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收件人: Susan Lu-盧麗安 <Susan.Lu@scinopharm.com>

標題: [WARNING: MESSAGE ENCRYPTED]USFDA - FMD 145 EIR - ScinoPharm
Taiwan, LTD. - FEI: 3002840477

12/02/2022

President and CEO Susan Lu

ScinoPharm Taiwan, LTD.

Shan-Hua No. 1 Nanke 8th Rd.; Shanhua Dist. Tainan City

Dear President and CEO Susan Lu:

The U.S. Food and Drug Administration (FDA) conducted an inspection at ScinoPharm Taiwan, LTD., FEI 3002840477, located at Shan-Hua, No. 1 Nanke 8th Rd.; Shanhua Dist., Tainan City, from 10/17/2022 to 10/25/2022. FDA has determined that the inspection classification of this facility is "no action indicated" ("NAI"). Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "'closed'" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom

of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Paul Mouris via telephone at 19146821113 or email at Paul.Mouris@FDA.HHS.GOV.

Sincerely,

Faith S Jones
CONSUMER SAFETY TECHNICIAN
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS



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