DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
International Compliance Team
10903 New Hampshire Avenue
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May 21, 2010

Mr. Cai Dongchen
Chairman, Chief Executive Officer
CSPC Pharmaceutical Group Limited
No. 276 Zhongshan West Road
Shijiazhunag, 050051
China

RE: Inspection of firm FEI 3007544161

Dear Mr. Dongchen,

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient manufacturing facility in Shijiazhunag, China on February 1-5, 2010 by FDA Investigator CDR Rochelle B. Young, RPh, MSA and Chemist Matthew R. Sleeter. Based on the inspection, we are classifying your facility as acceptable. It remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions concerning this letter, you may contact me at the above address or telephone numbers.

Sincerely,

Elizabeth L. Philpy
Compliance Officer
International Compliance Team

Enclosure: