东北制药总厂
NORTHEAST GENERAL PHARMACEUTICAL FACTORY
ADDRESS : NO.37 ZHONGGONG BEI STREET, TIEXI DSITRICT, SHENYANG, P.R. OF CHINA
P.O.:110026 TEL. NO. :86 24 22721818 FAX NO. :86 24 22724536

Date: Nov.5,2008

Re: FDA Bioterrorism Preparedness and Response Act of 2002

To Whom It May Concern:

Thank you for your recent inquiry about our compliance with the FDA regulations related to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act).

The events of September 11, 2001, highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A – Protection of Food Supply, Section 305, which requires the Secretary of Health and Human Services to develop a regulation to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA by December 12, 2003. Northeast General Pharmaceutical Factory is in full compliance with Section 305.

The Bioterrorism Act also includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A – Protection of Food Supply, Section 307, which requires the Secretary of Health and Human Services to develop a regulation to require that FDA receive prior notice for food imported or offered for import into the United States. Northeast General Pharmaceutical Factory is in full compliance with Section 307.

Finally, The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A – Protection of Food Supply, Section 306, which requires the Secretary of Health and Human Services to develop a regulation to established recordkeeping requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records. Northeast General Pharmaceutical Factory is in full compliance with Section 306.

Name, Title of
Officer or Regulatory Contact of the Company

Xie Dan QA director

Factory stamp & signature