

## SFDA reports high chromium in Biostar's drug

24 April 2012 | Regulatory | By BioSpectrum Bureau

### SFDA reports high chromium in Biostar's drug



**Singapore, June 01, 2012:** China based Biostar Pharmaceuticals has acknowledged the finding of chromium content higher than edible gelatin from a batch of its Xin Aoxing capsules following an onsite inspection by China's FDA. Xin Aoxing capsules were sold in China market in mid-2011.

As previously announced, on April 27, 2012, 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, SFDA authorities reported that 669 batches of gel capsules from 254 drug manufacturers in 28 provinces were found to have high chromium levels.

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 \$188,000 were also found to contain high levels of chromium. Additionally, during our own contemporaneously conducted inspection on May 22, 2012, samples from 3 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 \$36,000, which capsules, in the Company's estimation, were sold in the market in mid-2011."

He continued, "Once the Company's management was notified by the Xianyang SFDA about the batch of the gel capsules in

question, we urgently convened to, among other things: (i) identify the source of the tainted capsule batch, (ii) recall all such capsules as promptly and thoroughly as possible, and (iii) review and impose heightened quality control and assurance measures going forward. 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 4 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 Chinese pharmaceutical companies were not required to test their gel capsule inventories and purchases for chromium levels in 2011."

Mr. Wang continued, "Upon learning of the gel capsule batch in question containing high chromium levels, we immediately sent recall notices to all of our distribution centers and notified local SFDA offices in all provinces where our sales are made. 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.

"In addition, our Quality Control staff is 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. We anticipate completing this process by May 31, 2012. We intend to announce the results of this self-administered inspection in middle of June, when Xianyang SFDA, in turn, reviews and approves the conclusions of our inspection."