HPA Health Products Association

# CHINA UPDATES

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## THIS ISSUE

**Dietary Supplement Webinar**

**Dietary Supplement Analysis**

**Unsafe Gel Capsules**

**Vitamin C Down in 2011**

**Growing Export of Herbs**

**SFDA Cautions Students**

**Re-registration of Health Foods**

**SFDA: Non-special Use Cosmetics**

**SFDA: Guidance on Fast Testing Methods**

China Updates is a service provided by U.S.-China Health Products Association. The Newsletters will be issued as relevant material becomes available. China Updates will provide news on regulatory environment, new legislation, association activities and any information related to the natural health products industry in China.

## USCHPA Collaborates with U.S. DOC on Industry Webinar

The U.S. Department of Commerce is hosting a webinar entitled, "Selling Dietary Supplements in China" together with USCHPA and Euromonitor on June 12, 2012. China's dietary supplement industry continues to grow and evolve at neck break speed. It is estimated that China will surpass the U.S. within the next few years to become the largest market for finished dietary supplements. Although the market is growing fast, it is riddled with inconsistencies and problematic entry regulations.

If you are interested in doing business or are already engaged in China this webinar is vital to attend. For more information on the webinar and how to sign up, please visit USCHPA's website: www.uschinahpa.org. *(Source: USCHPA)*

## China to increase supervision over health food producers

BEIJING -- China will launch a campaign to check health food producers over food safety concerns, the State Food and Drug Administration (SFDA) said Wednesday on its website.

The SFDA said in the statement that the campaign, which will run from the end of May to the end of September, will check whether health foods meet the country's food safety criteria, especially those criteria on some heavy metals.

The statement said the major targets of the campaign include health foods meant to help consumers lose weight, lower their blood sugar levels, ease fatigue and improve sleep, among others, as these products are prone to include illegal chemical additives.

Manufacturers will be ordered to either rectify their improper actions and improve in a fixed time or lose their production licenses.

Health foods made from spirulina, bee propolis, pearl powder and fish oil, those sold in capsule form and products with exaggerated and fraudulent advertisements are also among the major targets.

The SFDA urged local authorities to build and perfect an archival system to supervise health food producers, and it also urged health food producers to improve their quality control system. *(Source: SFDA)*




## Analysis of China's Dietary Supplement Market

It was reported by China Industrial Research Net that the most popular health product in China is calcium, followed by protein powder, and vitamins rank the third. The demand of vitamins increased by ten percent annually in China's major cities.

The retail sales of vitamins from Shanghai, Guangzhou, Shenzhen, and Nanjing increased over twenty percent last year. According to the analysis, the China vitamin market trends are as follows: #1. Natural ingredients are more welcomed. #2. Compound vitamins are more popular than single vitamin. #3. Segment market will take more market share, for example, vitamins especially for people over 50 and for kids are easier to meet the market demand. #4. Well-known brands such as Pfizer-Wyeth and Hainan Yangshengtang are more accepted. Increasing raw material prices, international inflation, and higher labor costs are causing product's to become less competitive on pricing. Eighty percent of the market is taken by twenty percent of brands, among which foreign brands take up the majority.

Over thirty percent of China's population (400 million) are lacking in Vitamin C. The potential market is huge, but challenging to develop. Unlike U.S. consumers, Chinese are more likely to take dietary supplements designated as OTC from hospitals and pharmacies. This is mostly due to doctor suggestion as well as some insurance reimbursement. Chinese take dietary supplements mostly when they feel sick. However, rising medical costs and an increasing interest in supplements as part of a healthy lifestyle is helping to shift consumers towards other than OTC products. The entire dietary supplement market in China truly has a bright future. *(Source: China Industrial Research Net)*

## 254 Enterprises Producing Unsafe Gel Capsules

China's food and drug watchdog announced on Friday that 254 pharmaceutical enterprises, or 12.7 percent of all capsule makers in the country, were found to be producing unsafe drug capsules during a month-long inspection program that ended on Thursday. Of the 11,561 batches of drugs tested, 5.8 percent were found to contain excessive levels of chromium, according to the State Food and Drug Administration (SFDA), which began the checks after a media expose of companies producing such capsules. The agency ordered substandard drugs to be immediately taken off shelves, sealed, recalled and destroyed.

Meanwhile, every batch of capsules produced by problematic companies was checked one by one, the SFDA said in a statement. In April, reports implicated several Chinese pharmaceutical firms in the production of capsules made from industrial gelatin derived from scraps of leather material, which contains a greater amount of chromium than edible gelatin. Chromium can be toxic and carcinogenic if ingested in large amounts. A regulation on the production of edible gelatin issued by the Ministry of Health in 2005 explicitly banned the use of leather scraps in edible gelatin manufacturing.

The SFDA has urged local authorities to investigate and "severely punish" problematic pharmaceutical makers them in line with laws and regulations. Those suspected of crimes should be referred to the police, it said.

The statement added that local authorities have investigated 236 capsule makers, ordering 42 of them to halt production, closing down 84 production lines, revoking seven companies' capsule production licenses and referring 13 to police. *(Source: Xinhua News Agency)*


## Price of Vitamin C Down in 2011

According to Chinese Customs, China exported 176,400 tons of vitamins in 2011, 9.7 percent decline compared with the last year, with export value of 1.823 billion USD, 20.87 percent drop. This drop was mainly due to the price of Vitamin C.

Vitamin C took up 61.45 percent of China's whole vitamin export last year, which had a huge influence on these drops. In 2011, China exported 108,400 tons of Vitamin C a 5.45 percent decrease, which dropped its overall export value by 29.63 percent (561 million USD). Its unit price stood at 5.18 USD/kg last year falling by 25.57 percent.

According to the National Development and Reform Commission of China, the market size of vitamin C in China was about 20,000 tons in 2009, 120,000 tons for the whole world. However at the same time, China's Vitamin C producing capability reached 136,000 tons, and another 80,000 tons of Vitamin C was in plan of production. Production capacity surplus and price war among the enterprises led to the price drop. However, the export price of Vitamin E in 2011 stayed nearly the same as the year before. Meanwhile, the price of Vitamin B6 and B1 climbed up by 42.37 percent and 31.95 percent respectively, though they were in small quantity.

In 2011, the top ten export destinations of China's vitamins were U.S., Germany, Japan, Netherlands, Belgium, India, Thailand, Korea, Brazil, and Singapore. But the exports to these countries all suffered some decline, except Japan, Belgium, and Thailand. Export to India, Singapore, and Netherlands dropped over 20 percent in 2011.

China exported Vitamin products to 136 countries/regions last year, while US, EU and Asia were still its major exporting markets, which took up 91.35 percent of the whole export.

In 2011, 592 companies were involved in vitamin export, 235 companies less than that in 2010. Among the exporting companies, 122 of them were state owned enterprises, while 402 of them were private companies, which took up 67.9 percent of the exporting companies.

The top ten vitamin export companies in 2011 were as follows. Zhejiang Medicine, Zhejiang NHU Co., Ltd , CSPC Pharma, North China Pharmaceutical Group Co., Northeast China Pharmaceutical Group Co., Aland (Jiangsu) Nutraceutical Co., Ltd., Shandong Luwei Pharmaceutical Co., Ltd., Southwest Synthetic Pharmaceutical Co.Ltd.. Jiangxi Tianxin Pharmaceutical, and Zhejiang Hangzhou Xinfu Pharmaceutical Co.,Ltd. *(Source: China Chamber of Commerce for Import & Export of Medicines& Health Products)*

## One Billion USD: Growing Export of Herbal Ingredients

China's 12th Five-Year Plan set to increase the export of herbal ingredients. China is now seeing the fruits of this endeavor.

In 2011, China's herb extract exported 1.13 billion USD, 47 percent increase year on year. It was the first category that surpassed one billion USD value among the export of Traditional Chinese Medicine related products. The export volume reached 42,000 tons, grew by 14.9 percent over the last year. The price of herb ingredients was up by 28.2 percent, with an average price of 26.8 USD/kg.

In 2011, the import value accounted for 220 million USD, an impressive growth of 67.8 percent year on year; while the import volume reached 18,000 ton, 59.4 percent increase y/y. The most popular imported ingredients in 2011 were essential oils such as pennyroyal and domestic ingredients in short supply such as licorice extract. Both ingredients imports increased over 100 percent in 2011.

Except Latin America, all other overseas markets witnessed a good growth in demand of China's ingredients. Asia, Europe, and North America were the top three destinations of China's ingredients, which made up 82.6 percent of the whole export business.

**ASIA-** China's export volume of ingredients to Asia was 440 million USD, occupying 39.4 percent of the entire export business, increased by 18.8 percent year on year, Japan and ASEAN were the two main export destinations in Asia. As the second largest market of China's ingredients, Japan imported 170 million USD ingredients last year, which were mainly used as Traditional Chinese Medicine and health products there. The demand has been increasing steadily in recent years.

**ASEAN-** In 2011, China exported 107 million USD worth of ingredients to ASEAN countries a decrease of 6.71 percent year on year. The biggest drop was from Malaysia, 66.5 percent. It was reported that the decline in exports was caused by a drop in stevia imports to the country. Both the top two Chinese stevia exporters to Malaysia suffered 100 percent decrease last year. However, Singapore and India had a good growth in the same year in import of China's ingredients, increasing by 39 percent and 62 percent year on year respectively, accounting for 43.94 million USD and 28.06 million USD respectively. The most popular ingredients were pennyroyal and eucalyptus oil.

**Europe-** China's ingredients export to the European market saw a 63.2 percent increase in 2011 with a value of 290 million USD and a volume of 11,000 tons (15.1 percent increase). Last's years overall pricing increased by 41.8 percent. Main export destination countries in EU were Spain, Germany, France and UK. Spain and Germany ranked the fourth and fifth in China's ingredients export in 2011. Spain mainly imported ingredients for food dye, while Germany for health products, with a growth of 76 percent and 57 percent respectively.

**U.S.-** has been the most important exporting market for China's ingredients, who has been listed as the biggest importer for ingredients for many years. In 2011, China exported 180 million USD of ingredients to the U.S. an increase of 54 percent; while the volume was 8,050 tons an increase of 32 percent year on year. The most popular ingredients exported to the U.S. were licorice, including glycyrrhetate and licorice extract. Only the export of glycyrrhetate alone to the U.S. reached 16.64 million USD last year, up by 36.7 percent. U.S. mainly used the ingredients for the health products, which most Americans take everyday.

There were 1,402 companies exporting ingredients in 2011, an increase over 2010, which was 1,365. Private companies were the major exporters, taking up over 56 percent, while joint-ventures took up 32 percent, and SOEs 11 percent.

Most of China's ingredients witnessed stable growth in 2011. Here are a few examples. Eucalyptus oil (export value of 110 million USD, an increase of 26 percent), Glycyrrhetate (33.14 million USD, 17.5 percent increase), Rutin (29.6 million USD, 87.5 percent increase) Licorice extract (25.33 million USD, 28.3 percent increase).

However, at the beginning of this year, China's Import and Export Inspection and Quarantine Bureau set up a new rule for ingredient export that all the herb ingredients should be inspected as Hazchem and food additive, which will takes a longer time and cost more to finish all the inspection processes. And the export companies should have a QS certification for food manufacturing, which most of the ingredient companies don't have now. At this time, the ingredient manufacturing industry is in a transitional period to catch up with the new regulations. *(Source: China Chamber of Commerce for Import& Export of Medicines& Health Products)*

## SFDA Cautions Students About Fake Health Products

With high school and college entrance examination only days ahead, the State Food and Drug Administration (SFDA), China's food and drug watchdog suggests students to be cautious about fake health products.

Recently, parents of students are eager to engage their children's brain by feeding them health products, which some companies claim could enhance the intelligence of those who eat them.

This kind of eagerness, as said by SFDA has brought potential safety risks to consumers and favorable business opportunities to unscrupulous and in some cases illegal companies.

In the suggestions posted on its website, SFDA said, China has never approved any brain-invigorating health products. Those approved to have functions of improving memory, relieving physical stress, and enhancing immunity, do not have the benefits of enhancing intelligence. Consumers should be weary and cautious about products making exaggerated claims and promising too much.

SFDA also said that the raw materials of some health products are not suitable for students. Consumers should scrutinize the descriptions on the package, as to the suitable population, non-suitable population and the dosage of these products.

Consumers should not buy products that do not have an approved label. If companies or individuals are found producing or dealing illegal dietary supplements, consumers can promptly report them to the local food and drug supervision departments.

Local departments, however, should further strengthen monitoring and supervision of the dietary supplements that claim capable of improving memory, relieving physical stress, and strengthening the immune system, and must severely crack down on illegal activities.

Health products, as is mentioned in the suggestion, cannot replace drugs. Students should visit doctors if they feel sick or uncomfortable.

SFDA said, the best way to prepare for exams is to watch the diet, balance between rest and work, as well as to have a sound sleep and cheerful mind. Nothing can compare self-adjustment and mental relaxation. *(Source: SFDA)*

## SFDA issues Notice on the Re-registration of Health Products

In order to strengthen the registration of health products and tighten their entry threshold, Notice on the registration of health products are thus issued by SFDA evaluation center of health products:

First, when submitting re-registration materials, contents of the introduction materials shall be consistent with the approved certificates. Applicants, who insist on making alteration on the contents of the instruction, shall submit an application according to alteration procedures and relevant provisions of health products.

Second, in the event that applicants voluntarily alter the instruction and contents concerning the safety, quality, function of the products, i.e. Adjusting the suitable population, changing the dose, change the function, supplementary materials or specifications of the products, etc, SFDA has the right to give "no re-registration recommendation".

Third, in the event that applicants voluntarily alter the instruction and contents unrelated to the safety, quality, function of the products, i.e. adding product descriptions in the instructions, changing item names in the instructions, SFDA shall inform applicants to correct them to the original approved certificates and carry on with re-registration work.

Fourth, future evaluation work shall have to conducted in accordance with this Notice as of its issuance date. *(Source: SFDA)*

## SFDA Consults on the Proposal to Classify Non-Special Use Cosmetics

After 2 months of comment receiving, SFDA, China's food and drug watchdog, consult again on the draft measures to classify non-special use cosmetics, May 29th.

The draft measures, as said by experts, have changed how cosmetics shall be categorized in China dramatically and adjusted registration requirements for different types of cosmetics. The draft measures have also harmonized the way by which imported ordinary use cosmetics and domestic ordinary cosmetics are managed in China.

Here are the major changes in the revised draft:

**The definition readjustments for dark spot removal cosmetics**

Dark sport removal refers to cosmetics intended for whitening, dark circle lightening, and anti-acne. Such cosmetics will incorporated into the management system of dark spot removal cosmetics and are subject to administrative license management of special-use cosmetics.

**To strengthen safety risk monitoring of some products**

SFDA decides to conduct a 2-year monitoring of some products whose safety risks needs further confirmation, and determine whether these products will go into the management of special use cosmetics. The products are listed as follows:

- Hair product that claims to effect secretion control of oil on the scalp
- Hair product that claims to remove dandruff
- Product that claims to remove puffy eyelids
- Product that claims relieve body odor
- Product that claims to lighten dark circles
- Product that claims to remove keratin
- Product that claims to tan the skin
- Product used on lips (pigment-free product excluded) or around eyes (eyebrow pencils excluded)

**To strictly control products for special population**

Children (including infants) Cosmetic Application and Evaluation Guide (hereinafter referred to Guide) will be granted to further regulate the application and approval of imported children (including infants) products. While domestic ones should submit record materials according to Guide and be subject to future supervision.

Cosmetics are prohibited from calling themselves intended for special groups of population, such as women during pregnancy or breastfeeding. *(Source: SFDA)*

## SFDA Consults on the Guidance for the Identification of Fast Testing Methods

In order to enhance China's ability to test cosmetics and health food, improve the fast testing method, **Guidance for the identification of fast testing method** (hereinafter referred to as **Guidance**) is thus drafted according to Food safety Law and its implementing rules, and Cosmetics Hygiene Supervision Regulations for public comments. The deadline, as posted on the website of SFDA, China's food and drug watchdog, is June 5th, 2012.

**Identification scope**

Fast testing methods will be applied to the on-site preliminary screening of projects related to health food and cosmetics, which shall be characterized by fast, simple and convenient, sensitive and mobile.

**Identification procedure**

- unit (or individual) submit identification application to National Institutes for food and drug control(NIFDC) directly or at the recommendation of provincial food and drug agency with application materials attached .
- NIFDC will have experts organized to review the fast teting method submitted, and report examination results to SFDA.
- those testing methods approved will be shown on SFDA website for public comments for a whole month.
- NIFDC will collect those comments and send them to application unit (or individual), while applicants shall make further corrections on the testing methods accordingly, and explain the reasons if rejecting the comments.
- Committee of experts shall identify whether the methods are approved. NIFDC take responsibility of informing those disapproved in writing.
- Those approved are listed in fast testing methods for health food and cosmetics. The list and the methods will be published on SFDA website.

**Identification Principles**

- The technical performance of the fast testing methods (such as specificity, accuracy, sensitivity and durability) must comply with the technical requirements stipulated in the Guidance.
- The technical performance of the fast testing methods must meet the requirements of relevant national laws, regulations and standards.
- The submitted materials must be complete, effective and practical.
- The fast testing methods shall meet the relevant regulations concerning environmental protection, safety and hygiene.

**Application materials**

(一) Application materials

- application form of the identification of fast testing methods ( see Annex 1) ;
- drafting , verification and confirmtion of health food and cosmetics fast testing methods;
- the user comments on the product trial use;

- the application method is not violating the undertaking or intellectual property rights of other businesses or individuals;
- undertaking to voluntarily give up the patent granted by the State Food and Drug Administration (USFDA) ;
- other supporting materials. Application materials shall be submitted both in paper and electronic form. Three paper copies are required with seal or stamp on them.

(二) Technical materials

- the scope of application
- standard operating procedures ;
- description of the test results;
- the draft , technical specifications , and evaluation data of the verification results;
- other technical information.

**Verification of the methods**

- Scientif methodology shall be applied to verify the specificity, accuracy, sensitivity and durability of the methods.
- Fast testing methods shall be up to national standards. If there is no national standards, other ways shall be found to have further verification.
- Application units (or individuals) shall choose at least 3 registration and inspection agencies to verify their reported methods, and provide materials related to verification results, as well as evaluation of the results.
- The comments or results of trial use of the methods from supervision departments.

SFDA reserves all the right to explain Guidance . *(Source: SFDA)*

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

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