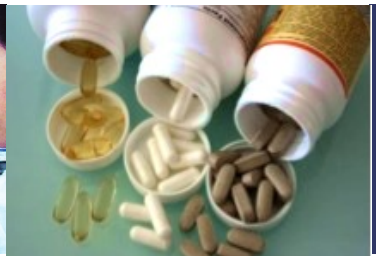
China Updates

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

U.S. – China HPA Health Products Association
www.uschinahpa.org



ISSUE 70
January 3, 2014

IN THIS ISSUE

China Bans Shenzhen Hepatitis B Vaccine

China's drug administration has suspended the use of two batches of hepatitis B vaccines after two dead cases occurred after vaccination.

The China Food and Drug Administration on Saturday published a circular urging relevant local authorities and disease control centers to suspend two batches of the vaccines produced by a Shenzhen-based company.

Two people in central China's Hunan Province died after receiving hepatitis B vaccinations from the company, and the suspicious two batches were found to have been sold to Hunan, Guangdong and Guizhou provinces.

The authority has informed relevant agencies in the three provinces and local drug administration in Shenzhen has been told to send a team to the company for investigation.

Chinese authorities last Friday issued a circular to ban the use of the recombinant hepatitis B vaccine produced by the Shenzhen-based BioKangtai company.

The circular, jointly issued by the China Food and Drug Administration (CFDA) and the National Health and Family Planning

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.

Commission (NHFPC), said that four cases of infants' deaths were reported in Hunan, Guangdong and Sichuan provinces after inoculation using the vaccine.

The CFDA and the NHFPC will carry out further investigation into the cases and inspection over the company, the circular said.

"The bodies of the two babies have been sent for autopsy. The vaccines are with the National Institute for the Control of Pharmaceutical and Biological Products for analysis," said Gao Lidong, deputy head of the Hunan Provincial Center for Disease Control and Prevention. "Investigations showed storage and transport of the vaccines met requirements and medical staff were qualified and did their work in line with regulations."

Biokangtai said it produced its vaccines in accordance with China's Good Manufacturing Practice for Drugs and inspected its products to ensure their high quality, according to a statement on December 16. (Source: Global Times/Guangzhou Daily)

China to Strengthen Infant-Formula Regulations

China's food and drug watchdog is strengthening quality standards for domestic infant-formula makers in an effort to rebuild consumer trust in a lucrative yet scandal-plagued industry.

China's State Food and Drug Administration said on Wednesday it would require the country's formula makers to take on primary liability for their products' safety, ensure product traceability and implement a product-recall system, according to the official Xinhua news agency.

Under the new regulation, which will be launched with a nationwide review of current producers' licenses, baby formula producers must register their products and packaging with provincial food and drug administrators, Xinhua said. Xinhua didn't say when the regulations will go into effect, but said review of licenses would be completed before May 31.

China's leaders have been cheering the rise of a homegrown dairy industry. They aim to rebuild consumer confidence after a 2008 scandal in which the industrial chemical melamine was added to domestic-made milk powder, killing six infants and causing 300,000 others to fall ill.

Foreign formula brands have been in particularly high demand following the incident, spurring Chinese consumers to stock up on foreign formulas they believe are safer. The rush to buy has drawn international attention, as grocery shelves as far-flung as the U.K. have been cleared out by Chinese buyers.

China's formula market reached 77 billion yuan ($12.68 billion) in total sales last year, according to market-research firm Euromonitor International. Foreign companies accounted for half of the top 10 sellers, with Mead Johnson holding the largest market share, 14.1%, according to Euromonitor.

That has put foreign participants under scrutiny. In August, regulators handed $100 million in fines to formula makers, most of which were international brands that authorities said had unfairly manipulated pricing in the market.

To regain confidence, the watchdog aims to heighten product inspection, raw material quality, safety controland manufacturing, Xinhua said, saying that there will be a grace period of two years for the new requirements. (Source: WSJ)

Hangzhou Sets up a Food & Drug Risk Alert System

To better strengthen the food and drug safety regulation, local FDA of Hangzhou in Zhejiang province set up a risk alert system targeting food and drug.

The system includes an information team that collects, releases and assesses risk level of food and drug, which is part of a comprehensive risk-avert system by local regulator.

The system covers fields including drug, medical equipment, health food, cosmetics, restaurant and other food. The risk levels range from average, quite severe, severe and very severe. The alert system is divided based on industry, area and government department. (Source: CFDA)

Shandong FDA Monitors Side-Effect of Cosmetics

Local FDA of Shandong province is to step up regulation on health food and cosmetics, promoting monitor on side-effect of cosmetics.

According to local authority, Shandong province has so far 268 health product and cosmetics production companies and 1,016 types of health products and cosmetics. Over 24,000 companies have set up electronic filing system to facilitate the local regulation’s monitor.

The local regulator has launched a special campaign to check over 29,083 companies that are producing cosmetics and operating related businesses. The campaign spotted over 1,067 illegal cases among all the local companies. 11 cases involved illegal health food production have been transferred to local police department.

Shandong now has 72 monitoring stations for side-effect of cosmetics, including 6 provincial-level stations. The stations have so far reported 254 cases of side-effect cases. All the cosmetics that are sold within mainland China with side-effect are all under the monitor of these stations. (Source: qilu.com)

Suzhou Tianma Partners with Korean Company to Produce Health Product

Suzhou Tianma Specialty Chemicals Co., Ltd plans to partner with Sungwoo Interchem Corp of South Korea to set up a branch company in efforts to tap into China’s health product market.

The investment values at $ 30 million and the company’s registered capital will be $120 million. Tianma will invest 90% in the registered capital.

The Korean’s Sungwoo started to get involved in health product service in 2006, doing business including selling health products like fish oil and plant extraction. In 2012, the company’s sales scale reached $30 million.

The branch company will be based in Suzhou of Jiangsu province. It will produce and sell health products as well as developing package materials. (Source: Securities Times)

Chinese Regulator Updates Regulation on Filing Non-Special Use Cosmetics

CFDA released a new regulation draft on filing system of non-special use cosmetics.

The regulation targets at all the domestic production companies, requesting these companies to register in the national filing system.

The provincial bureau will evaluate the registration information of the submitted material, and will deny

the application if the information is found incorrect.

Companies that serve as production agent should also explain the relation between their own company and the company that they work for so as to avoid any overlapping registration in the filing system.

Companies whose products are only for exporting should register under different columns with the other companies. All companies are asked to provide the date when the product is put into market and whether it has any agent production company under its management.

The provincial authority will confirm with the filing information including the formula of the product and its package. If the production company files the information for the first time, the authority will allocate a filing number for the company.

The submitted material should include two pictures of the product's package and a clear copy of the product's instruction book.

If the product is found to be substandard regarding its ingredient and label and the product has not been put into market yet, the company's filing application will be halted and corresponding revision is required.

The filing information will be released by the company, after the provincial authority reports the result to the company. If the company does not release the filing information in time, the system will automatically release the result.

If the production is found illegal during the evaluation, the authority will punish the company and release related information online.

One month before the product's filing information expires, the system will remind the company to refile. If the company does not refile in time, the system will delete its original information but will keep a copy of the information for reference in the future.

If the company has one of the following three situations, it should apply for information write-off: production suspension; name change of the product; change of the product formula.

The system also provides search for new substance that are allowed to be used in cosmetics. Users can search them by typing in the substance's standard Chinese or English name. (Source: CFDA)

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