



FDA U.S. FOOD & DRUG
ADMINISTRATION

NOV - 8 2017

Via United Parcel Service

Malik Zhu
General Manager
Shenzhen Union Technology Co Ltd.
4th, Buidling, Hi-tech Industrial Zone
Heping Community, Fuyong Street, Baoan District
Shenzhen, Guangdong, 518103
China

Re: 3011654863

Dear Mr. Zhu:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at the premises at the above referenced address on May 29 – June 2, 2017, by Cynthia T. Cain on behalf of the U.S. Food and Drug Administration (FDA). 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. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

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 reflects redactions made by the Agency in accordance with the FOIA and 21 CFR 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 released information, feel free to contact Mr. Michael Sturniolo at 301-796-6431 or write to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Room 3548
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Sincerely yours,

Bryan Benesch
Deputy Director for Regulatory Oversight and Analysis
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health

Enclosure: Summary of Inspectional Findings

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov