



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

December 24, 2008

Dr. Jo Shen
Scinopharm Taiwan, Ltd.
No. 1 Nan-Ke 8th Road
Tainan Science-Based Industrial Park
Tainan City 741
Taiwan

Dear Dr. Shen:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your API manufacturing facility in Tainan City, Taiwan by Investigator Michael A. Charles on October 20-23, 2008. An FDA-483 Inspectional Observations form was issued at the conclusion of the inspection.

We have reviewed your company's response dated November 11, 2008 with supportive documentation. Based on this response, 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 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 by phone at (301) 796-4753.

Sincerely,

A handwritten signature in blue ink, appearing to read "Marisa Stock".

Marisa Stock
Consumer Safety Officer
New and Generic Drug Manufacturing Team