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INSIDE THIS ISSUE

USCHPA Submits Comment Paper to CFDA

CFDA Released New Regulation Draft on Cosmetics Management

China to Relax Limit on Online Drug Sales

Zhengzhou Regulator Warns Online Purchasing of Foreign Health Products

Wal-Mart Feels Pinch From China Austerity Campaign

Imported cosmetics face stiffer regulation

Traditional Chinese Medicine Gets Traction Among Scientists



USCHPA Submits Comment Paper to CFDA

On November 5, 2014, China's FDA released two draft regulations for nutritional supplements entitled, "Administrative Regulations for Nutritional Supplements and Information Requirement for Nutritional Supplements". At this time, the draft regulations are defining "nutrients or nutritional supplements" as vitamins and minerals.

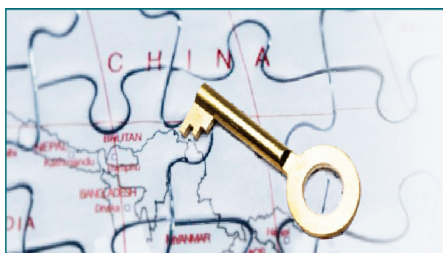
The USCHPA submitted their comments and requests for clarifications to China FDA on November 26, 2014. The association's major ask is that CFDA consider adding ingredients other than just vitamins and minerals to their definition of "nutritional supplement" such as Omega Fatty Acids, Lutein, Lycopene, amino acids, probiotics, Coenzyme Q10 and other ingredients that are nutritionally important to enhancing a healthy diet and lifestyle.

These new drafts are a step in the right direction and are the first step by CFDA to gain more control over the industry while streamlining administrative processes and creating a more open market for dietary supplements.

As mentioned, this is just the first step. There is still a lot of work a head. USCHPA sees this as a positive move by CFDA. The association will continue to share information with CFDA and all other relevant government agencies and organizations in order to encourage the continued development of China's dietary supplement industry.

The translated regulations and USCHPA's report to CFDA can be found on the association's site by clicking:

HERE



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CFDA Released New Regulation Draft on Cosmetics Management

The state drug and food regulator released the latest draft recently that addresses management of cosmetics production, ingredient, advertisement and promotion, as well as online sales.

The draft says that any new ingredient of cosmetics needs to go through a four-year observation period first before being put into use. Any use of new ingredient should be approved by the state regulator.

Cosmetics with special use, including products used for dying, whitening and sun-block, should gain approval from the drug and food monitoring department of State Council before being produced or imported. The non-special use cosmetics can be managed by filing.

The new draft also requires the online e-commerce platform to have the cosmetics vendors to register with their real names. The vendors should take the responsibility if any of its product is found illegal or substandard. For any e-commerce platform that does not obey this rule, the regulator can fine the company for 200,000 yuan at most.

Cosmetics are not allowed to indicate any medical function in its instruction book or ads. Those cosmetics company which are promoting illegally should be exposed by the provincial-level government in its official website and suspended from sales. (Source: CFDA)

China to Relax Limit on Online Drug Sales

In a recent drug seminar held by the local FDA of Guangdong province, the regulators said that the state authority is considering to relax its policy restriction on online drugs sales early next year, raising eyebrows of domestic vendors who are looking forward to sell prescribed drugs online.

According to data from CFDA, the annual value of B2C drug market in China reached 1.67 billion yuan in 2012 and exceeded 5 billion yuan last year.

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The market share of online drug sales is rising in the past few years as well. In 2013, online sales account for about 1% of total drug sales in the country, reaching 1 billion yuan.

“If the online drug sales platform can catch up with America, I am sure that the market value will exceed 100 billion yuan soon,” said Shi Zhenyang, CEO of Qilekang Pharmaceutical Co. Ltd, adding the upcoming relaxation will give more imagination to the domestic drug market. (Source:drug.39.net)

Zhengzhou Regulator Warns Online Purchasing of Foreign Health Products

Thanks to the popularity of communication apps like Wechat, many vendors are offering to purchase foreign products to their domestic clients or friends by promoting their business in those platforms.

The local regulator of Zhengzhou warns consumers that in face of rampant fake health products, consumers need to be cautious when choosing to resort to those vendors, even they know these people as friends, to buy foreign health products.

Mr. Zhou, a domestic agent of Australian health product purchase, said that most people who are selling foreign health products don't even know whether their partners, who are based overseas, are selling quality product to them or fake ones.

Many vendors are promoting their products among friends by the apps, and usually their friends will buy the products as they feel embarrassed to decline those requests.

The local regulator warns that health products are not drugs and cannot replace drugs to cure disease. Also, it is very likely to buy counterfeits from the online channels. Once that happens, it can be difficult for the consumers to trace the vendor and protect their due rights. (Source: Zhengzhou Daily)

Wal-Mart Feels Pinch From China Austerity Campaign

China's austerity campaign has taken a toll on sales of high-end handbags and expensive jewelry. Now Wal-Mart Stores Inc. says it is feeling the effect, too.

The Bentonville, Ark., retailer's same-store sales in China declined 1.6% from a year earlier for the quarter through July. One reason for the drop was lower sales of gift cards, moon cakes and other goods tied to China's culture of gift giving, said Scott Price, Wal-Mart's president for Asia and executive vice president of international strategy.

Mr. Price declined to be more precise about the factors behind the sales drop, and Wal-Mart doesn't break out its figures to that degree. He said unit sales have grown.

The retailer also has faced stiff competition in China from domestic rivals and rising e-commerce companies, experts say. Wal-Mart executives last year announced plans to close around 25 stores to refocus its business in the country.

The Chinese government's push to clean up excessive consumption at its state-owned enterprises has hit overall consumer confidence and retail, Mr. Price said in an interview Sunday on the sidelines of the Asia-Pacific Economic Cooperation CEO Summit. "The austerity campaign was broad-based," he said. "It wasn't limited to the luxury market."

Wal-Mart, which runs about 400 stores in China, is moving to cut costs and run more efficiently in the country, Mr. Price said.

Luxury companies have reported a negative sales impact tied to China's push to curb spending at its government-owned companies and chill a gifts-for-favors culture. In late 2012, Chinese leaders began an austerity campaign that halted lavish government banquets and barred bureaucrats from buying luxury goods.



China is a critical growth market for Wal-Mart. The company has the third-biggest market share in the country, according to research firm Euromonitor International. No. 1 is Sun Art Retail Group Ltd., a joint venture between Taiwanese conglomerate Ruentex Industries Ltd. and France's Groupe Auchan SA. China Resources Enterprise Ltd., which operates more than 4,000 stores under 10 retail brands, has the second-biggest share.

China is attempting to push overhauls beyond austerity, aiming to build a consumer-led, market-driven economy. Mr. Price said he is optimistic about those changes. "You have 1.2 billion citizens who want an increased quality of life. I think the reform programs will deliver that," he said.

Wal-Mart isn't concerned about slowing growth in the world's second-largest economy, Mr. Price said. He said he was sticking by a plan to have around 480 Wal-Mart stores in China by the end of 2016. "The growth at this point has slowed," Mr. Price said of the Chinese economy. "But that doesn't change our view that in the next five years, it's still an exciting place to be."

Online sales have been a bright spot in China, where Wal-Mart plans to rev up its online arm, Yihaodian,

Mr. Price said. Wal-Mart owns a 51% stake in Yihaodian and in the next few years will move to integrate the operation with Wal-Mart's brick-and-mortar stores, Mr. Price said. The retailer is researching shopping habits, he said, and enabling people to buy online and pick up goods in stores will be a multiyear, city-by-city process.

Mr. Price recently returned as Asia chief less than six months after Wal-Mart relocated him to Bentonville to run international strategy and business development. Mr. Price said leading Wal-Mart's Asia business from headquarters will test his ability to bridge time zones, but it also would enable him to give executives in countries such as China more autonomy. (Source: WSJ)

Imported cosmetics face stiffer regulation

A regulation covering imported cosmetics is poised to be tightened by China's food and drug authority.

Under the revision, the China Food and Drug Administration will be able to carry out onsite inspections of imported products.

Public opinion is being sought on the revision, which was announced by the authority on Saturday.

One of the draft's clauses requires an importer to present a certificate showing that a product has been placed on sale under specified cosmetics categories, such as skin whitening or sunscreen products.

According to the draft, imports must have labels in Chinese explaining the product details, such as the name, producer, ingredients and validity period.



The revision comes 24 years after the introduction of the country's first regulation covering the cosmetics industry in January 1990.

Wu Zhen, deputy director of the China Food and Drug Administration, said at a work conference on the revision that the current regulation has failed to keep up with latest developments in the cosmetics industry.

“ The social, industrial and supervisory environments of the cosmetics industry have all changed profoundly ... the legislation on the industry can provide the legal basis for the supervisory authorities,” he said.

The draft covers factors including the use of ingredients, production, certification from authorities, labeling and advertising, sales and penalties for misconduct.

Under the draft, cosmetics producers cannot exaggerate the benefits of their products, such as implying on the labeling or during promotions that they have medicinal qualities.

Retail sales of cosmetics in the country reached 162.5 billion yuan (\$25.5 billion) in 2013 to register year-on-year growth of 13.3 percent, according to the National Bureau of Statistics.(Source: China Daily)

Traditional Chinese Medicine Gets Traction Among Scientists

Traditional Chinese medicine teaches that some people have hot constitutions, making them prone to fever and inflammation in parts of the body, while others tend to have cold body parts and get chills.

Such Eastern-rooted ideas have been developed over thousands of years of experience with patients. But they aren't backed up by much scientific data.

Now researchers in some the most highly respected

universities in China, and increasingly in Europe and the U.S., are wedding Western techniques for analyzing complex biological systems to the Chinese notion of seeing the body as a networked whole. The idea is to study how genes or proteins interact throughout the body as a disease develops, rather than to examine single genes or molecules.

“Traditional Chinese medicine views disease as complete a pattern as possible,” says Jennifer Wan, a professor in the school of biological sciences at the University of Hong Kong who studies traditional Chinese medicine, or TCM. “Western medicine tends to view events or individuals as discrete particles.” But one gene or biological marker alone typically doesn’t yield comprehensive understanding of disease, she says.

To reach these goals, the overall quality of research on traditional Chinese medicine must improve. With studies of Chinese herbal remedies, for instance, rarely are scientists expected to provide authentication of herbs they’re studying, which makes it difficult to know what’s really in the concoctions. This hurdle also makes it harder for other scientists to replicate the findings, says Qihe Xu, a professor in renal medicine at King’s College London. Dr. Xu served as the coordinator of a recent 200-scientist consortium to study good practices for studying traditional Chinese medicine, dubbed GP-TCM.

TCM treatments of herbal concoctions could be authenticated and standardized with more scientific study, and could serve as leads for drug development, experts say.

One example of this possible development is Yale University pharmacology professor Yung-Chi Cheng’s work looking at four-herb combination known as PHY906 for reducing the side effects of chemotherapy. The treatment appears to contain

more than 60 chemicals. Researchers are studying it for its ability to reduce nausea and diarrhea and to enhance colon-cancer treatment.

The field also must develop standard definitions and ways of measuring TCM syndromes, important for research and clinical care, Dr. Xu says. His European Union-funded consortium published a set of guidelines for good practices last year in the journal *BMC Complementary and Alternative Medicine*, one of about 50 papers published by the consortium since 2010.

“If it’s not reproducible, it’s not science,” he says.

According to traditional Chinese medicine, disease arises from imbalances in the body due to unhealthy factors in the natural environment and one’s lifestyle. General symptoms like dry mouth or film coating the tongue are signals that certain bodily systems are out of whack. While Western doctors more focused on specific ailments may ignore these signs, TCM doctors often use the symptoms as guides for treating patients.

A doctor practicing TCM who knows whether someone has hot or cold syndrome could use that as a first clue in testing for problems involving the immune or metabolic system. Those problems could include gastritis, colitis, rheumatoid arthritis or cancer. One day there also may be effective treatments if a person’s constitution is taken into account when treating them, says Shao Li, deputy director of the bioinformatics division at Tsinghua University in Beijing.

In cities throughout China, doctors practicing Western and Chinese medicine can both be found. Many patients go to Western doctors for certain situations, such as acute illness, but seek out TCM guidance in others, often to prevent disease.

One promising area of TCM research several



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independent groups of scientists are investigating is the notion of hot and cold syndromes. The work is still in its early stages. But it could result in a new direction for TCM research by using the systems biology approach and integrating it with experience gleaned from TCM patient care, says Yale's Dr. Cheng, who also serves as chairman of the Consortium for the Globalization of Chinese Medicine.

In a series of studies, Tsinghua's Dr. Li and his colleagues examined people with hot and cold syndromes and whether they exhibited different signs of illness, including gastritis, a common digestive disorder in which the lining of the stomach becomes inflamed or irritated.

To gauge whether gastritis patients had cold or hot syndromes, researchers asked questions like whether individuals had chilly body parts or exhibited a preference for hot beverages or a susceptibility to catching colds. Doctors dug into their subjects' emotional states, asking whether they experienced so-called cold feelings like apathy. The scientists also measured proteins linked to gastritis and took measurements of the bacteria in the gut and imaged the bacteria in the tongue's coating.

They found some variations depending on whether patients were identified as hot or cold. They also found differences in the bacteria of patients' tongues that corresponded with tongue coating color and whether patients had been diagnosed with hot or cold syndrome.

These results suggest that some easily detectable and nonspecific symptoms could be clinically useful, Dr. Li says. However, it remains to be seen whether gastritis patients classified as having hot syndrome would actually respond to different treatment than those classified as cold.

In the Netherlands, Jan van der Greef, a professor of analytical biosciences at Leiden University, and his colleagues have looked at how getting classified as having hot or cold symptoms relates to rheumatoid arthritis.



They had a Chinese medicine expert identify participants by type and studied a network of chemicals produced by the body related to the immune system. They found higher levels of one steroid and 11 other molecules in the urine of arthritis patients depending on their TCM diagnosis.

That could mean that they would benefit from different disease-management strategies. Cold patients might benefit more from hormone treatments like prednisone, while hot patients might benefit from immune therapies, says Herman van Wietmarschen, a postdoctoral researcher at the Netherlands Organization of Applied Scientific Research and the first author on the paper. They published their work in PLOS One in 2012.

In another study, published in *Molecular BioSystems* in 2012, Dr. van der Greef's group looked at another important TCM construct known as Qi, known as life energy, or the forces within the human body and the environment. Again, they found differences between biological markers in the urine of people with different body classifications. TCM-based symptom patterns could be suitable for early detection of health problems, the authors say.

TCM was largely ignored by Western medicine until recent years, but is slowly gaining traction among some scientists and clinicians. The Cleveland Clinic in Ohio recently opened a herbal therapy center. The U.S. government established

the National Center for Complementary and Alternative Medicine in 1998. The organization now has a budget of over \$120 million to fund research on the efficacy and safety of alternative medicines, including those rooted in traditional Chinese medicine. (Source:WSJ)

China Updates is published weekly by the U.S. – China Health Products Association, a non-profit organization dedicated to the promotion of dietary supplements and nutritional ingredients. The association's major focus is the continued development of China's overall natural health product industry as well as offer business services to its global members.

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