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

Division of Manufacturing and Product Quality
Foreign Inspection Team, HFD-322
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May 9, 2002

Dr. I-Der Huang
President
China Chemical Synthesis Industrial Co., Ltd.
1 Tung-Hsing Street
Shu-Lin 238, Taipei Hsien, Taiwan, ROC
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Dear Dr. Huang,

We have completed review of the Inspection Report on the April 3, 2002 inspection of your Active Pharmaceutical Ingredient (API) manufacturing facility by FDA Investigator Larry K. Auston. We found your firm to be an acceptable supplier of Methocarbamol and Pravastatin sodium, bulk active ingredients. It remains your responsibility to assure continued compliance with current good manufacturing practices.

Additionally, we enclose a copy of the establishment inspection report (EIR) for the inspection. The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

You may contact me at the address or telephone number given above if you have any questions regarding this letter.

Sincerely,

Muralidhara B. Gavini, Ph.D.
Compliance Officer
Foreign Inspection Team

Enclosure: