DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA, CDER 10903 New Hampshire Avenue, WO51, Rm 5226 Silver Spring, MD 20993	September 16-20, 2013
	FEI NUMBER 307740441

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Yunxia Sun, Facility Manager

FIRM NAME	STREET ADDRESS
Joinn Laboratories Co., Ltd.	5 Rongjingdong Street
CITY, STATE AND ZIP CODE Beijing, China 100176	TYPE OF ESTABLISHMENT INSPECTED Good Laboratory Practice Facility

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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.

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1. The QAU failed to review the final study report to assure that the reported results accurately reflect the raw data of the study. Specifically,

A) the study report for Study (b) (4) states that body weight decreased by 21 percent for animal 11-7712 on day 17. However, the study table and raw data record show that animal 11-7712 had a 21 percent decrease in body weight on day 21.

B) the toxicokinetic report for Study (b) (4) states that the day 1 samples were assayed from June 6 to June 8, 2012. However, the raw data show that the day 1 samples were assayed from June 7 to June 11, 2012.

2. The study director failed to assure that the protocol, including any change, was approved and followed. Specifically,

A) for Study (b) (4), no protocol deviation was issued for the testing facility not receiving the toxicokinetic report from the test site within 50 days after shipment of the last toxicokinetic samples as stated in the study protocol.

B) for Study (b) (4), no protocol deviation was issued for the failure to retain reserve samples of (b) (4) (control article) as stated in the study protocol.

3. The study director failed to assure that all raw data, documentation, protocols, specimens, and final reports were transferred to the archives during or at the close of the study. Specifically, for Study (b) (4) external and internal correspondences were not retained in the study records.

4. The study director failed to assure that all experimental data were accurately recorded and verified. Specifically, in Study (b) (4), the dosing record shows that animal 10-1623 was treated with the test article formulation on 6/3/2010. However, animal 10-1623 died on 5/30/2010.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Francis J. Eng	Francis J. Eng- Investigator NIRAJ R. MEHTA- Pharmacologist ZHOU CHEN, Pharmacologist	9/20/2013