DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
11919 Rockville Pike, Room 409
Rockville, MD 20852
Tel: (301) 827-9004
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March 16, 2006

Dr. Steve H. Chang, President
Chunghwa Chemical Synthesis & Biotech Co.
1 Tung-Hsing St., Shu-Lin 238
Taipei Hsien, Taiwan, Republic of China

Dear Dr. Chang:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Taipei, Taiwan, by Investigator James P. McReavey and Chemist Kent C. Faul on December 2-7, 2005. A FDA-483, Notice of Inspectional Observations was issued to you at the conclusion of the inspection.

We have received your written response dated December 2[illegible] 2005. Based on the API 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. The corrective actions will be further evaluated during the next routine inspection. 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 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 regarding this letter, you may contact me at the above telephone number or address.

Sincerely,

Marybel Lopez
Compliance Officer
Foreign Inspection Team

Enclosure: