

CDER OC FOREIGN INSPECTION TRACKING SYSTEM DATA FORM

APPLICATION DATA

RECORD: 3418 CONTROL: 322-00-08-0181 DATE ENTERED: 8/18/2000
 CFN: 9615606 FEI: 3002914652 FIRM LOOKUP: FIRM TYPE: MA TYPE 4
 FIRM: SHANGHAI HUA LIAN PHARMACEUTICAL CO LTD - XIN LIAN PHAR
 STREET: 217 MING LE ROAD
 CITY: PUDONG ST-PROV: SHANGHAI COUNTRY: CH

| TYPE | NUMBER | SUPPLEMENT | USER FEE DATE | STATUS |
|------|--------|------------|---------------|--------|
| N | 20-687 | | 9/30/2000 | A |

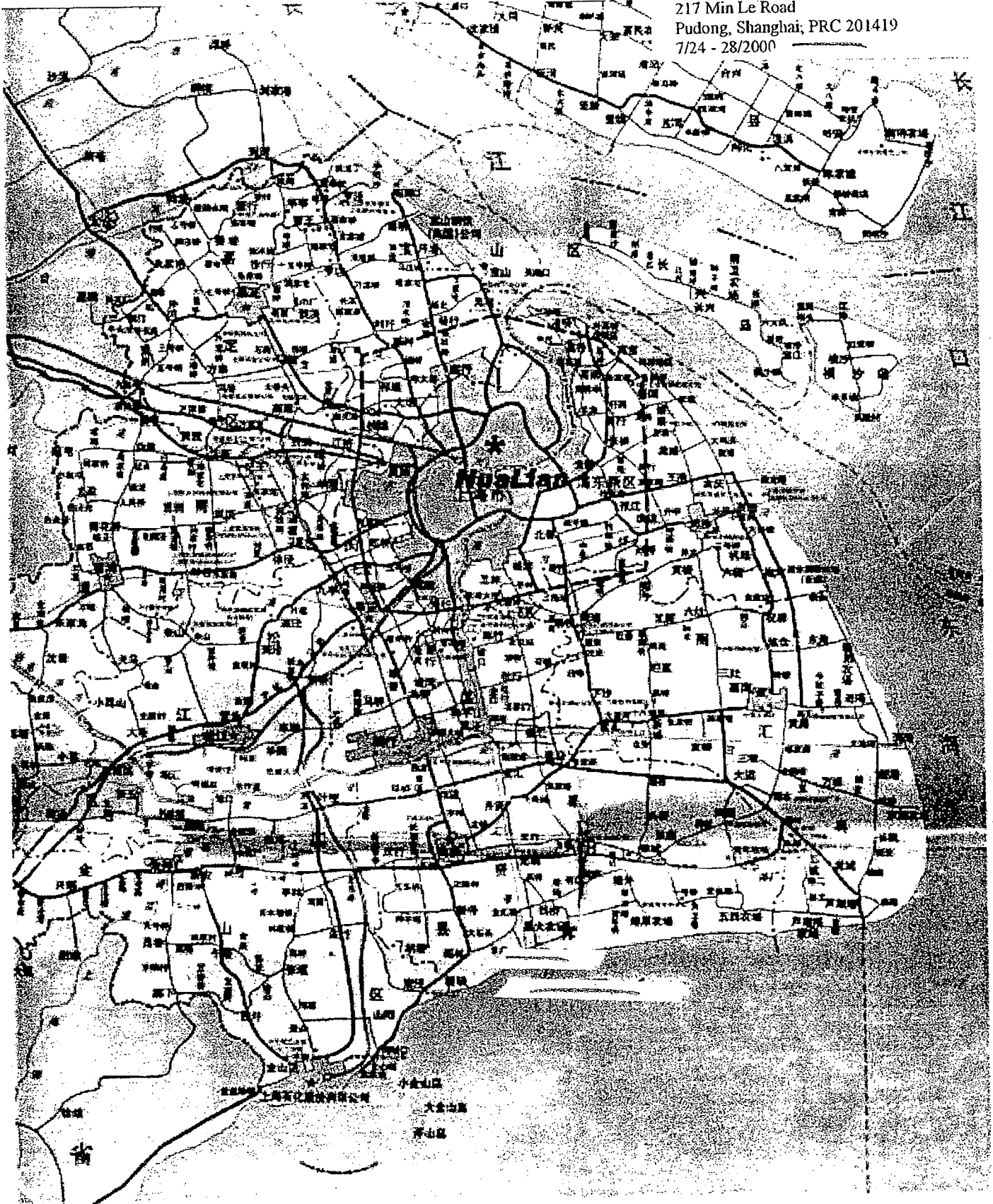
FIRST DATE EI: 7/24/2000 LAST DATE EI: 7/28/2000 DATE ENDORSED: 8/15/2000 DATE OF RECOMM: 8/15/2000
 INITIAL CLASS: AE DATE REC'D: 8/18/2000 ACTION TYPE: EIR PRIORITY: HIGH
 DATE DUE: 8/25/2000 DATE ASSIGNED: 8/21/2000 ASSIGNED TO: CSO COMP. DATE: 8/21/2000
 FINAL CLASS: AE RESC DATE: 05/2003 COMP. ACTION: CON COMP. DATE: 8/21/2000

COMMENTS: This was a compliance reinspection of this API manufactured scheduled following the previous PAI in 10/99 which found several GMP deficiencies and laboratory procedures which were not the same as described in the application. This firm does not have a DMF and the API mfg & testing procedures were submitted in the NDA, An untitled letter was issued 12/99. This inspection verified corrections following the previous inspection and untitled letter. Additional deficiencies re. Methods validation, laboratory standards, and HEPA filter & pressure differentials qualifications were noted. On 8/10, the firm's US agent submitted an interim response to these deficiencies. The firm has corrected or is in the process of correcting all deficiencies, and will be completed by Aug 31. Based on the previous verified corrections, and nature of deficiencies, this commitment appears satisfactory, CDER concurs with approval recommendation. *Final Response 8/18/00 satisfactory*

| PROFILES | STATUS |
|----------|--------|
| CSN | A |

| GMP PROBLEMS |
|--------------|
| 07 |
| 17 |

**APPEARS THIS WAY
ON ORIGINAL**



**CDER OC FOREIGN INSPECTION TRACKING SYSTEM
DATA ENTRY/CONTROL FORM**

CONTROL: 322-99-12-04 CFN : 9615606 **NEW CFN** FIRM TYPE: M TYPE EI: 1

FIRM: SHANGHAI HUA LIAN PHARMACEUTICAL CO LTD - XIN LIAN PHAR

STREET: 217 MING LE ROAD

CITY: PUDONG ST-PROV: SHANGHAI COUNTRY: CH

FIRST DATE EI: 10/25/99 LAST DATE EI: 10/28/99 DATE ENDORSED: 12/3/99 DATE OF RECOMM: 12/3/99

INITIAL CLASS: AA DATE REC'D: 12/14/99 ACTION TYPE: EIR USER FEE DATE: 10/19/99

PRIORITY: HIGH DATE DUE: 12/18/99 DATE ASSIGNED: 12/14/99 CSO: _____

COMPLETED: 12/15/99 FINAL CLASS: AA COMP. ACTION: _____ RESC DATE: 10/00

| TYPE | NUM | SUPPL | RECOM |
|------|--------|-------|-------|
| N | 20-687 | | W |

COMMENTS :

This was the initial inspection of this API manufacturer, covering mifepristone. The facility also manufactures betamethasone on separate equipment. CGMP deficiencies regarding labeling and handling of recycled solvent containers and calibration of a _____ analyzer were noted, but the firm's written response provides satisfactory corrections. The district recommends withholding approval because the laboratory procedures, (raw material, in-process, and finished product) described in the NDA are not the same as used in this laboratory, and the in-process _____ tests used to monitor critical reactions have not yet been finalized or validated. The firm's response states that an amendment has been submitted to correct the NDA errors. We concur in the withhold recommendation re failure to follow NDA commitments. Untitled letter re. NDA deficiencies.

| PROFILE | STATUS |
|---------|--------|
| CSN | N |

| TYPE | PROBLEM |
|------|---------|
| | 3 |
| | 9 |