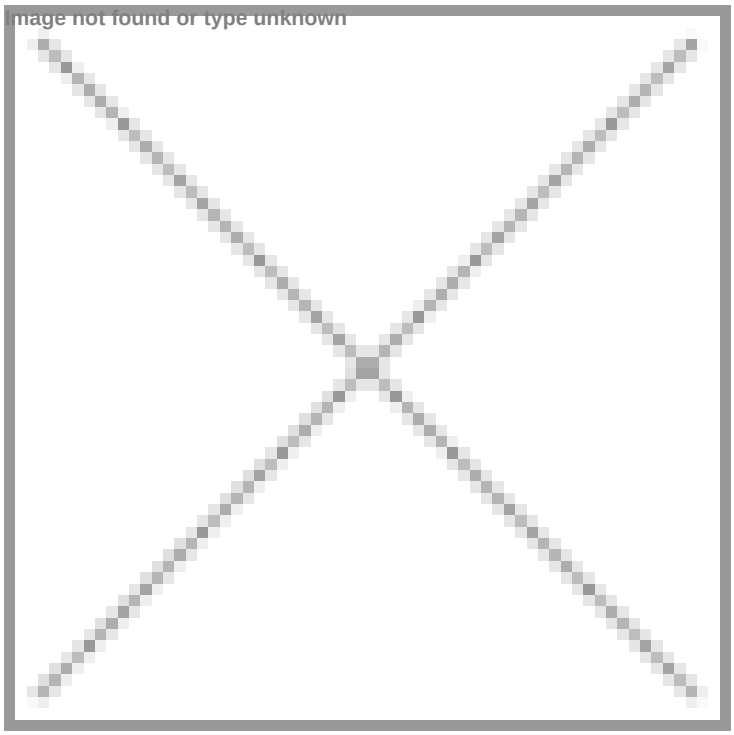
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Biostar recalls tainted capsule batch in China

31 May 2012 | News | By BioSpectrum Bureau

Biostar recalls tainted capsule batch in China



Singapore: Following an onsite inspection by Xianyang's State Food and Drug Administration (SFDA), China, samples from a batch of Biostar Pharmaceuticals' Xin Aoxing capsules were found to contain chromium content higher than edible gelatine. The capsules, in the company's estimation, were sold in the PRC market in mid-2011.

Biostar Pharmaceuticals is a PRC-based manufacturer and marketer of pharmaceutical and health supplement products in China for a variety of diseases and conditions.

As previously announced, on April 27, 2012, the SFDA launched an investigation of several capsule manufacturers based in Zhejiang, Hebei and Jiangxi provinces into their use of industrial gelatin, which contains impermissibly high chromium content. On May 25, 2012, following a nationwide inspection, the SFDA authorities reported that 669 batches of gel capsules from 254 drug manufacturers in 28 provinces were found to have high chromium levels.

As required by the SFDA in April 2012, the company purchased gel capsule inspection equipment to measure the chromium levels in gel capsules it used. Biostar also undertook an inspection of all samples of drugs sold and its current product inventory to ensure that all of the gel capsules it had purchased and currently used comply with the SFDA chromium content requirements. In addition, the company conducted checks of every batch of raw materials it uses in every production category and, except as discussed below, found no violations of the chromium content requirements.

Ronghua Wang, Biostar's chief executive officer and chairman, commented, "On May 25, 2012, we were informed by the Xianyang SFDA that samples from a batch of 150 cases of the Xin Aoxing capsules (each of the 150 cases contains 8,000 capsules), representing Biostar sales of approximately 1,188,000 RMB ($188,000) were also found to contain high levels of chromium. Additionally, during our own contemporaneously conducted inspection on May 22, 2012, samples from three batches of 380 cases of the Tianqi capsules were found to have high chromium levels (each of the 380 cases contains 7,200 capsules), representing Biostar sales of approximately 230,000 RMB ($36,000), which capsules, in the company's estimation, were sold in the market in mid-2011."

He added that the company urgently took steps to identify the source of the tainted capsule batch; recall all such capsules as promptly and thoroughly as possible; and review and impose heightened quality control and assurance measures.

"During our review, we determined that the capsule batch in question was purchased in May 2011 by one of our formerly employed purchasing managers who, in disregard of the company's policies, purchased four million capsules from a non-approved supplier. Due to this incident, his employment with the company was terminated in August 2011, immediately after we had become aware of this purchase. The company did not check the batch in question for the chromium levels at that time since PRC pharmaceutical companies were not required to test their gel capsule inventories and purchases for chromium levels in 2011," he said.

Mr Wang also said recall notices were sent to all of distribution centers and local SFDA offices were notified in all provinces. "Each distribution center is required to report to the company's management daily about the progress made in recalling all batches found to be manufactured using the tainted gel capsules," he said.

The company's quality control staff is also in process of completing a self-administered inspection of all drugs utilizing capsules as delivery method and capsule samples acquired during the period from June 2009 to April 2012.