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

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Team
10903 New Hampshire Avenue
Building #51, Room 4219
Silver Spring, MD 20993

TELEPHONE: (301) 796-3194
FAX: (301) 847-8742

6/28/2011

Dr. Steve Chang
President
Chunghwa Chemical Synthesis & Biotech Co., Ltd.
1 Tung-Hsing Street, Shu-Lin
New Taipei City, Taiwan

Reference: FEI 3002806677

Dear Dr. Chang:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Taipei Hsien, Taiwan by Investigator Paraluman S. Leonin and Chemist Javier O. Vega during the period of April 18-21, 2011. A FDA-483, Notice of Inspectional Observations, was issued at the conclusion of the inspection.

We have also reviewed your company's response, dated May 2[illegible] 2011, with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

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 Freedom of Information Act and 21 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 regarding this letter, you may contact me at the above address or number.

Sincerely,

Brian L. Belz
Compliance Officer
Division of International Drug Quality

Enclosure: EIR