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ASIA EDITION

China CRO facility undergoes US FDA inspection

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Singapore: For the first time, the US FDA has completed an inspection in China under its combined clinical trial and bioresearch monitoring program. Frontage Laboratories, a pharmaceutical contract research organization, announced that the FDA has concluded the inspection at its clinical research center in Zhengzhou, Henan Province and its bioanalytical laboratories in the Pudong district of Shanghai. The inspections spanned two weeks from late February to early March 2013.

The FDA inspections support the agency's review of an abbreviated new drug application and a new drug application. The Frontage China Clinical Research Center in Zhengzhou hosted agency officials for a one-week inspection of the Bioequivalence study in an ANDA application with no FDA Form 483 notices issued. The Frontage Bioanalytical labs in Shanghai hosted FDA for two weeks to inspect the bioanalytical support of one ANDA and one NDA application. One Form 483 was issued to the bioanalytical operations with findings that Frontage is immediately resolving with the agency.

"We are pleased that the FDA has approved of our efforts to bring industry leading drug development practices to China," said Dr Song Li, chairman and CEO of Frontage. "As more pharmaceutical companies seek to expand business in China, they are looking for a company that can provide clinical and bioanalytical research services with globally accepted quality standards. Frontage is the first company to offer such a combination in China that has been inspected by the FDA."

"Together with product development and regulatory services, we have been offering these newly inspected systems in China since 2006, supporting both multinational and domestic pharmaceutical firms," Dr. Li added. "Our regulatory, research and business development expertise supports companies targeting the Chinese marketplace with product introductions, leveraging its local relationships and experienced personnel. We are excited about our ability to bring FDA-compliant research to companies that wish to launch their products globally."

The Frontage inspection was the first in China under the FDA's Human Subject Protection (HSP)/Bioresearch Monitoring Initiative. Launched in 2006 as a part of the Critical Path Initiative, the HSP/BIMO Initiative is aimed at modernizing and strengthening the agency's oversight and protection of subjects in clinical trials and the integrity of resulting data.