**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

<table>
<thead>
<tr>
<th>DISTRICT OFFICE ADDRESS AND PHONE NUMBER</th>
<th>DATE(S) OF INSPECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738</td>
<td>08/16-17/2016</td>
</tr>
<tr>
<td>Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a></td>
<td>FEI NUMBER</td>
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<tr>
<td>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED</td>
<td>3010671506</td>
</tr>
<tr>
<td>TO: Zheng Guo Li, General Manager</td>
<td>STREET ADDRESS</td>
</tr>
<tr>
<td>FIRM NAME</td>
<td>South of YueGui Road 118, Huachuan Block</td>
</tr>
<tr>
<td>Zhejiang Bangli Medical Products Co., Ltd.</td>
<td>TYPE OF ESTABLISHMENT INSPECTED</td>
</tr>
<tr>
<td>CITY, STATE AND ZIP CODE</td>
<td>Drug Product Manufacturer</td>
</tr>
<tr>
<td>Yongkang City, Zhejiang Province, CHINA</td>
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**OBSERVATION 1**

There is no Quality Unit.

Specifically, your firm has no Quality Unit. The following responsibilities of a functioning Quality Unit are not performed (this list is not comprehensive):

- There is no stability program
- There is no practice of retaining reserve samples
- There are no Master Batch Records maintained
- There is no control of drug product labeling
- There is no practice of performing line clearance
- There is no Quality Control Laboratory to determine the purity/potency of drug products
- There is no examination and/or testing of Raw Material APIs
- There is no cleaning validation program
- There are no equipment cleaning procedures established
- There is no equipment qualification program
- There is no equipment maintenance program
- There is no process validation program
- There is no deviation investigation program
- There is no OOS investigation program
- There is no change control program
- There is no complaints investigation procedure
- There is no annual product review performed

**DATE ISSUED**

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<tr>
<th>08/17/2016</th>
<th>EMPLOYEE(S) NAME AND TITLE (Print or Type)</th>
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<tr>
<td>Peter E. Baker, Investigator</td>
<td></td>
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**FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE**

**INSPECTIONAL OBSERVATIONS**
OBSERVATION 2

Production Batch Records do not include complete data.

Specifically, your production batch records do not include basic information including (but not limited to):

- The batch numbers for APIs used in the formulation
- The drug formulation information
- Excipients used in the manufacturing process
- Equipment used during the manufacturing process
- Manufacturing instructions (time [ ] etc.)

OBSERVATION 3

There is no final disposition decision for finished drug products.

Specifically, your firm lacks a Quality Control Laboratory. Additionally, there are no quality agreements in place with any customers to delegate who is responsible for determining conformance to the specifications (e.g. purity, potency).

There is no assurance that distributed drug products are to be tested for conformance to product specifications prior to patient use.

OBSERVATION 4

Peter E. Baker, Investigator

08/17/2016
Specifically, during this inspection your firm did not provide any documentation generated prior to January 2016 despite numerous requests. No explanation was provided regarding the refusal to provide information for drug product distributed to the United States prior to this date.

Additionally, your firm refused to provide full distribution information for drug products exported to the United States. Your firm refused to provide product names, batch numbers, and dates of distribution for those products exported to the United States.

OBSERVATION 5

Distribution procedures are inadequate.

Specifically, your firm receives finished drug product from contract manufacturers. These products are labeled at your facility indicating that they are manufactured by your firm, and then shipped to consumers in the United States. There is no finished product testing data available for these products indicating the suitability for human use. Your firm refused to provide the amount of drug products distributed in this manner.

OBSERVATION 6

Batch records were not made available for review.

Specifically, your firm refused to provide batch records for multiple products exported to the United States (e.g. [redacted] Patch, [redacted] Patch, among others). No explanation was provided regarding the reason for refusing this request.
OBSERVATION 7

In-Process controls are inadequate.

Specifically, during my walk-through inspection of the manufacturing unit on 08/16/16, I noted the presence of several [redacted] co-mingled patches of different sizes and colors within the [redacted] area. These products were unlabelled, and the batch numbers could not be determined. According to the responsible manufacturing employee, these are [redacted] products. This employee was unaware that products are to be assigned batch numbers and identified/stored appropriately.

OBSERVATION 8

Drug products are manufactured in insanitary conditions.

Specifically, during my walk-through inspection of the manufacturing unit on 08/16/16, I noted the presence of [redacted] flies within the [redacted] patch manufacturing area. The product contact surfaces were covered in a layer of residue buildup, including what appeared to be residual API from the previously manufactured product.

OBSERVATION 9

There is no practice of labeling APIs.

Specifically, during my walk-through inspection of the manufacturing unit on 08/16/16, I noted the presence of multiple unlabeled drums of APIs to be used in manufacturing. There is no documentation available to determine the batch number, supplier information, or any other critical data for these unlabeled drums.
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STREET ADDRESS
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TYPE OF ESTABLISHMENT INSPECTED
Drug Product Manufacturer

OBSERVATION 10
Manufacturing equipment is not maintained appropriately.
Specifically, during my walk-through inspection of the manufacturing unit on 08/16/16, I noted the presence of lubrication oil leaking into product contact surfaces within your (blank) patch manufacturing equipment. Your (blank) patch manufacturing equipment appeared to be in significant disrepair. The responsible employees were unable to determine the type of oil being used, as the container was unlabeled.

OBSERVATION 11
Training practices are inadequate.
Specifically, your cGMP training presentation is provided by your administration department. When interviewed, the administration employee who provided the most recent training was unable to describe the basic contents of his PPT slides, and has no previous experience with cGMP regulations.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Peter E. Baker, Investigator

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08/17/2016

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 5 of 5