DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

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June 29, 2015

Mr. Song Xiangyi
General Manager
Tianjin Pacific Chemical & Pharmaceutical Co., Ltd.
27 Baoyuan Road
Jinnan District Development Zone
Tianjin, 300350
China

Reference FEI 3006024287
Reference inspection date: March 30 – April 3, 2015
Establishment Locale: Tianjin, China

Dear Mr. Xiangyi:

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 the above address or number.

Sincerely,

Rebecca Frey-Cooper, PHD
Chemist
Inspection Assessment Branch

Enclosure: EIR

Tianjin Pacific Chemical
Pharmaceutical Co., Ltd.
Tianjin, China

FEI: 3006024287
EI Start: 03//30/2015
EI End: 04/03/2015

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Pharmaceutical Co., Ltd.
Tianjin, China

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SUMMARY

This cGMP inspection of an Active Pharmaceutical Ingredient (API) manufacturer was conducted pursuant to FY2015 Performance Goal Surveillance Inspection and FACTS Assignment # 11498750 and C.P. 7656.00F Active Pharmaceutical Ingredients Process Inspection. The previous inspection of 9/2011 was classified as NAI, two verbal comments regarding the insufficient environmental monitoring of the microbiology laboratory and there had been no appropriate monitoring of the laminar flow hoods used in the microbiological sampling rooms was discussed. At the time of this inspection, the firm had no U.S. customers and had not shipped any API to the U.S.

This inspection covered Quality, Facility/Equipment, Materials, Laboratory and Production Systems. The inspection resulted in five verbal comments were observed and discussed with the firm's management:

- The user name of the analyst was not printed on the HPLC chromatogram of Difluprednate lot # 01EF40700.
- OOS # 201501 the second month accelerated stability study of Abiraterone Acetate API. QA did not provide the necessary explanations to why it did not need a CAPA.
- The supplier's name was not documented on the COA of Dehydroisoandrosterone 3-Acetate batch # 20131003 (Starting Material of Abiraterone Acetate).
- The Difluprednate Working Reference Standard lot WSEF1301 was stored in one brown glass bottle, which is not sub-package into individual vials to avoid contamination/degradation due to the multiple usages.
- There was no print out of the HPLC injection sequence example: intermediate-3 lot # 03CA1401001 of Abiraterone Acetate.

At the conclusion of this inspection, the five verbal comments were discussed with firm`s managements. Management agreed to comments and immediate correction promised.

No FDA -483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Tianjin Pacific Chemical & Pharmaceutical Co., Ltd.
Location:	27 Baoyuan Road Jinnan District Development Zone Tianjin, China
Phone:	22 8851 8581
FAX:	22 8850 8582
Mailing address:	27 Baoyuan Road Jinnan District Development Zone Tianjin, China

Tianjin Pacific Chemical
Pharmaceutical Co., Ltd.
Tianjin, China

FEI: 3006024287
EI Start: 03//30/2015
EI End: 04/03/2015

Dates of inspection:	3/30/2015, 3/31/2015, 4/1/2015, 4/2/2015, 4/3/2015
Days in the facility:	5
Participants:	Azza Talaat, Investigator

HISTORY
No major changes in the firm history since the last inspection. Tianjin Pacific Chemical & Pharmaceutical Co., Ltd is a privately owned company and was founded in 2001 at the current location. The firm uses chemical synthesis processes to manufacture over ten non-sterile APIs for both the domestic and international market including steroids, anti-hypertensive, anti -inflammatory, anti-malaria, etc. The total number of staff is 345 in which 183 in production, 51 in Quality, and 25 in R&D. The working hours Monday- Friday in three shifts. Chemwerth is the regulatory agent of Tianjin Pacific for three APIs Abiraterone Acetate, Difluprednate, and Clocortolone Pivalate. Chemwerth helped the firm to submit the DMFs to FDA. Chemwerth Pharmaceutical Technology Co., Ltd., a subsidiary of Chemwerth, Inc., is the regulatory and sales agent on behalf of Tianjin Pacific Chemical & Pharmaceutical Co., Ltd.

The previous inspection of 9/2011 was classified as NAI, two verbal comments regarding the insufficient environmental monitoring of the microbiology laboratory and there had been no appropriate monitoring of the laminar flow hoods used in the microbiological sampling rooms was discussed.

INTERSTATE COMMERCE/JURISDICTION
The firm manufactures Active Pharmaceutical Ingredients. **Exhibit #1** is a list of all products being manufactured in this facility. Attached is **Exhibit #2** is a list of products shipped to the Chemwerth since the last inspection. The following DMF have been submitted for review:

Abiraterone Acetate	[redacted]	Filed 7/30/2014
Difluprednate	[redacted]	Filed 7/22/2013
Clocortolone Pivalate	[redacted]	Filed 9/09/2011

At the time of this inspection no DMF were referred in ANDA.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
On 03/30/2015, Credentials were shown to Mr. Song Xiangyi General Manager and the most responsible person on site. **Exhibit # 3** is the firm Organization charts. Also present from Chemwerth (Shanghai Office) was Mr. Jim Yin General Manager, Mr. Wilson Qiu Associate Director Regulatory and GMP Compliance, Mr. Frank Chen, Manager Regulatory and GMP Compliance. In addition I interviewed or discussed operations with the following individuals:

Li Ju	Quality Director
Liu Ning	Quality Manager
Liu Wei	QA Manager
Sun Xiuyu	QC Manager