



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality, HFD-320
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January 17, 2002

Mrs. Jo Shen, Ph.D.
President & CEO
ScinoPharm Taiwan, Ltd.
Number 1, Nan-ke 8th Road
Tainan Science-based Industrial Park
Tainan County, Taiwan R.O.C. 741

Dear Mrs. Shen:


We have completed review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical manufacturing facility in Tainan, Taiwan on October 22-24, 2001 by FDA investigator George Flynn, and FDA Chemist Shing Liu.

We have also reviewed the November 9, 2001, written response to the FDA-483 observations. Based on this response, we are classifying your facility as acceptable. The corrections described in the response will be evaluated during the next routine inspection.

Additionally, we enclose a copy of the EIR for the inspection. This report is being provided to you for information purposes. 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.

If there is any question about the above information, feel free to contact me at the address or telephone numbers provided above.

Sincerely,


Melissa Garcia
Compliance Officer

Enclosure: