

Date Assigned: 05/07/2007 **Inspection Start Date:** 05/07/2007 **Inspection End Date:** 05/11/2007
Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd. , 217 Ming Le Road , Pudong Shanghai
Firm Mailing Address:
FEI: 3002914652 **JD/TA:** **County:** **Est Size:** []
Phone: **District:** IOG **Profiled:** Yes
Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

FACTS ASSIGNMENT #838569

PURPOSE:

This is a routine inspection of an API manufacturer. The inspection was conducted as the request of CDER Foreign Inspection Team (FIT) thru the ORA Division of Field Investigation to cover the manufacturing and analysis of Mifepristone bulk active pharmaceutical ingredient (API). The inspection was conducted in accordance to CPGM 7356.002F, Active Pharmaceutical Ingredient (API) Process Inspection under PAC Code 56002F.

HISTORY:

The plant was previously inspected by FDA on July 24-28, 2000 and management was issued the form FDA 483. I reviewed and verified the FDA 483 corrections and found them acceptable on this inspection.

CURRENT FINDINGS/SAMPLES:

I evaluated the Quality, Material, and Laboratory systems, as well as performed a limited review of the Production and Facility and Equipment systems. I found two deficiencies, both noted on the form FDA 483 which was issued to Mr. Yao Ming Gu, President Business Unit of APIs and Intermediates on May 10, 2007 at the closeout meeting.

No sample was collected, but management was provided a copy of Appendix B which contains instructions on submitting profile samples upon FDA request.

CORRECTIONS/REFUSALS:

Mr. Gu promised to respond to the observations in writing.

No refusals were encountered.

RECOMMENDATION: Acceptable - CSN

DISTRICT CLASSIFICATION: VAI

FINAL CLASSIFICATION: Pending

DISTRIBUTION:

Orig & Exhibits: CDER Office of Compliance, DMPQ, FIT (HFD-322)

cc & 483: ORA DFI (HFC-130) w/ no Exhibits

cc cs: [] Investigator []

Endorsement Location: IOG

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
[]	07/30/2007 02:51 PM ET	[]	08/02/2007 02:14 PM ET
[]	06/20/2007 06:52 PM ET		ET
	06/20/2007 06:45 PM ET		ET



FEI:3002914652

Inspection Start Date: 05/07/2007

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Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd. , 217 Ming Le Road , Pudong Shanghai

Related Firm FEI: Name & Address of Related Firm:

Registration Type

Registration Dates

There are no Registration Types

Establishment Type

Industry Code

M	Manufacturer
M	Manufacturer
M	Manufacturer
M	Manufacturer

60	Human and Animal Drugs
64	Human and Animal Drugs
65	Human and Animal Drugs
66	Human and Animal Drugs

District Use Code:

Final Inspection Report

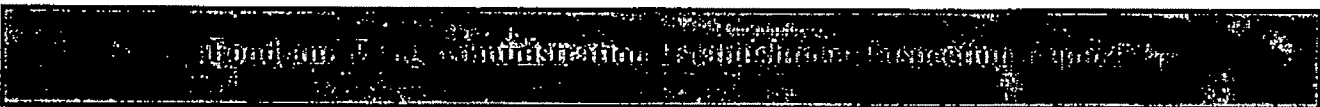
FEI: 3002914652 **Inspection Start Date:** 05/07/2007 **Inspection End Date:** 05/11/2007
Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd., 217 Ming Le Road , Pudong Shanghai

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
56002F	Manufacturer	65 J C S		Surveillance	Correction Indicated (CI)
Final Decision?	District Decision Date	District Decision Type	District Decision Made By		Org Name
Y	07/30/2007	Voluntary Action Indicated (VAI)	[]		CDER-DMPQ

Remarks:



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Inspection Start Date: 05/07/2007

Inspection End Date: 05/11/2007

Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd. , 217 Ming Le Road , Pudong Shanghai

Products Covered

Product Code	Est Type	Description	Additional Product Description
65 J C S 38	Manufacturer	Mifepristone (Progestin); Human - Rx/Single Ingredient; Active Pharm Inged/Chems for Further Manuf	Mifepristone tablets 200mg

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
[]	INV	[]	56002F	Manufacturer	65 J C S	75
Total Hours:						75

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Inspection Start Date: 05/07/2007

Inspection End Date: 05/11/2007

Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd. , 217 Ming Le Road , Pudong Shanghai

Inspection Result

EIR Location
IOG

Trips Num
2007-089D

Inspection Summary
FACTS ASSIGNMENT #838569

This is a routine inspection of an API manufacturer. The inspection was conducted as the request of CDER Foreign Inspection Team (FIT) thru the ORA Division of Field Investigation to cover the manufacturing and analysis of Mifepristone bulk active pharmaceutical ingredient (API). The inspection was conducted in accordance to CPGM 7356.002F, Active Pharmaceutical Ingredient (API) Process Inspection under PAC Code 56002F.

FIRM INFORMATION:

The plant manufactures Mifepristone, Betamethasone } bulk API in separate facilities and equipment. The plant was previously inspected by FDA on July 24-28, 2000 and management was issued the form FDA 483. I reviewed and verified the FDA 483 corrections and found them acceptable on this inspection.

PROCESSES COVERED:

I evaluated the Quality, Material, and Laboratory systems, as well as performed a limited review of the Production and Facility and Equipment systems.

CURRENT FINDINGS:

Deficiencies were found on this inspection and were noted on the form FDA 483, Inspectional Observations. The FDA 483 was issued to Mr. Yao Ming Gu, President Business Unit of APIs and Intermediates on May 10, 2007 at the closeout meeting. Mr. Gu said he will respond to the FDA 483 observations in writing.

FDA 483 Observations:

- (1) The firm does not perform, at a minimum, an identity testing of incoming lots of Before releasing into the manufacturing process for usage.
- (2) The firm does not perform full analysis of incoming lots of In a periodic basis and compare the results to the certificates of analysis.

No refusal was encountered. No sample was collected.

IB Suggested Actions

Action	Remarks
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Referrals

Org Name	Mail Code	Remarks
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Refusals

Inspection Refusals: No refusal

Samples Collected

Date: 08/10/2007

Recall Numbers

Page: 5 of 6

Related Complaints

FEI: 3002914652

Inspection Start Date: 05/07/2007

Inspection End Date: 05/11/2007

Firm Name & Address: Shanghai Hua Lian Pharmaceutical Co., Ltd. , 217 Ming Le Road , Pudong Shanghai

Sample Number

Recall Number

Consumer Complaint Number

FDA 483 Responses

483 Issued?: Y 483 Location: IOG

Response Type	Response Mode	Response Date	Response Summary
Adequate, Requires Verification	Letter	06/20/2007	

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Pudong, Shanghai 200020 P.R. China

FEI: 3002914652
EI: May 7- 11, 2007
[]

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FBI: 3002914652
EI: May 7- 11, 2007
[]

FACTS ASSIGNMENT #838569

SUMMARY OF FINDINGS

This is a routine inspection of an API manufacturer. The inspection was conducted at the request of CDER Foreign Inspection Team (FIT) thru the ORA Division of Field Investigation to cover the firm's manufacturing and analysis of Mifepristone bulk active pharmaceutical ingredient (API), which is used to produce Mifepristone tablets 200mg (NDA 20687). The inspection was conducted in accordance to CPGM 7356.002F, Active Pharmaceutical Ingredient (API) Process Inspection under PAC Code 56002F.

The Shanghai Hua Lin Pharmaceutical plant manufactures Mifepristone, Betamethasone, [] bulk API in separate facilities and equipment. The plant was previously inspected by FDA on July 24-28, 2000. The inspection was classified voluntary action indicated (VAI), and management was issued the form FDA 483 for the following observations:

1. The [] Related Substances test methods and the [] (residual solvent) test method were incompletely validated.]
2. No stability data to support [] month expiration date for Mifepristone working standard
3. The [] method to analyze for impurities was not validated
4. The [] method to analyze for [] residual solvent in Mifepristone was not validated
5. (a) HEPA filter efficiency was not established during validation, and there are no written procedures in place to monitor the efficiency of the HEPA filters on a periodic basis.
(b) The HEPA filter validation did not determine particulate counts under dynamic or working conditions, and there are no written procedures to monitor particulate counts on a periodic basis during production
(c) Pressure differentials of each room relative to the inside corridor of the [] suite are not monitor, and there is no pressure differential monitoring device in the micronizing room.

I reviewed and verified the corrections to the FDA 483 observations on this inspection and found them acceptable.

Prior to beginning the current inspection, I presented my credentials to Mr. Yao Ming Gu, President Business Unit of APIs and Intermediates, who was the most responsible person on site. Mr. Gu delegated responsibility for this inspection to Mr. [] Quality Senior Engineer of the Business Unit of APIs and Intermediates. Mr. [] accompanied me throughout the inspection and facilitated my request for plant tour and record review. During the inspection, I evaluated the Quality, Material, and Laboratory systems, as well as performed a limited review of the Production and Facility and Equipment systems. I found two deficiencies, both noted on the form FDA 483:

- (1) The firm does not perform, at a minimum, an identity testing of incoming lots of [] [] before releasing into the manufacturing process for usage.

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(2) The firm does not perform full analysis of incoming lots of []
[] on a periodic basis and compare the results to the certificates of analysis.

The form FDA 483, Inspectional Observations, was issued to Mr. Yao Ming Gu, President Business Unit of APIs and Intermediates on May 11, 2007 at the closeout meeting. Each FDA 483 observation was discussed with Mr. Gu and management. Mr. Gu promised to respond to the observations in writing.

No refusal was encountered.

ADMINISTRATIVE DATA

Inspected firm: Shanghai Hua Lin Pharmaceutical Plant
of Shanghai Pharmaceutical Group Co., Ltd.
Location: 217 Ming Le Road
Pudong, Shanghai, China
Phone: []
FAX: []
Mailing address: 12th, No. 200, Taicang Road
Shanghai, 200020 P.R. China
Dates of inspection: May 7 - 11, 2007
Days in the facility: 5
Participants: [] Investigator

LOGISTICS

The Jing An Hilton Shanghai is located in downtown Shanghai and has restaurants nearby. It is about 1 hour from the Shanghai Pudong Airport and 1 - 1.5 hours from the plant. Daily transportation to and from the plant is provided by the firm. Phone calls to the US can be made in the hotel room with the government MCI calling card. Internet access is available in the hotel room as well. The weather is warm in May.

HISTORY

The history of the company remains unchanged since last reported in the July 2000 EIR. The plant is still located in the Shanghai Pudong development zone and continues to produce Mifepristone in [] commercial scale batches. The plant employs [] employees with [] working in the quality unit and [] in production. It operates []
[] The factory currently produces Betamethazone []

[] The company organizational chart is shown in Exhibit 1.

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[]

Regulatory Agent

[]

Importer & Broker

[]

FDA Correspondences

Mr. Yao Ming Gu, President
Business Unit of API & Intermediate
12th, No. 200, Taicang Road
Shanghai, 20020 P.R. China
Telephone : []]
Fax: []]

CHANGES

In 2005, the firm changed its business name to Shanghai Hualin Pharmaceutical Plant of Shanghai Pharmaceutical Group Co. Ltd.

PRODUCT DISTRIBUTION

Mifepristone Commercial Scale Batches

Year
2005
2006
2007

[]

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FBI: 3002914652
EI: May 7- 11, 2007
[]

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On May 7, 2007 I presented my credentials to Mr. Yao Ming Gu, President – Business Unit of APIs and Intermediates. Mr. Gu was the most responsible person on site at the opening meeting, and was issued the FDA 483 at the closeout meeting. Mr. Gu delegated inspection responsibility to Mr. [] Senior Manager QA – Business Unit of APIs and Intermediates. Mr. [] accompanied throughout the inspection, facilitated my request for plant tour and document review, and was the back-up interpreter for the company. Ms. [] was the primary interpreter on this inspection. Mr. [] Vice President – Business Unit of APIs and Intermediates was present in the conference room during the inspection but did not participate in the inspection.

Key persons on the inspection

Mr. Gu Yaoming.....President API & Intermediate Business Unit of SPG
Mr. [].....Vice President API & Intermediate Business Unit of SPG
Mr. [].....Senior Manager QA API & Intermediate Business Unit of SPG
Ms. [].....QA Specialist API & Intermediate Business Unit of SPG
Ms. [].....QA Specialist API & Intermediate Business Unit of SPG
Ms. [].....QA Specialist API & Intermediate Business Unit of SPG
Mr. [].....General Manager Shanghai Hualin
Mr. [].....Deputy General Manager Shanhai Hualin
Mr. [].....Deputy General Manager Shanhai Hualin
Ms. [].....Director Quality Department
Mr. [].....Manager QA Department
Mr. [].....Deputy Manager QC Department
Mr. [].....Director Production Department
Mr. [].....Supervisor Logistics
Mr. [].....Supervisor Regulatory Affairs
Mr. [].....Regulatory Specialist
Mr. [].....Supervisor Equipment & Maintenance Dept

The responsibilities of key managers are shown in **Exhibit 2**.

QUALITY SYSTEMS

The firm's quality system is managed by Ms. [] Director Quality Department but daily responsibilities of quality control are carried out by Mr. [] QA Manager and Mr. [] QC Manager. In total they supervise [] employees.

In evaluating the quality system, I reviewed procedures and records on annual product reviews (2004-2006), change controls, manufacturing deviations, laboratory OOS investigation, customer complaints, and employee training. The firm did not do any rework or reprocessing since the last inspection. No major deficiency was found.

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MATERIAL SYSTEM

The plant has [] warehouses

[] The [] warehouses are temperature and humidity controlled.

Aside from spatial segregation, raw materials and finished products are separated by color-coded tags to identify their usage status (i.e. yellow is quarantine; green is approved; orange is sampled). They are sampled according to an approved sampling plan, and each lot is tested to determine conformity to the supplier's COA specifications, except for []

See FDA 483 Observations 1 and 2. Approved raw materials, containers and closures and finished products are used on a first-in, first-out basis.

All records are maintained in hardcopy; no computerized system is used.

MANUFACTURING

I toured the manufacturing facility on May 7 and found the facility and equipments suitable for use. The firm was manufacturing Mifepristone during the inspection. I observed [] (batch MIF-07-0405) in the [] suite on May 9. I noticed lumps of crystals of darker shades of yellow amongst powders of golden yellow in color. The firm tested the lumps for assay and impurity to assure me they were within quality. The analytical results showed the lumps did meet release specifications.

I compared the commercial process in batch records MIF-041006 and MIF-060602 to the DMF process and found them to be similar. I reviewed the COA results against raw data, and found no discrepancy. All manufacturing records are maintained in hardcopy; no computerized system is used.

LABORATORY

The laboratory housed a chemistry and microbiological section and has the proper instruments to analyze Mifepristone. It was found to be well staffed with QC analysts working in the chemistry and microbiological group. The firm's Mifepristone release specifications and test methods were found to be the same as those described in the DMF.

In evaluating the laboratory operations, I reviewed *instrument calibration and maintenance* [] *equipment qualification* [] HL-YZ-4001-01 dated Jan 11, 2006 and [] *qualification report* HL-YZ-4064-00 dated Jan 4, 2006, *holding time study* for [] *intermediate*, and *stability data* supporting the [] retest date. I also reviewed training procedures and selected training records, and found employees are provided with initial and periodic training that commensurate with their job functions.

All laboratory records are maintained in hardcopy; no computerized system is used.

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[]

VOLUNTARY CORRECTIONS

A form FDA 483 dated July 28, 2000 was issued to the firm on the previous inspection. On this inspection, I reviewed and verified the corrective actions to the 483 observations.

OBJECTIONABLE CONDITIONS/DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection a Form FDA 483, Inspection Observations was issued to Mr. Yao Ming Gu, President Business Unit of APIs and Intermediates on May 10, 2007. Individuals present during this discussion are listed in **Exhibit 3**. Each observation was discussed with Mr. Gu and management. Mr. Gu said he will ask Mr. [] Consultant, to respond to the FDA 483 observations in writing on behalf of the company. Mr. [] said he will respond within 30 days.

Observations listed on form FDA 483

OBSERVATION 1

The firm does not perform, at a minimum, an identity testing of incoming lots of [] before releasing into the manufacturing process for usage.

[] and crude Mifepristone, as well as the finished API Mifepristone. [] and transferred to a [] for storage at the plant. When the [] arrives, an employee reviews the Certificate of Analysis and transportation records to ensure the [] is dedicated to transporting. [] Other than reviewing the certificate of analysis, the firm's receiving procedure for [] does not require [] to be tested, at a minimum, for identity.

OBSERVATION 2

The firm does not perform full analysis of incoming lots of [] on a periodic basis and compare the results to the certificates of analysis.

The firm does not perform any analysis of [] before usage.

For [] the firm does not audit the supplier on a periodic basis, nor conduct full specification testing at least annually and compare the test results to the supplier's COA. The firm only performs an identification testing by IR of each new lot at receiving.

REFUSALS

I was not refused any request(s) during the inspection. Firm management provided requested information timely and was cooperative throughout the inspection.

GENERAL DISCUSSION WITH MANAGEMENT

At the beginning of the close out discussion, I pointed out that it was not possible to cover and review all aspects of the firm's operations and, therefore, management should not view the observed deficiencies as all-inclusive. At the conclusion of the close out discussion, I informed management of their responsibilities under the FD&C Act and penalties were also discussed.

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EI: May 7- 11, 2007
[]

Management committed to correct the deficiencies including those presented verbally and stated they would respond formally in writing to each.

SAMPLES COLLECTED

No sample was collected. I provided management with a copy of Appendix B which contains instructions on submitting profile samples upon FDA request.

EXHIBITS COLLECTED

1. Company Organizational Chart
2. Responsibilities of key managers

ATTACHMENTS

Form FDA 483, Inspectional Observations dated May 11, 2007

[]

[]
Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Food and Drug Administration CDER Foreign Inspection Team (FIT) 11919 Rockville Pike, 4 th Floor Rockville, MD 20852 USA	DATE(S) OF INSPECTION May 7 - 10, 2007
	FEI NUMBER 3002914652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Gu Yao Ming, President, Business Unit of APIs & Intermediates

FIRM NAME Shanghai Hua Lian Pharmaceutical Plant of Shanghai Pharmaceutical Group Co. Ltd.	STREET ADDRESS 12 th , No. 200, Taicang Road
--	--

CITY, STATE AND ZIP CODE Shanghai, 200020, P.R. China	TYPE OF ESTABLISHMENT INSPECTED API Manufacturer
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THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) OBSERVED:

1. The firm does not perform, at a minimum, identity testing of incoming lots of [] before releasing for usage.
2. The firm does not perform full analysis of incoming lots of [] on a periodic basis and compare the results to the certificates of analysis.

[] May 10, 2007

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE []	EMPLOYEE(S) NAME AND TITLE (Print or Type) Investigator	DATE ISSUED May 10, 2007
--------------------------	------------------------------	--	-----------------------------

[] [] [] []
[]
U. S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Manufacturing & Product Quality
Foreign Inspection Team, HFD-325
Montrose Metro II
11919 Rockville Pike
Rockville, MD 20852

June 20, 2007

Re: **F.E.I. No.: 3002914652**
Establishment Investigation: May 7 - 10, 2007
Inspectional Observations: Response

Dear Mr. []

Please find herewith enclosed a response to the Inspectional Observations issued at the conclusion of this inspection. A desk copy has been sent to Mr. [] for his reference.

Thank you for your attention.

Sincerely,

[]

[]

[]
President

[]

Encs.

cc: Mr. [] Investigator
U.S. Food and Drug Administration, [] District Office

This document constitutes trade secret and confidential commercial information exempt from public disclosure under 21 C.F.R. 20.61. Should FDA tentatively determine that any portion of this document is disclosable in response to a request under the Freedom of Information Act, Danco Laboratories, LLC requests immediate notification and an opportunity for consultation in accordance with 21 C.F.R. 20.45. Contact telephone number is []

[] []

F.E.I. No.: 3002914652

Inspectional Observations: Response

OBSERVATION: "1. The firm does not perform, at a minimum, identity testing of incoming lots of [] before releasing."

RESPONSE: [] , not for use in []

Considering its intended use and the relative danger and difficulty in testing [] the firm relies on the qualified supplier's release data to approve this auxiliary material for use (Certificates of Analysis). For these reasons, testing of [] [] lots is not performed prior to their release for use.

OBSERVATION: "2. The firm does not perform full analysis of incoming lots of [] on a periodic basis and compare the results to the certificates of analysis."

RESPONSE: In response to the Observation transcribed above please note the following:

- Regarding [] please refer to the response to the previous Observation.
- In order to address the Observation transcribed above, SOP HL-FX-4001 has been revised in order to reflect the specifications and methods followed for the testing and release of lots of [] intended for the packing of drug substances as well as those followed to annually verify critical supplier results as reflected in the Certificates of Analysis provided for every lot shipped to the firm. Please refer to the attached translation of this revised procedure and of the related supplier specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
Foreign Inspection Team, HFD-325
11919 Rockville Pike
Rockville, Maryland 20852

TELEPHONE: []
FAX: []

July 27, 2007

Mr. Yao Ming Gu, President
Business Unit of API & Intermediate
Shanghai Hua Lian Pharmaceutical Co., Ltd
12th No. 200, Taicang Road
Shanghai, 20020 P.R. China

Dear Mr. Gu:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your manufacturing facility in Shanghai, China on May 7-11, 2007 by FDA Investigator [] An FDA-483 Inspectional Observations was issued to you at the conclusion of the inspection.

We have received and reviewed your firm's response dated June 20, 2007 with supportive documentation. Based on this inspection, we are classifying your facility as acceptable for active pharmaceutical ingredients (APIs). However, it remains your responsibility to assure continued compliance with Current Good Manufacturing Practices (CGMPs). This letter is not intended as an endorsement or certification of the facility.

Additionally, we enclosed a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or telephone numbers.

Sincerely,

[]
Compliance Officer
International Compliance Team, HFD-325

Enclosure: