DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	08/16-17/2016
	FEI NUMBER 3010671506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zheng Guo Li, General Manager

FIRM NAME	STREET ADDRESS
Zhejiang Bangli Medical Products Co., Ltd.	South of YueGui Road 118, Huachuan Block
CITY, STATE AND ZIP CODE Yongkang City, Zhejiang Province, CHINA	TYPE OF ESTABLISHMENT INSPECTED Drug Product Manufacturer

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) (WE) OBSERVED:

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Peter E. Baker, Investigator	08/17/2016

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	08/16-17/2016
	FEI NUMBER 3010671506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zheng Guo Li, General Manager

FIRM NAME	STREET ADDRESS
Zhejiang Bangli Medical Products Co., Ltd.	South of YueGui Road 118, Huachuan Block
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yongkang City, Zhejiang Province, CHINA	Drug Product Manufacturer

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 (b) (4) 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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	PEB	Peter E. Baker, Investigator	08/17/2016

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	08/16-17/2016
	FEI NUMBER 3010671506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zheng Guo Li, General Manager

FIRM NAME	STREET ADDRESS
Zhejiang Bangli Medical Products Co., Ltd.	South of YueGui Road 118, Huachuan Block
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yongkang City, Zhejiang Province, CHINA	Drug Product Manufacturer

There is no document control program.

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. (b) (4) Patch, (b) (4) Patch, among others). No explanation was provided regarding the reason for refusing this request.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	PEB	Peter E. Baker, Investigator	08/17/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	08/16-17/2016
	FEI NUMBER 3010671506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zheng Guo Li, General Manager

FIRM NAME	STREET ADDRESS
Zhejiang Bangli Medical Products Co., Ltd.	South of YueGui Road 118, Huachuan Block
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yongkang City, Zhejiang Province, CHINA	Drug Product Manufacturer

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 (b) (4) co-mingled (b) (4) patches of different sizes and colors within the (b) (4) area. These products were unlabeled, and the batch numbers could not be determined. According to the responsible manufacturing employee, these are "(b) (4)" 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 TNTC flies within the (b) (4) 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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	PEB	Peter E. Baker, Investigator	08/17/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Bldg 51, Rm 4225 Silver Spring, MD 20993 Phone: (301)-796-3334 Fax: (301)-847-8738 Industry Information: www.fda.gov/oc/industry	08/16-17/2016
	FEI NUMBER 3010671506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zheng Guo Li, General Manager

FIRM NAME	STREET ADDRESS
Zhejiang Bangli Medical Products Co., Ltd.	South of YueGui Road 118, Huachuan Block
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Yongkang City, Zhejiang Province, CHINA	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 (b) (4) patch manufacturing equipment. Your (b) (4) 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)*	DATE ISSUED
		Peter E. Baker, Investigator	08/17/2016