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 Branch
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August 1, 2014

Dr. Steve Chang
President
Chunghwa Chemical Synthesis & Biotech Co., Ltd
1 Tung-Hsing Street, Shu-Lin Dist., 23850, New Taipei City
Taiwan, ROC

Reference: FEI 3002806677

Dear Dr. Chang:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your Active Pharmaceutical Ingredient (API) manufacturing facility in New Taipei, Taiwan by Investigator Azza Talaat during the period of May 16, 2014 to May 21, 2014.

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).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

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,

Alicia Mozzachio
Branch Chief
Division of International Drug Quality

Enclosure: EIR