



China's Dietary Supplement Sector and Key Issues

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Introduction

The U.S. – China Health Products Association (美中健康产品协会) is a U.S. non-profit 501c6 incorporated organization under the law of the U.S. Internal Revenue Service. The association represents companies from around the world that are involved in the manufacturing, marketing, distributing, retailing, publishing, trade show organizing, advocating, educating, analytical testing/certifying, researching or any other business endeavor that promotes dietary supplements (膳食补充剂) and other natural health products.

Although China's health food product (保健食品) industry is still developing, the potential for sizeable growth is significant due to China's rapid economic growth, expanding middle class and increasing consumer demand for natural products that promote health and well being. Over the past three years, the U.S. – China Health Products Association has been analyzing both the regulations and the market environment of China's health food product industry. During this time, the association has gained a better understanding of the complexities involved and is now in a position to make informed recommendations.

It is the association's opinion that regulatory reform would greatly improve China's dietary supplement industry as well as bring greater safety and confidence to its consumers. The association understands that for the last few years, CFDA and expert panels have been researching and debating on industry reform for the health food product industry and the association strongly supports those efforts.

Article 56 of the "Food Safety Law Revised Draft" states that the State Council will release implementation regulations for the health product industry at a later date.

The association and its members are hopeful that the State Council in conjunction with CFDA will be prepared to release new legislation for the industry in 2014. Prior to the release of those anticipated regulations, the association would like to take this opportunity to make some suggestions that will help to better the industry for government, industry and consumers.

In advance, the association and its members thank China's Legislative Office of the State Council for taking the time to read and consider the association's comments and suggestions in regard to China's Food Safety Draft regulations focusing on the area of "Health Food Products".

CFDA's Current Health Food Product Regulations

China's health food product industry began about 20 years ago and is currently ranked fourth in sales behind the United States, Japan and Europe. Total sales for 2012 were approximately \$15.8 billion.¹ However, the exact figure is hard to determine due to ambiguities in China's regulatory system, definition and overall concept of what a "health food product" actually is.

As a result of the difficulties involved in researching the market size, the association's first observation is that the term "health food product" is too broad a concept and by definition can include anything that is healthy for humans to consume.

Furthermore, health food products are marketed in a variety of ways in China that further confuse the situation. For example, we found calcium tablets being sold as OTC drugs, as health food products with a blue hat registration from CFDA and as general food. There are also Traditional Chinese Medicine (TCM) companies selling herbal-based products as health food products with blue hat registrations.

The ambiguous nature of the current regulatory system and market environment has created a confusing overall experience for consumers and sends mixed messages about the role of health food products. In fact, most consumers in China believe that health food products are a type of medicine due to their history of being sold in pharmacies as OTC as well as some unscrupulous companies overstating their functions.

To address the above confusion, the association's first suggestion would be to consolidate the industry under the term "dietary supplement". This is the term that is globally accepted and it also gives a much clearer definition of what the products are and what their purpose is. The association invites CFDA and the State Council to consider using the U.S. FDA regulatory framework for dietary supplements.

The U.S. Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994 as the following:

"A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as

¹ Figure provided by China Health Care Association and China Chamber of Commerce

*enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft-gels, gel-caps, liquids, or powders”.*²

U.S. FDA regulations are based on notification not registration. Any ingredient that fits into the category of dietary supplement as defined by DSHEA is allowed to be used in a dietary supplement product. U.S. FDA has the legal ability to remove or deny market entry of any ingredient or product they deem is not a dietary supplement.

DSHEA is responsible for consolidating the industry of dietary supplements with its own set of regulations separating it from general food and drugs. This is a very important aspect of U.S. law in that it clarifies to government, industry and consumers that dietary supplements are products that supplement the diet to ensure adequate intake and help support vital functions of the body. Dietary supplements are not allowed to make claims of treating or curing disease as this type of claim is reserved for drugs.

In contrast, China has a registration system, which is lengthy, costly and is structured very much like that of a pharmaceutical registration, which includes animal testing and in some cases human trials. The system also involves a variety of agencies with sometimes conflicting or overlapping authority such as CFDA, Ministry of Health (MOH), Administration for Quality Supervision Inspection and Quarantine (AQSIQ), etc. The registration process is also based on products not ingredients. This results in redundant testing and registration procedures on products containing similar ingredients most of which have been available in China as well as globally for decades with high records of safety. If one company registers a product with vitamins A, B, C and D with CFDA and then another company wants to market a product also with vitamins A, B, C and D, they also have to go through the entire CFDA process, which does not make sense.

The association has heard that CFDA and its advisory board is considering having three different categories for health food products such as: Nutritional supplements (vitamins/minerals), Herbs, and Bio-Active Ingredients (specialty nutrients such as CoQ-10 and Amino Acids). If this is true, creating these categories would produce further inconsistencies and misunderstandings about health food products. As mentioned earlier, the State Council and its advisory board should seek to create one category called “dietary supplements” in order to streamline the industry for government, industry and consumers.

Safety of Dietary Supplements

Dietary supplements have a long history in the U.S. dating back over 100 years. However, it wasn't until 1994 with the passing of DSHEA did the industry really become organized. Prior to 1994, the industry was in a gray area, consumers were unclear if dietary supplements were food or a type of medicine that could cure or treat disease. Also,

² http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#what_is

legislation to oversee the safety of the industry was lacking. With DSHEA in affect, the industry has clear regulations including current Good Manufacturing Practices (cGMP) and Adverse Event Reporting (AER) both of which are specific to the dietary supplement industry. Furthermore, the Federal Trade Commission oversees compliance in regard to the marketing of dietary supplements to ensure marketers are not making illegal health claims to cheat consumers. Those companies that break the law are severely penalized facing heavy monetary fines and in some cases criminal penalties including jail time.

In the first six months of 2012, the U.S. FDA received 540,381 reports of adverse events in relation to drugs. Between the years 2007 -2012, U.S. FDA only received 6,300 reports for dietary supplements, which is an average of 1,050 per year. Furthermore, many of those reports could not positively connect the adverse event to the dietary supplement in question. Based on the above comparison, dietary supplements are extremely safe.

Savings in Government Healthcare Costs and Overall Benefit to GDP

If the regulatory system moves toward a system of notification and one based on ingredient not product approvals, the benefits to government, industry and consumers will be substantial. One such benefit would be savings in health care expenditures. The Chinese government has spent a great deal of effort and money reforming the healthcare system, which has resulted in the increased life expectancy of its citizens from age forty-five in 1950 to seventy-five in 2010.³

Although this is a great accomplishment, it has resulted in the creation of an expanding elderly population with a shrinking work force. By 2050, the population of those sixty years or older will triple to 33% of the total population.⁴ This will place increased economic pressure on the government to fund healthcare costs. To make the situation worse, healthcare expenditures per capita have increased five fold from 2002 to 2012.⁵

If dietary supplements become more readily available in potencies that reflect the latest in scientific and nutritional research, dietary supplements will compliment these efforts by promoting health and lifestyle changes for Chinese consumers as well as contribute to the country's overall GDP. These savings and benefits to the government and consumers alike have been clearly documented in the U.S. Here are some published examples:

Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements⁶

September 23, 2013 – This study was conducted by Frost and Sullivan with funding from the Council for Responsible Nutrition. The report revealed huge annual savings in Healthcare costs as follows:

³ United Nations - <http://data.un.org/Data.aspx?d=PopDiv&f=variableID%3A68>

⁴ United Nations - http://esa.un.org/wpp/unpp/panel_indicators.htm

⁵ World Health Organization - <http://apps.who.int/gho/data/node.country.country-CHN>

⁶ CRN/Frost and Sullivan - <http://www.frost.com/sublib/display-market-insight.do?id=285115104>

- **\$2.06 billion** annual savings in costs related to Coronary Heart Disease (CHD) If all US adults aged 55 and older diagnosed with CHD took daily supplements of Omega-3.
- **\$1.52 billion** annual savings in costs related to Coronary Heart Disease (CHD). If all US adults aged 55 and older diagnosed with CHD took daily supplements of the B vitamins folic acid, B6 and B12.
- **\$4.38 billion** annual savings in costs related to Coronary Heart Disease (CHD). If all US adults aged 55 and older diagnosed with CHD took daily supplements of phytosterol and psyllium fiber.
- **\$57.4 million** annual savings in costs related to Macular Degeneration and Cataracts. If all US adults aged 55 and older diagnosed with Macular Degeneration and Cataracts took daily supplements of lutein and zeaxanthin.
- **\$1.87 billion** annual savings in costs related to Osteoporosis Fractures. If women over the age of 55 diagnosed with osteoporosis took daily supplements of Calcium and Vitamin D.
- **\$851 million** annual savings in costs related to Osteoporosis Fractures. If women over the age of 55 diagnosed with osteoporosis took daily supplements of Magnesium.

Impact of Oral Nutritional Supplementation on Hospital Outcomes⁷

February 13, 2013 – was published in the *Journal of Managed Care* as well as presented to the European Society for Clinical Nutrition and Metabolism annual congress in Leipzig, Germany. The study was led by Dr. Tomas J. Philipson from the University of Chicago who with his team analyzed over 1 million inpatients and came to the following conclusions:

Patients that were given Oral Nutritional Supplements (ONS) had a shorter hospital stay by 2.3 days (21.0% decline) and decreased episode cost of \$4,734 (21.6% decline). Also the study found that ONS reduced readmission levels of these patients after 30 days by 6.7%.

Dietary Supplement Users Tend to Make Healthier Lifestyle Choices⁸

March 22, 2012 – The report was conducted by the Council for Responsible Nutrition and found that 71% of supplement users made better choices in regard to eating a balanced

⁷ American Journal of Managed Care - <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n2/Impact-of-Oral-Nutritional-Supplementation-on-Hospital-Outcomes/>

⁸ Council for Responsible Nutrition - <http://www.crnusa.org/prpdfs/CRNPR13-ConsumerHealthHabits061113.pdf>

diet, visiting their doctor on a regular basis, getting a good night's sleep, exercise regularly and maintaining a healthy weight compared to 61% or non-supplement users.

The Economic Contribution of the Dietary Supplement Industry⁹

April 5, 2010 – The economic study was conducted by Dobson and DaVanzo and funded by the Natural Products Foundation to record the impact the dietary supplement industry has on the U.S. economy. At that time, the dietary supplement industry was worth over \$24 billion in sales. The industry's overall economic impact to the U.S. economy exceeded \$US 60 billion or 0.5 percent of the U.S. GDP. Some of the report's detailed findings:

- Total tax contribution to the U.S. economy was \$10.1 billion
- For every dollar spent by the dietary supplement industry, \$2.71 is contributed to the U.S. economy
- For every job created by the dietary supplement industry, 2.29 jobs are created in the U.S. The dietary supplement industry is responsible for creating approximately half a million jobs across 100 different industries.

Balanced and Fair Trade

The U.S. and China have a unique and dependent relationship in regard to the dietary supplement industry. The U.S. is the largest manufacturer and marketer of finished dietary supplement products and China is the largest supplier of dietary supplement raw materials, which are used to produce thousands of U.S. finished dietary supplements. Upwards of 70 percent of the raw materials used by U.S. manufacturers are sourced from China.

In 2011, the China Chamber of Commerce estimated export values of ingredients were worth \$1.1 billion. These ingredients normally enter the U.S. market with little resistance as they are viewed as dietary supplement ingredients. In accordance with U.S. FDA's "Bioterrorism act of 2002", Chinese suppliers need only register their facility and give notice of shipment to U.S. FDA. Both these requirements are free of charge and can be done online in a matter of minutes. Although these ingredients originate from China, these same ingredients are not allowed back into China as finished products without going through lengthy and costly registration procedures. Restructuring China's current regulatory system to one of notification will allow both the U.S. and China to benefit by creating a more balanced exchange of goods.

The U.S. would be able to export more products to China, which in turn would increase the export of raw materials from Chinese suppliers to the U.S.

⁹ Dobson/DaVanzo and Natural Products Foundation -
<http://www.naturalproductsfoundation.org/index.php?src=news&srctype=detail&category=News&refno=20>

Specific Issues with Current CFDA Regulations for Health Food Products

U.S. – China Health Products Association understands that China’s regulators have set up the current system in order to protect consumers from fraudulent and unsafe products. However, it is the association’s opinion that the current system suffers from regulatory contradictions, harmonization issues and a lack of transparency that stifles industry growth. With the reorganization of CFDA, the revising of the Food Safety Law and new regulations on health food products on the horizon, this is the perfect opportunity to review the health food product industry in China and make necessary regulatory adjustments to improve safety and access for manufacturers and consumers alike. Industry reform will also benefit Chinese consumers by increasing the availability of dietary supplements, which are freely available in the U.S. and other international markets. Consumers will also enjoy lower prices due to manufacturers saving money on the high costs of registration and redundant product testing.

Areas of concern are CFDA’s product registration process, allowable functional claims, ingredient potency restrictions and overall clarity of the Food Safety Law.

CFDA Product Registration

Prior to market entry, manufacturers must register dietary supplements with the CFDA. Due to the complexities and transparency issues involved in the registration process, domestic as well as U.S. and other foreign manufacturers hire 3rd party Chinese registration consultants to facilitate registrations. The process requires enormous investments of both time and money. A typical registration can take between two and three years to complete and cost well over \$50,000 per product (SKU) depending on the product’s ingredients and how much the consultant charges. However, if an ingredient is new to the market, it can take as long as five years and well over \$100,000. After market entry, the registration is valid for only five years and then must be renewed, which adds unnecessary administrative processing to a product that has already been in the market for five years and approved to be safe by CFDA.

The global dietary supplement industry is continuously evolving and improving due to scientific and technological advancements. Because of CFDA’s lengthy registration process, dietary supplement companies are unable to introduce new products rapidly or reposition product lines to best suit consumer demands. This results in a significant reduction in the variety of products that offer the latest developments in nutritional health as well as increases retail pricing due to the high costs of registrations.

The amount of time and money required for registering products lacks justification and plays no role in enhancing consumer or product safety. CFDA should consider replacing its registration system with a notification system based on approved ingredients not individual approved products. This shift would allow more CFDA agents and officials to be allocated toward market surveillance, which would help rid the market of suspect or

dangerous products. Increased surveillance will increase the safety of the industry as well as enhance consumer confidence, which are both currently lacking.

As we have witnessed over the years, government regulations that strengthen market surveillance are the most effective at protecting consumers and building confidence. As examples, we can see that CFDA's increased surveillance of the dairy and cooking oil industries has certainly helped to increase safety and rebuild consumer confidence.

Functional Claims

CFDA has a list of 27 approved functional claims that marketers of health food products are allowed to make. Draft regulations are now in place that are scheduled to reduce this list further to 18. Health food products can only apply these claims to their products after going through a lengthy testing process including animal and sometimes human testing, which is very similar to the approval process for drugs. There are three main issues with this current list and process.

First, the list of 27 functions is too restrictive with regard to what health food products are known to support. For example, the ingredients Glucosamine and Chondroitin are supported by years of solid scientific research from a variety of international sources to benefit joint health, but "joint health" is not an approved claim. There are many other examples of products that are left out because there is not a suitable functional claim.

The association recommends going with a structure / function claim system similar to what the U.S. FDA uses for dietary supplements. This allows marketers to convey to consumers that dietary supplement ingredients can be helpful in supporting structures or functions of the body. For example, Fish Oil and Co-enzyme Q10 are both known to be beneficial to the cardiovascular system. This terminology clearly tells the consumer that these ingredients are helpful to their cardiovascular system, but it does not state that these ingredients can cure or treat cardiovascular disease. This is an important distinction and one that unfortunately has not been successfully made in China.

Second, regardless of whether or not an ingredient has been tested and known to be safe and have a specific function, it nevertheless has to go through all testing procedures every time a company submits an application. This is redundant and adds time and fees to the registration process. If an ingredient has already been established to have a certain function and is safe for human consumption, it should not have to undergo testing each time a company wants to register it. A more practical solution would be to adopt a structure/function claim system based on a list of approved ingredients and their known functions according to scientific evidence.

Third, the above system of testing for a functional claim requires testing be done on animals. The practice of testing dietary supplements on animals is not practiced in the

U.S. or EU. It is unnecessary as dietary supplements have been well researched and studied over the years.

This year it was reported that CFDA is in the process of ending animal testing for the cosmetic industry and we highly commend this decision. We urge the State Council to follow up by stopping the unnecessary testing of dietary supplements on animals.

Potency Levels

CFDA has potency-level restrictions that do not always coincide with current dietary supplement research. For example, the latest research indicates that pregnant women should supplement their daily diets with the following substances to meet their increased nutritional needs: calcium (Ca) 1300mg, iron (Fe) 25mg and folic acid (acidum folicum) 600mcg. This research is also reflected in the Daily Reference Intakes (DRI) for nutrients established by National Academy of Science's Institute of Medicine, which is a U.S. non-profit organization that advises policy makers and industry leaders on matters of improving public health. CFDA's *Regulations for Application and Evaluation of Nutritional Supplements* subsection IV states, "Supplements should be reduced by 1/3 to 2/3 of the recommended dosage for pregnant women." Per CFDA regulations on daily intakes, calcium would be reduced by 50 percent, iron by 48 percent and folic acid by 44 percent.

With potency limitations in place, there is no room for the industry to adjust potencies to match current research. Furthermore, using the previous example, calcium, iron and folic acid taken below the recommended levels will not be effective at supporting optimal health for pregnant women and their unborn child. In addition, limitations become a trade barrier to U.S. companies that have time-tested, scientifically based products that have been used for decades, but are not allowed to enter China due to potency issues.

Conclusion

China's dietary supplement industry has great potential and a growing number of consumers are interested in purchasing products that will enhance their overall health. Regulatory reform will expand China's dietary supplement market benefiting both domestic and foreign enterprises and will allow China to surpass the EU, Japan and the U.S. to become the largest market for dietary supplements in the world. Free and open access to dietary supplements benefits the government, the industry and most importantly consumer's health. Furthermore, supporting industry expansion will create jobs, generate more tax revenue as well as support existing Chinese industries such as retail, shipping, distribution and research / development, etc. The below listed recommendations are for the Legislative Office of the State Council's consideration as a foundation to bring China's dietary supplement industry to the forefront.

Furthermore, the Ministry of Commerce (MOFCOM) has been working to encourage domestic spending. The dietary supplement industry falls into the category of consumer goods and would certainly contribute to MOFCOM's goal. Dietary supplements are one of

those items that Chinese typically purchase in abundance when traveling overseas. When this happens, China loses RMB and in country retailers lose sales. The association feels adopting the term dietary supplement and moving toward a system of notification based on approved ingredients, will not only improve the health of China's citizens, it will also assist MOFCOM in their pursuit of increasing domestic spending and keeping RMB spent in China.

Recommendations

- Replace the term health food product with the term dietary supplement. This will help to consolidate the industry and dispel confusion about what these products are and what they do.
- Replace CFDA's product registration process with a notification system. Notification would eliminate the need for re-registration and free up CFDA personnel and resources to enforce market surveillance, which would enhance consumer protection. Removing the added expense of registering products will also reduce costs to consumers.
- Dietary supplement approvals should be based on ingredients not products. Product approvals are responsible for redundant testing of products made with similar ingredients that are already known to be safe for human consumption and have been used internationally for years. In fact, many of these ingredients have already been approved by China's Ministry of Health as new resource foods.
- Adopt a function/structure claim system that allows for a broad range of statements to be made about dietary supplement ingredient's functions based on scientific evidence. No medical treatment or disease claims should be allowed. The current 27 claims allowed are more similar to drug claims and should be abandoned.
- Stop testing dietary supplement products on animals. This is redundant and unnecessary. Dietary supplements have decades of research available to satisfy risk assessment.
- Increase the transparency of the approval process. Currently, the documents necessary and costs involved are not clearly defined. Companies are left to pay exorbitant fees to registration agents without clear understanding of the actual fees involved.
- Overhaul dietary supplement ingredient potency restrictions, or at a minimum alter the restrictions so they are utilized as recommendations that serve as guidelines. We

urge that the recommendations be made more flexible to coincide with the latest in nutritional science recommendations.

- CFDA should allow all ingredients that are already approved of as new resource food by MOH to be used in dietary supplement delivery forms such as capsules, tablets, soft-gel capsules, chewable tablets, effervescent tablets, two piece capsules, liquids and powders. For example, fish oil is approved as a food by MOH and can be added to food products. However, if it is placed in a dietary supplement delivery form, it is not allowed without a CFDA “blue hat” registration. This does not make sense since MOH already approved fish oil as safe for human consumption.

Another example is chewable milk tablets, which are popular in China and sold nationwide as food. But they are in a tablet form, shouldn't they require a “blue hat” registration according to CFDA regulations? This confuses all involved including, government, industry and consumers.

Comments on Article 56 of the Revised Draft of the Food Safety Law

What constitutes a new ingredient or new to the market under the proposed new food safety regulations?

This is unclear especially since for the last ten years or so thousands of dietary supplements have been imported legally into China from all over the world under general food importation regulations controlled by the Administration of Quality Supervision Inspection and Quarantine (AQSIQ). So literally hundreds of dietary supplement ingredients have already been in China's market and consumed by its citizens. How could these be classified as new?

Also is this based on new products or new ingredients? If there is a finished product already legally in China by one company, can another company enter a product with the same formula or would this be considered a “new” product to the market? If the ingredients and formula are the same, how could that be justified as new?

This is why the association suggests going with an ingredient approval process similar to the U.S. FDA as well as what MOH already uses for new resource foods. Once the ingredient is accepted by MOH, then it is available for all companies to use in their finished products.

Because many dietary supplement products have already been selling in China as food, the association would suggest reviewing these products and ingredients and begin to build a list of these ingredients similar to what the U.S. FDA did back in 1994. What they did was state the following: “The Dietary Supplement Health and Education Act (DSHEA) requires that a manufacturer or distributor notify FDA 75 days in advance if it intends to market a dietary supplement in the U.S. that contains a "new dietary ingredient." The manufacturer (and distributor) 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” then there is no notification necessary. “The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994”.¹⁰ U.S. FDA accepted all the ingredients that were already present in the market prior to October 15, 1994.

CFDA could do the same beginning with all ingredients that are proven to be in the market and sold legally as of January 1, 2014. Any ingredients not on this finalized list and attempting to be marketed in China after January 1, 2014 would first have to be submitted to CFDA for evaluation and risk assessment.

¹⁰ <http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm109764.htm>