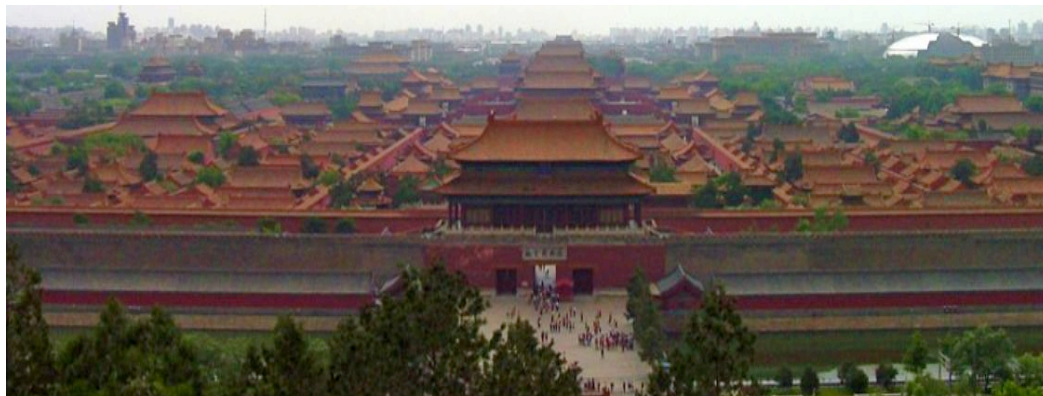


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TSI Group Launches Website in China

Joe Zhou, TSI Group Ltd. co-founding partner and CEO, based in Shanghai, China, has announced the company has launched its TSI China website at www.TSIChina.com.

The website, presented in the Chinese Simplified Han language, highlights how TSI China is strategically positioned to serve customers looking to purchase their proprietary Pureflex® family of pharmaceutical and supplement grade glucosamine and chondroitin ingredients, GlucosaGreen™ line of vegan glucosamine ingredients, Ostivone® ipriflavone bone health ingredient, Ginkgo 24/6/5™ line of ginkgo biloba ingredients, Opteava™ line of green tea ingredients as well as Promilin®, a bioactive complex of amino acids, and other ingredients manufactured by TSI facilities in China

As part of their expanded business strategy, TSI China will also be the exclusive distributor for Cargill's Regenasure® non-shellfish glucosamine and Metabolic Technology, Inc.'s HMB Calcium in the China market. TSI China services also include partnering with companies seeking assistance in registering and selling their functional ingredients into the China market, or for companies

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looking to partner with distributors for their products in China or for companies looking to locate a reliable Asian manufacturing partner to produce products for brands entering the emerging Chinese market.

“TSI China offers a state-of-the-art quality and analytical quality control infrastructure, as well as strategic sourcing, three ingredient manufacturing facilities and several finished dose manufacturing facilities under their services umbrella. We provide a well-established manufacturing base offering customers immediate access to a reliable partner for total supply chain management,” stated Zhou.

“We have invested heavily in the development of innovative products and established strategic collaborations that will develop market changing products for our global customers,” added Zhou.

According to Zhou, the future of dietary supplement manufacturing in China is very optimistic for the several reasons.

“China has become one of the major supplement markets in the world and many of the foremost global brands are here, having brought quality culture with them,” Zhou said. “These well-established companies will increase Chinese manufacturers’ understanding of quality aspects of supplement manufacturing,” notes Zhou.

TSI Group Ltd. is a Hong Kong registered global researcher, developer and manufacturer of ingredients and finished products with offices in the U.S., EU, Australia, Japan, and China. The North American division (www.TSIInc.com), under the direction of Larry Kolb, is based in Missoula, MT.

TSI Pharmaceuticals of Australia, a manufacturer of finished dose products for Australia and Southeast Asia, was acquired during the 2012 TSI rebranding and expansion program.

TSI Pharmaceuticals supplies and packages an extensive range of non-scheduled, complementary, listed and registered products in a range of formats from uncoated or coated tablets to softgels and hard two-piece gelatin and vegetarian capsules of all sizes. (Source: Baker Dillion Group)

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China’s Organic Food Must Build Trust

Until recently, Chen Tao worked at Alibaba, a Chinese Internet Company, as an in-house censor deleting inappropriate postings. Now, he drives six hours every weekend from his home in Chengdu, the capital of Sichuan province, up into the mountains to the north of the city to purchase wild mushrooms, free range eggs and organic honey.

Chen founded Nanxiachun Ecological Farming in 2011 with his friend Liu Zhihong to sell organic countryside produce via direct home delivery to a few hundred families in Chengdu. Liu started this business out of concern for food safety for his child. He is bankrolling Nanxiachun with the profits from his successful cosmetics business. Chen and Liu have already spent one million RMB (about US\$160,000) on their business and have yet to see any returns, but the two entrepreneurs are undeterred.

Nanxiachun is just one of hundreds of entities around China entering the organic farming business. Organizations like Share the Harvest and Little Donkey in Beijing, and Tony’s Farm in Shanghai run urban farms and farmer’s markets, while experimenting with community supported agriculture (CSA) cooperatives and buying clubs through selling produce online and over social networks. Some initiatives, like the Beijing Organic Farmer’s Market, have seen tremendous growth meeting the demand for safe food from China’s middle class. The fair began in 2010 as an art project, and now boasts more than 60,000 followers on Sina Weibo and grosses 10,000RMB weekly for farmer-producers.

These urban farmers represent the latest development in a back to the land movement that arose in the 1990’ s outside China’s most developed cities. Back then, urban nostalgia for country living gave rise to rural bed and breakfast hotels and restaurants known as nongjiale (happy farmhouses), and the model proved very successful in raising rural incomes.

The model reached a peak in 2006, marked by a visit from Hu Jintao, then China’s president, to the “original” nongjiale outside Chengdu and the announcement of the slogan to promote a “New Socialist Countryside,” incorporating “multi-functional” and “ecological” agricultural methods to increase productivity and establish clear standards for green and “hazard-free” food.



But local governments used rural tourism and ecological farming as an excuse to remove farmers from their lands and sell land use rights to developers, while massive conglomerates like the Wanda Group and COFCO snapped up land from peasants with small plots.

In the past few years, the problems of food safety and pollution in China have become more acute than ever. Now, the city folk are taking the idea of organic farming more seriously; Chen is a perfect example. But Chen faces major hurdles, such as guaranteeing the organic pedigree of his produce.

Fortunately, there is a growing number of Chinese experts who can help entrepreneurs like Chen, as the idea of organic production catches on. Shi Yan, director of Beijing-based Share the Harvest and the chief operator of the Little Donkey Farm, has a Ph.D. from Renmin University in agricultural ecology. She has authored several studies on organic agriculture in China and also spent time in America studying the concept of CSA. “CSA is the starting point for a rural renaissance,” said Shi, “New agricultural methods and new farmers – young people willing to stay in villages and work there – will create a new village model.”

Steffanie Scott, associate professor in the environmental management at the University of Waterloo, has studied organic agriculture in China since 2010. According to Scott, the Chinese CSA model differs greatly from its original concept in North America, in part due to extreme lack of trust between urban consumers and rural producers.

“In the West, the CSA illustrates an alternative economic model in which a producer’s costs, including the costs of environmental stewardship and economic risk, are divided fairly among consumers,” wrote Scott in a summary of her research findings. “Most Chinese CSAs operate more closely to a dominant market approach, with producers as entrepreneurs taking the risk, consumers dictating choices, and the use of market-based price setting.”

Establishing this trust can be the key to success. Little Donkey Farm, one of the first CSA cooperatives in the nation, grew from less than 50 members in 2009 to about 1000 today – growth Ms. Shi attributes to strong relationships built up between the farm and urban consumers, rather than government support and certification.

Chen now spends much of his time in rural Pingwu county dealing with his suppliers. The farmers tell him that organic farming costs too much time and money.

Some try to disguise defective eggs by placing Nanxiachun’s company logo over cracks and others buy up cheaper mushrooms and try to pass them off as organic. Chen also mediates between the Nature Conservancy, an environmental group working in a nearby national park, and the farmers, who complain that protecting the park’s wild pigs is costing them money in destroyed crops.

In addition, obtaining organic certification in China is an arduous, expensive process and often marred by corruption. Supply can be unreliable and many organic farms suffer from cash flow problems.

The International Federation of Organic Agriculture Movements estimates China’s organic market to be worth more than \$1 billion, but it makes up 1% of the overall foodstuffs market. The American organic industry, in contrast, is worth more than \$30 billion and commands 10% of the overall market.

For private venture capitalists and foreign producers, this represents great growth potential, but the concerned Chinese entrepreneurs may have loftier goals in mind as well. “If only city folk and farmers can work together and learn to trust each other,” said Liu on the long drive back to Chengdu, “then we can make money, protect the environment, maybe even save China.” (*Source: www.tealeafnation.com*)

China to Limit Aluminum Levels

China is considering further limiting the use of aluminum-containing food additives to lower the health hazards posed by high aluminum exposure.

The Ministry of Health on Friday publicized a draft amendment to the nation's food additive standards to solicit public opinions.

Under the standards, aluminum-containing additives are prohibited from being used in puffing food, as a risk evaluation shows Chinese children aged between 7 to 14 consume too much aluminum through such foodstuffs.

Moreover, swelling agents made of aluminum potassium sulfate or aluminum ammonium sulfate cannot be used in fermented flour products.

Chen Junshi, a researcher with the National Expert Committee for Food Safety Risk Assessment, said last year that 32.5 percent of Chinese consumed an amount of aluminum that exceeded safe levels.

Aluminum-containing additives are believed to be the major cause of the problem, as many Chinese staple foods, such as noodles and steamed buns, are made with additives that contain aluminum.

High aluminum intake is believed to be harmful to the central nervous system. It is known to have an effect on the development of children's nervous systems, which can affect their mental development. (*Source: Xinhua News*)

China: New Government Appointments

The State Council, or China's cabinet, on Saturday announced a number of appointments and removals of government officials.

Wang Yongqing, Shu Xiaoqin and Wang Zhongwei were appointed deputy secretary-generals of the State Council, with Shu also serving as director of the State Bureau for Letters and Calls. Meanwhile, Wang Zhongwei was removed from his post as vice minister of culture.

He Jianzhong was appointed vice minister of transport. Xu Zuyuan no longer holds the position.

Xiang Zhaolun was removed from his post as deputy secretary-general of the State Council and appointed vice minister of culture, replacing Wang Zhongwei.

Wang Guoqiang, Ma Xiaowei, Chen Xiaohong, Wang Pei'an, Liu Qian, Yin Li, Cui Li and Xu Ke were appointed deputy directors of the newly created National Health and Family Planning Commission.

Ma Zhengqi was appointed deputy director of the State Administration for Industry and Commerce. Wang Dongfeng and Teng Jiakai were both removed from the position.



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Nie Chenxi, Tian Jin, Wu Shulin, Yan Xiaohong, Sun Shoushan, Li Wei and Tong Gang were appointed deputy directors of the newly created State General Administration of Press, Publication, Radio, Film and Television.

Yin Li, Liu Peizhi, Wang Mingzhu and Teng Jiakai were appointed deputy directors of the China Food and Drug Administration.

Shi Yubo, Liu Qi, Wang Yumin, Zhang Yuqing and Xu Yongsheng were appointed deputy directors of the National Energy Administration.

Chen Lanhua, Fu Xuanyi and Zhu Wangyu were appointed deputy heads of the State Railway Administration.

Chen Xu was appointed permanent representative of China to the Organization for the Prohibition of Chemical Weapons (OPCW), replacing Zhang Jun.

The State Council also removed Qian Xiaoqian from his positions as deputy head of the State Council Information Office and deputy head of the State Internet Information (*Source: China Daily*)

Hutchison and Nestle to Develop Herbal Medicine

Hutchison Whampoa's pharmaceutical unit has joined forces with Swiss food giant Nestle to develop a new drug, which they said had the potential to be the first Chinese herbal-ingredient-based drug candidate to conduct a large-scale clinical trial for registration in a major disease area.

London's Alternative Investment Market-listed Hutchison China Meditech (Chi-Med), 70.4 per cent owned by Hutchison Whampoa, formed an equally owned joint venture in November last year with Nestle's wholly owned Nestle Health Science to develop nutritional and medicinal products derived from botanical plants.

Last week, the venture said the first patient had been enrolled to begin treatment in a phase-three clinical trial for a botanical-ingredient-based oral drug aimed at treating patients with moderate ulcerative colitis, a disease of the large intestine. The trial is expected to take 24 months.

Chi-Med chief executive Christian Hogg said the firm had spent 13 years identifying 15,000 "molecular level" substances by breaking down some 1,300 herbs, and come up with a "library" of data. The substances are being screened for medical efficacy.

"Back in the early 2000s, there was a lot of talk in Asia about bringing traditional Chinese medicine to the world, but it has taken this long to do it in a scientific and methodical manner," Hogg said. "It is only now that all this effort is reaching the final stages of registration trial."

Chi-Med started discovery work in 2003 and won approval from the United States Food and Drug Administration in 2005 to go into clinical trial for the oral drug, Hogg said last week.

He would not disclose the amount of money spent so far but said the drug's efficacy and safety had been demonstrated in more than 400 patients. He also declined to divulge the budget for the stage-three trial, which will enrol more than 2,500 patients, mainly in the US and Europe.

However, he said some health-care sector analysts had estimated the drug's total development cost to be in the hundreds of millions of US dollars.

Hogg expected Chi-Med's operating cash flows to be sufficient to fund the project, and the firm has no equity or bond fund-raising plans. He said the amount of cash injected into the joint venture depended on milestones achieved in the clinical trial.

Chi-Med had US\$86 million of cash at the end of last year and generated US\$15.7 million of cash from operating activities last year. Its drug manufacturing business on the mainland last year posted a net profit of US\$15.5 million, which was mostly offset by an underlying net loss of US\$8.7 million on drug research and development and a US\$3.6 million net loss on health product retailing in Europe.

Although Nestle Health Science was set up just over two years ago to venture into medicinal product development for chronic diseases, its chief executive, Luis Cantarell, said it could leverage Nestle's huge resources in developing nutritional products.

Chi-Med has partnered with European pharmaceutical firm AstraZeneca to develop oncology drugs, and with US-based Janssen Pharmaceuticals to work on immunology drugs. *(Source: South China Morning Post)*

New Recipe for Food Safety

Baby formula products with Hero Nutraderense labels were taken off store shelves in many cities on the Chinese mainland and removed from major online shopping websites immediately after a television report exposed the brand's safety issues on March 28.

National broadcaster CCTV reported that Import and Export Co., an authorized dealer of major Swiss baby formula maker Hero Group, allegedly mixed expired milk powder into Nutraderense products, changed production and expiration dates and repackaged them.



The latest baby formula scare again highlights the loopholes in China's food safety regulatory system while dealing another blow to consumers' confidence in the country's dairy products.

Xile Li'er is suspected of smuggling baby formula powder made only for the European market by Hero Group and repackaging it as Nutraderense baby formula, for which the company had a legal import certificate, the Administrative Committee of the Suzhou Industrial Park in east China's Jiangsu Province, where the company is located, said at a press conference on March 28.

According to the committee, of the 17 batches of baby formula products with the Nutraderense label that had been tested by food safety authorities, at least seven failed to meet protein standards.

The quality supervision authorities in Suzhou closed down Xile Li'er's production line in November 2012, as the company did not have a license for food production, the CCTV report said. Despite the closure, the company's milk powder products were still on sale in many cities on the Chinese mainland until the end of March. Many consumers were enraged about the time gap, leading many to question the state of the food safety regulatory system.

China's food industry has already been tainted in recent years by a number of scandals, including pesticide-tainted vegetables, pork contaminated with clenbuterol or chemically reconstituted to resemble beef, and oil scooped up from the gutters and resold to eateries.

The worst scandal occurred in 2008 when the melamine-tainted baby formula caused at least six infant deaths and sickened 300,000 others.

The founding of the China Food and Drug Administration (CFDA) during the latest cabinet restructuring in March is widely seen as a broader government effort to recover the crippling damage dealt to consumer confidence in China's food safety by fixing the weak links of the regulatory system.

The CFDA, which started operations on March 22, is a ministerial-level agency that has integrated regulatory functions of the State Council's Food Safety Office, the State Food and Drug Administration (SFDA) as well as food-related regulatory duties from the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the State Administration for Industry and Commerce (SAIC).



People have long blamed insufficient communication and coordination among different government departments with duties on food safety for regulatory loopholes and the buckpassing among them in the wake of scandals. Prior to the restructuring, the SFDA was in charge of food safety in the catering industry, whereas the responsibilities of food safety regulation in the manufacturing process and market were assumed by the AQSIQ and the SAIC, respectively.

The new regulator, however, will be responsible for supervising the full process of food's production, circulation and consumption.

According to the CFDA's organizational structure issued on March 31, the new watchdog's function of supervising food safety has been intensified compared with its predecessors.

Out of the 17 departments directly under the new regulator, three departments are put in charge of food safety regulation. They respectively undertake the responsibilities of analyzing food safety risks during the production and distribution procedures and making suggestions about reducing these risks, supervising local governments to discover and correct the practices that may jeopardize food safety, as well as analyzing statistics on food safety, issuing warnings, organizing cross-department information sharing and formulating risk-monitoring plans.

Meanwhile, the CFDA will appoint a chief food safety supervisor.

Wang Yukai, a professor at the Chinese Academy of Governance, said that as food safety regulation requires expertise in certain fields, candidates for this position must have strong academic backgrounds as well as rich management experience.

The CFDA also has also set up 10 positions for food and drug inspectors, who will be charged with the task of supervising local law enforcement on food safety.

New departments of the CFDA also include the Department of Media and Communication, the Department of Legal Affairs and the Policy Studies Office, whose duties used to be fulfilled by the Department of Policies and Regulations in the SFDA.

Local governments should take the overall responsibility for food safety of local residents, according to the State Council's restructuring plan.

The State Council issued a plan to streamline the national food safety regulatory system during the 12th Five-Year Plan period (2011-15) last July, which demands that local food safety regulators at provincial, city and county levels be equipped with standardized facilities by the end of 2015. It also emphasizes the responsibility of governments at county level and above for local food safety regulation.

Zheng Fengtian, Vice Dean of the School of Agricultural Economics and Rural Development at the Beijing-based Renmin University of China, told Economic Information Daily that local governments might ignore certain food safety risks to protect enterprises in the areas under their respective jurisdiction. For example, in a county whose economy heavily relies on its agricultural sector, government officials tend to intentionally overlook unsafe production procedures in local farm produce processing companies as most products are sold out of the county.

Pilot Reforms

Since the beginning of 2010, the Chinese Government has launched three different pilot programs aimed at reforming local food safety regulatory systems in southern Guangdong Province, northwestern Shaanxi Province and northern Tianjin Municipality.

In Shenzhen and Shunde in Guangdong, the food safety authority is put under the market supervision bureau and charged with the tasks of drafting local regulations and supervising food production, circulation, catering industry and quality of edible farm produce.

In another reform in Shaanxi's Weinan City, all functions concerning food safety under government departments of agriculture, animal husbandry, quality supervision, industry and commerce administration and health have been transferred to the local food and drug bureau, which is in charge of issues involving administrative licensing, law enforcement and technical tests.

The reform in Binhai New Area in Tianjin is widely seen as the direct inspiration for the reform on food safety regulatory system at the national level. Inside sources told Economic Information Daily that the reform in Shenzhen and Shunde was deemed too timid while Weinan's model was deemed too drastic.

Zhang Tiejun, Director of Binhai's Food and Drug Bureau, said that during the reform, the regulation of catering businesses, nutritional additives, cosmetics and hygienic conditions of public venues previously under health authorities, the regulation of food production previously under quality supervision authorities and the regulation of food circulation previously under the industry and commerce administration authorities, have all been transferred to his agency.

Another component of the reform is the establishment of a food product- and drugtracing system, which is used to monitor the procedures of the supply of raw materials, processing, circulation and end consumption.

Under Binhai's model, an extensive network of food and drug regulation covering all villages and urban communities has been established. Zhang said that all 27 townships and sub-districts in Binhai have a food and drug regulatory station, which employs full-time coordinators. He added that all the 351 villages and communities have a liaison office for food and drug safety issues, along with a part-time information officer. Supervisors from Zhang's bureau are stationed in every township and sub-district to ensure laws are enforced at the basic level.

While Binhai's model has proved effective during the pilot program, copying it in other places of China faces some challenges, ranging from a large number of food and drug safety personnel required, to the huge amount of money needed to set up a food-tracing system and the difficulties of monitoring food safety in the vast rural areas, according to Economic Information Daily. (Source: www.Beijingreview.com)



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21 CFR 111 Dietary Supplement GMP Overview

About this Course

These guidelines are intended to be applicable to dietary supplements as defined and covered by the United States Food and Drug Administration's Code of Federal Regulations Title 21, Part 111 [Current Good Manufacturing Practices in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements] also known as 21 CFR Part 111, but may also be applied to dietary ingredients and other components. This course provides an in-depth review of the guidelines and provides case-studies involving the review of recent Warning Letters initiated to Dietary Supplement companies for non-compliance to 21 CFR 111 GMPs.

This course is geared to those individuals involved in the dietary supplement industry including those from the following areas:

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WILD Unveils TCM Medicinal Blends

WILD Flavors GmbH (WILD) is excited to present their newest innovative product line based on ancient herbology principles of Traditional Chinese Medicine (TCM). By partnering with experts in Beijing, China, along with Subhuti Dharmananda, PhD (Institute for Traditional Medicine; ITM), WILD has successfully created three different TCM-inspired herbal blends based on Detoxification, Immunity and Blood Glucose Management.

Each blend contains ingredients specially identified as supporting TCM principles for the associated platforms. In addition, WILD has conducted sensory testing to optimize product taste.

The Blood Glucose Management Blend has been clinically tested to show a significant decrease ($p < 0.01$) in blood glucose compared to a placebo According to Dr. Dharmananda, “the four ingredients have been subjects of intensive investigation into their effects on blood sugar and are combined in accordance with the TCM principles of ‘tonifying qi and nourishing yin’ to normalize the distribution of sugars, reducing their contribution to thick, sweet blood and driving them into healthy metabolic use.”

“Using proprietary natural flavors and Resolver™ technology, we are able to supply an efficacious blend of Chinese herbs that can be used in many supplement applications,” adds Heather Biehl, WILD Associate Director, Health Ingredient Technology and Solutions® (H.I.T.S.). The TCM herbal blends can be successfully used in a variety of applications including teas, carbonated drinks, juices, dry beverage mixes, tablets, chews, gummies, nutritional bars, and gels.

WILD's TCM Blends address consumers' growing interest in holistic health and healing. Recent trends show consumer focus towards a healthier lifestyle, and WILD's TCM line allows for the capability to capture profits of the ever-growing U.S. natural and functional market. *(Source: www.wildflavors.com)*

If you have China related news that you would like to share with the association for publication in its newsletter please contact us at:

news@uschinahpa.org

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