

CHINA UPDATES

Your Trusted Source for Market Intel on China's Natural Health Product Industry



ISSUE 63
November 13, 2013

**We Know the China Market.
Need Help?**

Click here to connect with an expert on China focused manufacturing, sales, distribution and marketing.



IN THIS ISSUE

New Dietary Supplement Draft Regulations are Flawed

China FDA Update its Regulation on Cosmetics Filing

Guangdong Set Up its First Nutrition and Health Industry Association

TCM Export is expected to Surge

Newest Pollution Concern: 'Ugly' Sperm

New Dietary Supplement Draft Regulations are Flawed



Chewable Milk Tablets

China's Food and Drug Administration (CFDA) has set forth on reforming the dietary supplement industry with promise of releasing new regulations in 2014.

At this point, everything is still in draft form and is being researched, by CFDA and the State Council to see how best to regulate their industry.

Although there are a variety of issues with the current system, I'll just point out one that is very confusing and needs to be addressed before regulators move forward.

China Updates is a service provided by U.S.-China Health Products Association. The Newsletters are issued approximately three times a month. China Updates provides news on regulatory environment, new legislation, association activities and any information related to China's natural health products industry.

China's FDA has stated that "general food" is not allowed to be sold or imported in the form of capsules, tablets, soft-gels or two piece capsules. It must be registered as a health food product with the CFDA. However, there are a variety of products that are approved as food in China by the Ministry of Health (MOH) such as fish oil, DHA Algal Oil, Noni, Phosphatidylserine, Lactobacillus acidophilus, CLA, Milk Minerals, Milk Protein just to name a few.

Here's the problem. In the market you can find Fish Oil added to cooking oil obviously being sold as food, but if a company puts fish oil in one of the dosage forms mentioned above then it needs to go through extensive testing to

ensure safety. This process can take 2-3 years and cost over US\$ 50,000 to obtain CFDA's registration, which is known as a "blue hat" since the registration logo looks similar to a blue hat.

At the same time, we can see chewable milk tablets (pictured above) being sold in the market as food. Wait a minute, I thought food was not supposed to be sold in the form of tablets, capsules, soft-gels or two piece capsules?

This obviously has consumers and industry confused. If something is accepted as food by Ministry of Health that means it has already gone through extensive research to ensure that it is safe for human consumption. Putting it into a tablet or capsule is not going to change the fact that it is food.

As regulators move forward with rolling out new regulations the first step should be to allow any ingredients that are deemed safe for human consumption by MOH to be consumed by mouth in the forms of liquids, powders, tablets, soft-gels, chewable tablets or two-piece capsules. This move would be very helpful to regulators, industry and consumers. *(Source: Jeff Crowther -USCHPA)*

China FDA Updates its Regulation on Cosmetics Filing

To better regulate production approval of cosmetic product and product information filing, CFDA is going to update related regulations as follows:

- 1) From June 1st, 2014, domestic non-special use cosmetics should put product information on record online, based on Domestic Non-special Use Cosmetics Information Filing Regulation. The filed information should be confirmed by provincial FDA and then get released by the official website of CFDA for public reference. Those companies which do not file accordingly will be punished by the FDA based on Cosmetics Hygiene Regulation.
- 2) The cosmetics which claim to contribute to whitening skin or address the skin pigmentation issue are all classified as freckle-removing products. From January 1st, 2015, these products must get approved as special-use cosmetic products before producing. The related products which are produced before that date can be sold till expiration.
- 3) From January 1st, 2014, the provincial FDA which has already set up cosmetic technology accreditation institution and has related staffs to examine the technology can start to file application to the CFDA to take charge of approving imported non-special use cosmetics. After training by CFDA, the provincial



So little. So much.

Powerful Phospholipid EPA & DHA
Excellent User Experience
Smaller Dose, Easy Digestion

 

www.superbakrill.com

FDA can start to take charge of approving imported non-special use cosmetics from June 30, 2014.

According to the Domestic Non-special Use Cosmetic Information Filing Regulation, all companies with non-special use cosmetics produced in P.R.C, are required to file the product information before putting the product into market.

The product information includes the product safety assessment, product technology introduction, producing equipment list, technology requirement and product testing report.

The company with product only for export should file the information to provincial FDA where this product is produced. The information will be checked by the provincial FDA within five working days.

The provincial authority will check the product in three months after the company filed its information. Those which are not up to the national standard will be punished. Products can apply to the authority for revision or update to the filed information.

The product which has got its information filed should refile its information in four years after the first filing.

If the product involves ingredient extracted from animal organ or blood, the filing information should include the origin and quality of the ingredient, as

well as the approval of use from the origin country.

If the product is for children or infant, the formula principle and producing process as well as quality control should be based on Children Cosmetics Application and Approval Guidance.

The product, which has passed the risk assessment based on national risk assessment guidance on cosmetics, can exempt from related toxicology tests.

The update on the domestic non-special use cosmetics is to simplify filing material and promote online filing. It also aims to simplify the accreditation but strengthen the after-file regulation.

The information will be released to the public so as to promote social surveillance. If the product involves original company as well as company that are in charge of actual production, both of these two companies are required to file information for future regulation. At the same time, online database can coordinate all the data so as to avoid repetition.

The update also aims to launch two-track management of risk assessment and toxicology test in efforts to cultivate company's self-managing capability.

The current cosmetics regulation was drafted in the 1990s, when the skin whitening product sold in the



market were mostly to change the skin color by physical covering the spot. But as technology progresses, the above products have faded away from the market.

The skin whitening products sold in the market now are mostly have the same working function with freckle-removing products, but these two kinds of products are regulated as special use product and non-special use product separately. The update is to better regulate the new skin whitening product. (Source: CFDA)

Guangdong Set Up its First Nutrition and Health Industry Association

Guangdong recently set up its first nutrition and health industry association. The Association had the first gathering last week to elect the committee members.

Li Kang, principal of Southern Medical University, was elected as the chairman of the Association, and Zhang Yong, vice chairman of Guangdong Health Association as the secretary general.

This Association was launched by eight local companies that are involved in production and sales of nutrition and health products and was supported by officials of provincial civil affairs bureau, social organization managing bureau, provincial health bureau and provincial FDA.

The Guangdong Nutrition and Health Industry Association will be the first provincial level association to provide professional and market-oriented guidance to companies that involve in health industry in this province. It will also devote to strengthen assistance and service to companies in this field comprehensively.

Experts expect the Association to serve as bridge between government and local companies to boost the development health industry in Guangdong province. (Source: Technology Daily)

TCM Export is Expected to Surge

This year's Canton Fair, the annual China Import and Export Fair held in Guangdong province, saw the TCM export to be growing rapidly, especially in Asian market.

"Our sales grow very fast in Hong Kong and Southeast Asian market, which was a 30%-40% growth," said a director surnamed Hu of a Nanjing-based TCM group, whose major TCM products include ganoderma spore oil and lycopene.

Mr. Hu said many clients from Eastern Europe and America are also very interested in these products and wanted to give them a try. He said the Canton Fair would help them better tap into western market.

In this year's Canton Fair, TCM companies are increasingly aware of brand value. A director surnamed Hu with a Heilongjiang-based TCM companies said they usually exported the company's raw material to Japan and Korea for processing, which help them to at least double the product value. Now they are in the Canton Fair to promote the processed product with their own brand.

Many companies said that it was still very difficult to promote TCM worldwide due to obstacles including trade barrier. "In some western countries, we've had some client base, including in Germany. But it is not in a large number," said a director of Hebei Meisheng Co. Ltd.

"I hope that the government and industry association will be more coordinated. They could promote TCM by all channels and organize local TCM companies to explore into the foreign market together."(Source: Yangcheng Evening News)

Newest Pollution Concern: 'Ugly' Sperm'

The fifty shades of gray hovering above China's cities could be sapping the country's men of their virility.

That's the message from one Chinese newspaper website citing findings from a sperm bank in Shanghai that monitored samples over a decade and found two-thirds were "affected" to various degrees by environmental factors.



Potentially a source of couples' bedroom disputes, the report is one of two this week feeding a frenzy of speculation on the Chinese Internet about how the country's notorious pollution impacts reproductive health. Sperm can grow to be "ugly" and "not able to swim," the head of the sperm bank, Li Zheng, told the Shanghai Morning Post (in Chinese), a newspaper owned by the military-run Liberation Daily.

Smoke rises from chimneys and facilities of steel plants on a hazy day in Benxi, Liaoning province November 3, 2013.



GMP Services
注册服务

To learn more about NSF cGMP Services, [click here](#)
Experts in auditing, consulting, training and testing

欲了解更多服务信息请点击
审核、咨询、培训和测试专家团队

The discussion first erupted on Tuesday after a little known publication called the China Business Review ran a headline bound to get attention in a country more obsessed than most with children: "Smog Can Impact Humans' Reproductive Ability and Immune System." Below, the newspaper showed a rendering of how dust particles harm different organs in the human body.

Both articles cite a new "green paper" on climate change issued by the China Meteorological Administration and the Chinese Academy of Social Sciences. As one might expect, the report is mostly concerned with minimizing the carbon footprint of China's urbanizing population, though it does making a passing mention, on page 248, of the negative effects on human health of air pollution. Particulate matter can "influence reproductive abilities," it says.

While neither the green paper nor the initial China Business Review story offered any data to support their claims, that hardly seemed to matter to the country's microbloggers, who have long expected the worse from the air they breathe.

A study in July found that air pollution from coal combustion likely cut life expectancy in parts of China by more than five years during the 1990s. This week, China's official news agency Xinhua reported a doctor saying that an eight-year old girl from the eastern province of Jiangsu had contracted lung cancer from prolonged exposure to harmful particles having lived near a dusty street.

The Wall Street Journal called Beijing's United Family Healthcare for its take on what doctors should be telling their patients, but the hospital declined comment. "Our (obstetrician and gynecologist) chief refused the interview, because there is no data or document to explain the pollution's impact to pregnant women," wrote spokesperson Yafei Zhu.

Previous studies have shown exposure to high levels of pollution can reduce the success rate of in vitro fertilization and drawn a link between toxic air and reduced fertility in men. In September, local media reported that scientists at Shanghai Jiao Tong University, Nanjing Medical University and Zhejiang University, the Chinese Academy of Sciences would conduct a national research study in 2014 to examine how toxins in the environment, including pollution, impact women trying to give birth.

Mr. Li from the Shanghai sperm bank says it has been facing a lack of qualified sperm donors and quality sperm in the last decade, and that only one-third of its sperm meets World Health Organization standards, according to Wednesday's report in the Shanghai Morning post. A spokesperson at Ruijin Hospital, which houses the sperm bank, said Mr. Li was not available for comment.

Another recent study led by Chinese scientists shows a strong link between smaller air pollution particles and a range of serious health conditions.

Scientists said the smaller the airborne particles, the more likely they are to cause illness, suggesting the need for monitoring of particulate matter of 1 micron or less in diameter — a category of pollution rarely monitored.

In recent years, many locations across the country have been blanketed with heavy air pollution, raising concerns for public health. Among the main categories of pollutant measured is PM2.5, which can enter the respiratory system and contribute to a range of illnesses, including cardiovascular disease.

Readers of the China Business Review article were far from reticent. The post elicited 441 comments, including one that sardonically proffered a silver lining: "Yes! No need to use condoms anymore." (Source: WSJ)

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

Copyright © 2013 U.S.-China Health Products Association. All rights reserved.