



Center for Drug Evaluation and
Research
Office of Pharmaceutical Quality
Office of Surveillance
Division of Quality Surveillance
Assessment
10002 New Hampshire Avenue

08/11/2017

Chunghwa Chemical Synthesis & Biotech Co., Ltd
Shu-Lin District
1 Tung-Hsing Street
New Taipei City, Taipei , TW

Reference: Inspection Date(s): 03/27/2017 - 03/29/2017

Location: Chunghwa Chemical Synthesis & Biotech Co., Ltd
1 Tung-Hsing Street
Shu-Lin District
New Taipei City, 23850 , TW

Dear Dr. Chih-Ping Yang,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works 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 Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 240-402-6594.

fda_phone

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Jeneen A. Huff-
robersone -S

Digitally signed by Jeneen A. Huff-
robersone -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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cn=Jeneen A. Huff-robersone -S
Date: 2017.08.11 09:48:36 -04'00'

FEI: 3002806677

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration
www.fda.gov