

Shandong Taibang gets SFDA approval

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Singapore: The indirectly owned subsidiary of China Biologic Products, Shandong Taibang Biological Products, has received a manufacturing approval certificate from the China State Food and Drug Administration for Human Coagulation Factor VIII (FVIII). With this certificate, the only approval remaining for Taibang's commercial production of FVIII is the SFDA's good manufacturing practice certification of the FVIII production line itself.

Taibang began research for FVIII in 2007 and successfully developed the technology in 2008. The Company conducted clinical trials from 2009 to 2010. In June 2010, the Company submitted required materials to Center for Drug Evaluation for approval to start manufacturing and passed on-site products verification in January 2011. The Company received official manufacturing approval certificate on June 21, 2012. FVIII will be primarily used in the treatment of hemophilia A.

Mr David Gao, chairman & CEO, said, "Receiving SFDA manufacturing approval represents the culmination of more than five years of work and the first technological approval of a coagulation factor product developed by Taibang. With the addition of Factor VIII, we should soon be able to offer three major categories of blood products: albumin products, immunoglobulin products and coagulation factor products. This will further strengthen our competitive position as a leading plasma-based biopharmaceutical company in China."

"We are very proud to bring FVIII to hemophilia A patients in China," continued Mr Gao. "We believe that Human Coagulation Factor VIII addresses a critically unmet need of a large patient population and helps ease under-supply of coagulation products. Although it is not possible to specify a definitive timeframe in which we will receive GMP approval, we expect our FVIII production to be inspected by SFDA and then GMP-certified by the end of 2012. Going forward, we intend to continue to develop and manufacture life-enhancing, effective, quality-assured products."