepted a young foreigner. This left a lasting impression on him that he carries to this day

That experience is one of the reasons why Israelsen is so passionate about working to bridge the natural health traditions and industries between China and the United States and to build long-lasting partnerships that will benefit consumers in both countries.

Israelsen is a lawyer by training, and it was in his capacity as in-house counsel for Nature's Way Products, one of the early Utah dietary supplement companies, that he saw how urgent it was to create a legal category within the federal government to protect

consumers' access to vitamins, herbs and all other dietary supplements.

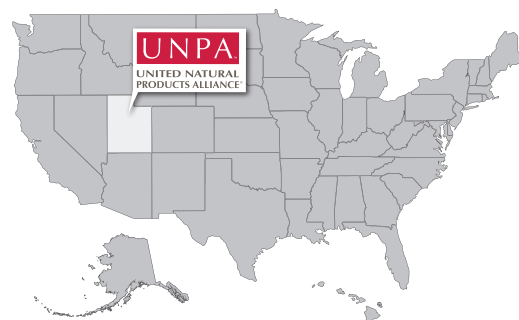
This engagement led Israelsen, Nature's Way and seven other Utah supplement companies to form the Utah Natural Products Alliance in 1992 to address this growing problem. The association's name was changed to the United Natural Products Alliance (UNPA) in 2005 in recognition of the organization's national and international membership base.

Due in great part to their collective efforts, the landmark Dietary Supplement Health and Education Act, known as DSHEA, was passed and is credited with creating the modern dietary supplement industry in the United States.

Twenty-six years later, Israelsen still leads UNPA as president. The organization now represents more than 100 best-in-class companies around the world, with a focus

on regulatory and legislative advocacy, education and best practices.

He continues to be an ardent advocate for strong quality standards and bringing together organizations from around the world, particularly from China, to create a community of honorable, highly regarded businesses that respect their cultural traditions while serving natural health consumers everywhere. ■



UNPA is headquartered in Salt Lake City, Utah

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Beijing Tong Ren Tang: Interpreting TCM for a new generation

Many companies strive to bring products based on ancient Chinese medicinal wisdom into the modern era, but few have been around as long as Beijing Tong Ren Tang Chinese Medicine Company Ltd.

Founded in 1669 to provide Chinese medicines for emperors and royal families, the company is now a Hong Kong-based retailer and wholesaler, with more than 2,000 Chinese medicine and healthcare products, a business spanning 20 countries and annual revenues of more than U.S. \$161.3 million. With the growing importance of Traditional Chinese Medicine around the world, the company is uniquely positioned to propel awareness and usage of these products to an increasingly receptive global audience.

But adapting ancient products over three centuries to make them relevant in the modern global market is no easy undertaking.

The company's historical pedigree is like few others. Beginning in the 8th year of the Emperor Kangxi of the Qing Dynasty, noted imperial physician Dr. Yue Xianyang set up the Tong Ren Tang Drugstore in Beijing. His philosophy, and the company's name, is based on the expression of Tongren, derived from the Book of Changes by Confucius, about the concepts of harmony and selflessness.

Spanning three centuries



Edna She

In keeping with this philosophy, the company states both an economic and cultural mission—to develop, manufacture and sell products, as well as serve the people by educating

them to live in a healthy way, noted Edna She, regulatory affairs specialist for the company.

She attributes Tong Ren Tang's success to the fact that it has stayed true to its roots, while also managing to innovate and adapt to modern demands and standards.



Pictured: A Tong Ren Tang wellness center (above) and a manufacturing facility (right).

Employees of the company, she explained, understand that they have to respect these traditions but don't necessarily have to stick with everything.

"We have to innovate new products, but not forget the origins as we manufacture high-quality and effective products. For example, She noted that the company's herbs are processed using 20 kinds of work operations and 52 processing methods that follow ancient code, while combining modern pharmaceutical technology for quality standards (the company has production lines that are certified under Australia Therapeutic Goods Administration and European GMP standards).

A widening platform

The strategy has worked well in China, Hong Kong, Macau and Taiwan, and Tong Ren Tang's recognition is now growing throughout Southeast Asia and Australia. The company has become a leading Chinese medicine product retailer and now sells more than 800 products overseas in more than 100 pharmacies. Among its best sellers are Kunbao Pill, a popular formula for women to ease menopause symptoms, and Ganmao Qingre Granule, which is used in relieving cold and fever.



In 2014, the company broadened its health services with the introduction of Chinese wellness centers to provide one-stop medical and wellness treatments for young, upscale consumers, who are receptive to Chinese medicine and personalized treatment programs.

As its awareness rises in Asia, She said the company is setting its sights on business development in Europe and the United States. With the growth of American and European interest in both physical and mental balance from natural products, she said, "we see the most potential for development in these markets."

For more information, visit <https://www.tongrentangcm.com/en/index.php>.



China health products chamber plays varied role for domestic, foreign companies

Chamber's broad mandate helps foreign companies establish business, serves as industry advocate

By Karen Raterman

Over the past decade, China's market for medicines and health products has seen double-digit growth, making China not only one of the largest global markets for these products, but also one of the fastest-growing markets in the world. The China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) is, perhaps, the trade association that has helped to facilitate this market expansion. Its mission is to promote international trade and cooperation in medicinal and health products, facilitating both import and export.

The United Natural Products Alliance recently signed a Memorandum of Understanding Partnership with CCCMHPIE (see article, page 8).

Founded in May 1989, CCCMHPIE operates directly under the Ministry of Commerce of China. It currently boasts a diverse membership of more than 2,400 companies, including most of the major manufacturers and trading companies of pharmaceutical and health products in China, and it covers a wide range of products, from Traditional Chinese Medicine and pharmaceuticals to nutraceuticals, functional cosmetics and health products.

The group has a broad mandate. First, it helps international companies build, sustain and grow their businesses in the country. Through its vast network of membership and extensive coverage of geographic areas throughout China, the agency assists foreign companies to successfully export their products, establish their business locally and source products in China.

"For international companies, the greatest barrier is that they don't have sufficient knowledge about the Chinese market,

the law, regulations and standards in China," said Zhongpeng Zhang, director of the National Technical Service Center for Trade at CCCMHPIE. "To enter the Chinese market, companies have to understand the policy environment, market needs and habit of use in China." It is also helpful to understand the history of health products in China, features of traditional health products and future market development in China, he added. CCCMHPIE can be a partner in gaining this knowledge.

Ongoing regulatory efforts, including Blue Hat

CCCMHPIE is active on the regulatory front, as well, working to formulate and implement government policies regarding the import and export of medicines and health products. The association serves as the voice of industry, representing concerns of business to all levels of government. The group lobbies the government on trade issues via a number of channels, including face-to-face

meetings with governmental departments and participation in government task forces and special committees, as well as conducting original research. CCCMHPIE also takes part in bilateral and multilateral talks between the Chinese and foreign governments on medicinal products.

One of the most difficult tasks for companies entering the China market is its Blue Hat certificate program, which requires a "registered" or "filed" approach, depending on the type of ingredient used in the product. CCCMHPIE can provide important insights on this program, such as which products can be filed and which must be registered, Zhang noted. "In accordance with regulations on registering and filing health foods, the following products can be filed," he



CCCMHPIE conducts seminars and workshops for companies on policy interpretation and market analysis.

said. One group is health foods, whose ingredients have been listed in the catalog of health food ingredients. The second is first-time imported health food that falls into the category of nutrients, such as vitamins and minerals. "The first-time imported health food should have the nutrients of supplementary vitamins and minerals included in the catalog of health food ingredients. The others should be registered," Zhang explained.

The trade group is also entrusted by the Chinese government to handle a broad spectrum of additional functions. It organizes the tendering of export quotas for medicinal and health products and implements government programs to assist small- and medium-sized Chinese companies in their effort to break into international markets, as well as develop government strategies to create export bases for medicinal products.

Belt and Road Initiative

One of the initiatives that the Chamber is participating in is a broader program in China called the Belt and Road Initiative, which is considered one of the biggest foreign spending programs since that implemented after World War II. The program is designed to promote trade growth, energize two-way investment and support inclusive and sustainable development by creating relationships between "Belt and Road" countries,

including countries in Southeast Asia, South Asia, Central and Western Asia, the Middle East, Africa, and Central and Eastern Europe.

According to CCCMHPIE, participants in the initiative recognize the importance of promoting a more dynamic, inclusive and sustainable economic globalization and work to resist protectionism, as well as promote unimpeded trade cooperation.

As a part of these initiatives, CCCMHPIE develops specific trade strategies for industry. This includes organizing and participating in trade fairs throughout the year, including the Medicinal and Health Product Hall at the Guangzhou Chinese Commodity Import and Export Fair, the second largest fair in the world.

The Chamber will also be involved in a new forum in 2018, announced by President Xi Jinping at the Belt and Road Forum last year. The China International Import Expo will take place Nov. 5-10, 2018, at the National Exhibition and Convention Center in Shanghai. The forum will target participants with advanced medical equipment, biopharmaceuticals, health products and cutting-edge biotechnology. The Medical Equipment and Health Care Products hall will focus on products such as medical equipment, bio and pharmaceuticals, nutrition and supplements and welfare and elderly

care products and services. The expo will also include seminars and workshops on policy interpretation, market analysis, new products and technologies, as well as supply and demand matchmaking and technical consultation on market access, among other topics.

Quality standards and guidance

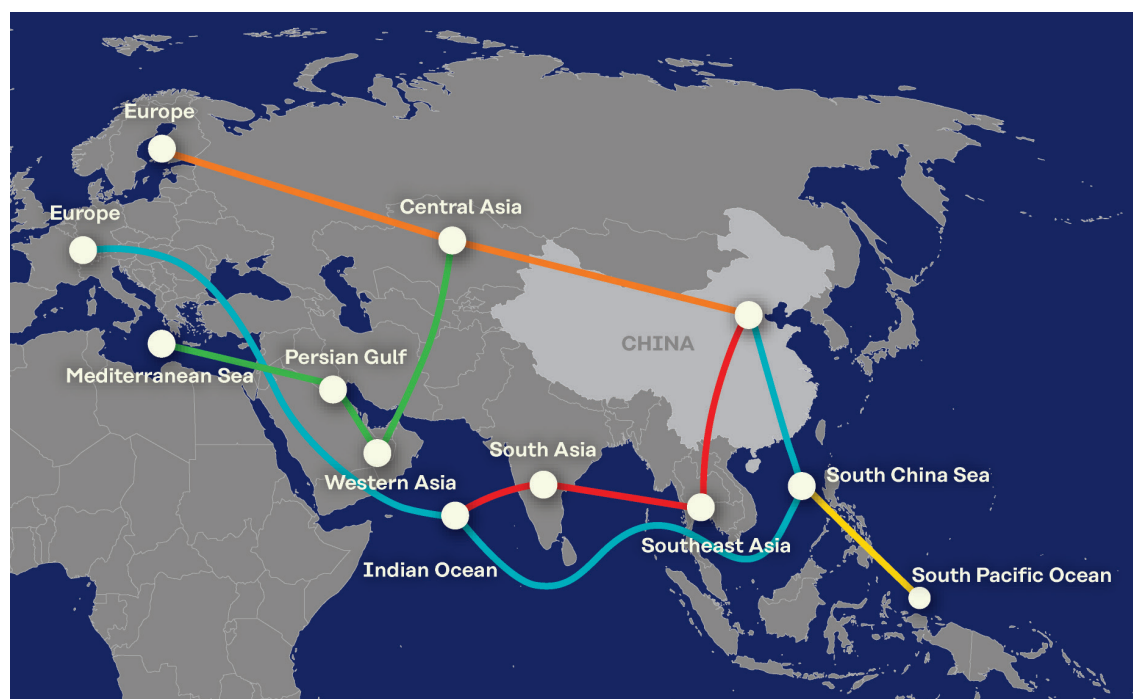
In addition to creating platforms for Chinese and foreign companies to connect, one of CCCMHPIE's key responsibilities is to formulate quality standards for export products, such as its "Green Trade Standards of Imported and Exported Medicinal Plants and Preparation." This program has been adopted by the government and now has widespread international recognition.

The organization is also a leader in providing prompt and effective guidance to Chinese companies facing anti-dumping and countervailing measures. In the past several years, Chinese medicinal products have been a major target for anti-dumping allegations. CCCMHPIE has successfully helped its members defend legitimate interests in trade disputes.

Overall, CCCMHPIE plays an important and active role in promoting the commercial credibility of its members. It recommends exemplary companies and their product to overseas buyers, using a system of evaluation that has helped

to create a credible environment for doing international business.

For more information, visit the CCCMHPIE website: <http://www.cccmhpie.org.cn/English/default.aspx>.



China's Belt and Road Initiative seeks to build inclusive trade practices between Asia, the Middle East, Africa and Eastern and Central Europe.

Chinese botanicals as dietary ingredients in the United States

How importers must meet FDA requirements for cGMP compliance

By James Neal-Kababick

Since 2007, the U.S. Food and Drug Administration (FDA) has implemented the final rule for current Good Manufacturing Practices (cGMP) of dietary supplements, which established that botanical ingredients used as dietary supplements must meet requirements for strength, identity, purity and potency and be free from reasonably anticipated contaminants, such as pesticides, solvents, pathogens and heavy metals.

In subsequent years, U.S. manufacturers have expanded their testing requirements for dietary ingredients used in supplements to conform to this rule. This has caused a great deal of confusion for many botanical importers as they have been faced with increasing demands for documentation and data to support ingredient quality.

This article will address the most important initial test that all manufacturers of dietary supplements must conduct or have done on their behalf—identity testing—and look at the unique challenges of Chinese botanicals from this aspect.

Challenge of Chinese botanicals

China benefits from one of the oldest botanical healing modalities—Traditional Chinese Medicine (TCM). In TCM practice, a large number of plant, animal and mineral drugs are used to treat patients. One of the commonly accepted practices of TCM is botanical substitution. That is, when one botanical is not available for a treatment plan, a different botanical with the same type of properties may be substituted within reason. This is often the case when practitioners are in

different regions or attempting collection in different seasons.

The practice of species substitution, while perfectly acceptable in TCM, is not allowed in the United States under the current regulations. In the U.S., all botanical ingredients must be listed by their Latin binomial and include the plant part used. The exception to using the Latin binomial is the use of a secondary common name. The regulations reference *Herbs of Commerce* for secondary common names associated with specific Latin binomials.

Perhaps the most disastrous result of species substitution was in the late 1990s. About 100 patients in Belgium developed end-stage renal failure and many also developed kidney or bladder cancer. The causality was linked to the substitution of *Stephania tetrandra* with *Aristolochia fangchi*. The manner in which the botanical was utilized was not keeping with traditional TCM methods, where the plant would have been used in a decoction, resulting in less user risk. There are other examples of species substitution in the U.S., as well. Suffice to say that while this practice is allowed within the scope of TCM, it must never be practiced when marketing botanicals in the U.S. market.

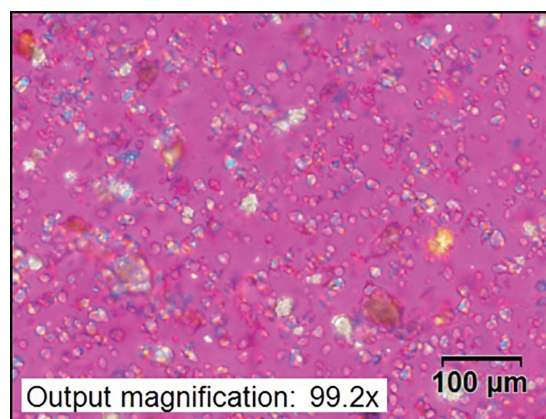
Another common problem arises from confusion over TCM names. Many

botanicals may have similar and easy-to-confuse Chinese names. Take the prior example. When a company asks for Fang Ji, they probably want Han Fang Ji (Rx. *Stephania tetrandra*) but may be getting Guang Fang Ji (*Aristolochia fangchi*). These misunderstandings are usually not intentional but arise from confusion over what is being sought by the buyer.

Identity testing

Under the dietary supplement cGMPs, FDA states that at least one identity test must be conducted to ensure proper identity. However, one test may not be enough. It may depend on issues surrounding the botanical offered. The most commonly utilized methods in the United States for identity testing are macroscopic examination, microscopical examination and high performance

Stephania microscopy polarize-light microscopy with first-order red filter



Stephania sample showing atypical calcium oxalate crystals, which indicates *Aristolochia* spp adulteration.

thin layer chromatography (HPTLC). However, both microscopy and HPTLC require specialized training and years of experience to master.

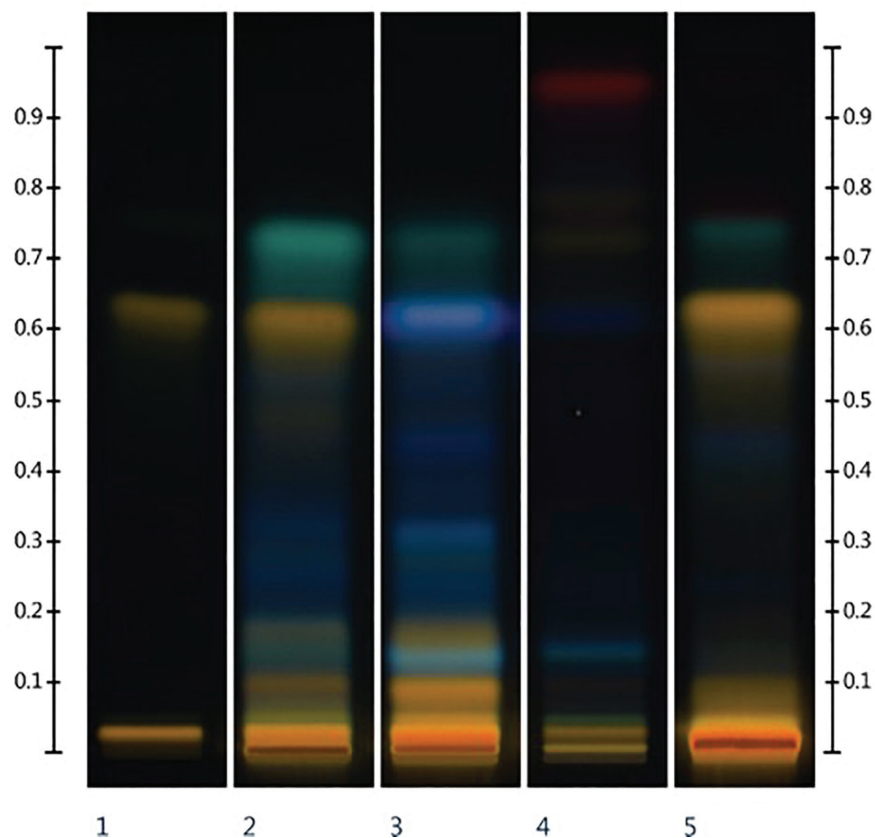
In the case of whole botanical material (whole ginkgo leaf, for example), macroscopic examination—comparing the physical appearance to the profile for authentic material—would be adequate. However, when a botanical is processed further into a tea cut or powder, macroscopic examination is not adequate. The use of microscopy and/or HPTLC is a good choice here. There is a trend toward utilizing both, as one test will detect things that the other misses and vice versa.

Identity of an extract is more complicated, especially TCM extracts, since many are made using traditional decoction techniques that render a chemical profile different than a lab-prepared, methanol-extracted botanical. For that reason, it is important to know how the extract is prepared. This requires good communication between seller and buyer or their laboratory. The laboratory must prepare references that are consistent with the extraction process utilized by the manufacturer.

Additionally, if excipients, such as maltodextrin, lactose, cellulose powder or dicalcium phosphate, are utilized, this must be declared. For example, if astragalus extract is prepared using the decoction method and dried on maltodextrin, then the identity test should be for water-extracted astragalus dried on maltodextrin and not just for astragalus. The additional metric of the carrier needs to be confirmed by microscopy and perhaps by Fourier-Transform infrared spectroscopy.

When a product is a standardized extract, it gets even more complicated. Take, for instance, ginkgo standardized to 24-percent flavonoid glycosides and 6 percent terpene lactones. Identity is not just for ginkgo leaf but also for ginkgo leaf extract and, in particular, for a 24/6 extract. One has to consider the limitations of the identity test and whether or not a single test will ensure proper identification. In this case, an HPTLC profiling method capable of detecting

Ginkgo aglycone profile by HPTLC showing adulteration of sample



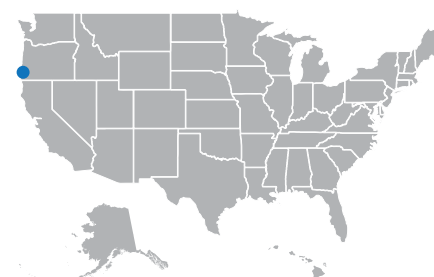
Lane 1: standard, Lane 2: adulterated sample, Lane 3: authentic extract, Lane 4: authentic leaf, Lane 5: Sophora japonica leaf. Note the large yellow band and minor yellow band from sophora (R_f 0.62, $\sim R_f$ 0.5), along with other bands indicative of ginkgo extract. This indicates a ginkgo extract adulterated with sophora extract.

admixture with free aglycones, including those from sophora spp., is needed. Thus, both a standard HPTLC glycoside profile and an aglycone profile are desired and illustrate when a single ID test is not sufficient to ensure proper identity.

Establishing stateside partners for quality control

In many cases, it may benefit the vendor to establish a relationship with a stateside expert, such as a natural products testing laboratory or university, to determine acceptable testing protocols to meet cGMP regulations. Having U.S.-based laboratory data can benefit the seller and increase confidence in the botanical ingredient being sold. Further, by working with a partner in the U.S., who understands your products and how they are made, can really help when problems such as conflicting laboratory results arise.

James Neal-Kababick is founder and director of Flora Research Laboratories LLC, a natural products research and testing laboratory celebrating its 25th year serving the dietary supplements industry. He is recognized globally for pioneering work in phytoforensic science and the advancement of analytical techniques for dietary supplement analysis. For more information, visit www.floraresearch.com.



The growing impact of the clean-label movement on the supplement category

Manufacturers seek botanicals and natural additives to meet consumer demand

By Karen Raterman

It is increasingly clear that consumers around the globe want “clean” ingredients, that is, ingredients with no artificial preservatives, sweeteners, flavors and no colors from artificial sources, in the products they purchase, as well as transparency about those products. As this trend spreads globally, it is also expanding to new product categories—and supplements and nutraceuticals are no exception.

But understanding what this means for a specific product or brand is difficult because there is no universal definition of a clean-label product, and the term means different things to different consumers.

Defining clean label

Research firms Nielsen and Label Insight have worked to put some parameters around the clean-label trend, noting four key segments:

- Products that are free from artificial ingredients, such as colors/ flavors, sweeteners and preservatives
- Products that are free from undesirable ingredients
- Products that contain recognizable and fewer ingredients
- Sustainable products, including those that are non-GMO, certified organic, sustainable, fair trade and humane.¹

There is also growing evidence that these clean-label attributes are having a big impact on product purchasing behavior. According to the

Nielsen Transparency Insight study, 73 percent of consumers say they feel positive about brands that share information on the “why behind the buy,” and 68 percent say they are willing to pay a premium for products that don’t contain ingredients they perceive negatively.

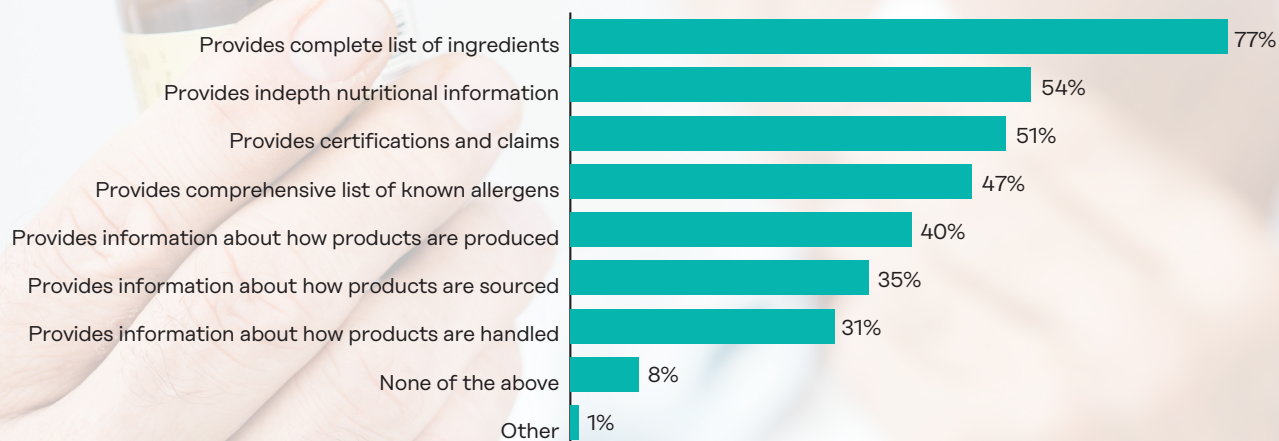
Clean labels for supplements

It is also evident that demand for transparency is moving beyond food and beverages into new segments, such as dietary supplements, pet products, cosmetics and personal care.

“If you take any hot-button issue that would drive consumer influence and purchasing decisions, you have to peel back whatever key ingredients are being used and look at it through a new filter,” said Steve Peirce, CEO of ingredient supplier Ribus. “People are now picking up all kinds of products and looking at the ingredient list. They want to be able to pronounce what’s on the label and have some idea where these ingredients are coming from.”²

According to the Transparency Insight study, use of transparency-related claims in supplements and personal care products is expanding and reached double-digit growth between 2016 and 2017. Organic supplements lead the growth at 25 percent, while “natural” presence in supplements saw 11 percent growth, and natural and botanical extracts in personal care jumped 13 percent.³

Which of the following factors do you use to determine whether a food manufacturer is being transparent about its products?



Source: 2016 Label Insight Transparency ROI Study

The shift toward new categories is having a significant impact on supplement ingredients, from active ingredients to excipients. For example, botanical ingredients, which already are perceived to be “clean,” are now seeing use in new product segments and as a potential alternative to animal-based proteins.

Botanicals have clean image

As consumers seek more protein in their diets, manufacturers are looking for new protein sources, which is leading to the use of botanical ingredients, such as fava beans and pumpkin-seed protein, in functional foods.

“If you don’t want to use animal-based proteins in a product, these are good, viable options,” said Randy Kreienbrink, vice president of marketing for BI Nutraceuticals. “I would say botanicals are pushing the envelope in all of these areas. Science, clean label and transparency are all growing, and there is more validation for herbs and these different uses,” he added.⁴

Animal proteins in supplements and nutraceuticals are an area ripe for a cleanup, noted Jeffrey Brams, general counsel and vice president of product development, science and international, for supplement maker Garden of Life. “Collagen as a category is enjoying a huge renaissance for energy,” he said. “But the way most cows and chickens are farmed, it’s challenging for an ethical brand to get behind an ingredient with collagen. There is definitely an opportunity to create farming practices that are sustainable and non-GMO, as well as ingredients without soy, hormones and all the other aspects we care about in the meat and poultry aisle. It would be nice to see cleaner ingredients showing up in collagen supplements, bone broth and other products.”⁵

“68 percent are willing to pay a premium for products that don’t contain ingredients they perceive negatively.”

New focus on binders, excipients

As the clean-label trend gains momentum, supplement manufacturers are also looking to replace traditional additives, such as binders, excipients and emulsifiers, with more natural alternatives. And while the supplement industry has had a few years to observe market trends and seek non-GMO substitutes, for example, the spotlight has now turned toward manufacturing processes and a careful review of additives.

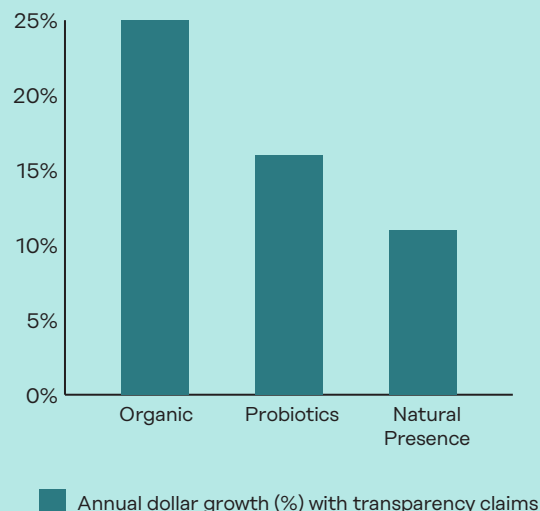
Brams noted that the clean-label phenomenon is long overdue, especially in the supplement category. It’s not hard to make a tablet, he said, but the industry has been using the same technology and the same binders and excipients for many years. “Shouldn’t the products we provide be different from what you can get in the over-the-counter and drug aisles of stores?”⁶

Garden of Life didn’t manufacture tablets for years because it couldn’t find additives that met its standards. Brams explained that Garden of Life’s ingredients have to be fully traceable, certified organic and Non-GMO Project Verified. “It requires discipline, but we are several steps further down the road.”⁷

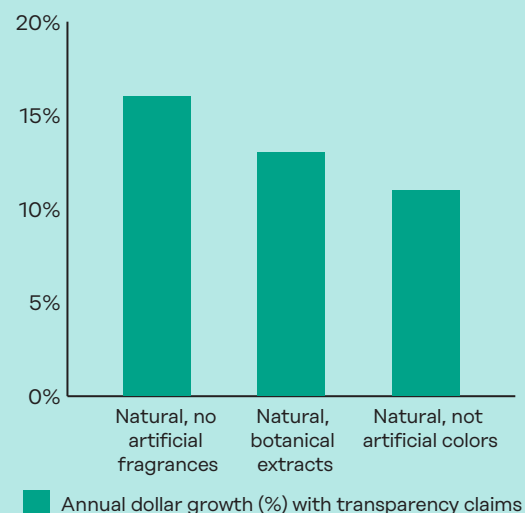
Ingredient companies such as Ribus are working to replace additive ingredients by developing rice-hull-based options, such as its Nu-Flow and Nu-Rice, which serve as binders and flowing agents. It also offers a new, rice-based substitute for magnesium stearate called Nu-Mag. Like Nu-Rice, it is a blend of rice extract, rice hulls, gum Arabic and sunflower oil to provide a lubricant similar to stearic acid. All the Ribus ingredients are label friendly because they are made from rice-bran extract.⁸ ■

Transparency demand exists beyond food and beverages

Vitamins, Minerals and Supplements



Personal Care



Source: Nielsen Product Insider, powered by Label Insights, 52 weeks ended April 15, 2017.

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