DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	02/12/2013 - 02/27/2013* FEI NUMBER 3004839646

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brian D. Williamson, President & CEO

FIRM NAME	STREET ADDRESS
JCB Labs LLC	7335 W 33rd. St. N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wichita, KS 67205-1225	Producer of Sterile Drug Products

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 WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm's contract laboratory Certificate of Analysis, dated 01/04/2013, for repackaged Propoven (propofol) 1% - 20 mL injection, Lot 121030@1, reads in part; "***the method(s) used for testing are not validated***". As such, you do not have scientifically sound test procedures to assure that the components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, according to Section 6.0 of your firm's "Environmental Monitoring of the Cleanroom Facility Procedure No.: 3.020", date effective: 09/21/12; the frequency of your environmental monitoring program is as follows:

- Air Samples (non-viable & viable) performed (b) (4)
- Surface Samples in Class 5 area performed (b) (4)
- Surface Samples in Class 7/8 areas performed (b) (4)

On 2/12/13, your firm's President/CEO stated environmental monitoring is not performed with each production run of Propoven (propofol) 1%, however, microbial surface sampling is performed (b) (4) (b) (4) Propofol is a known microbial growth promoting formulation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Monica M McClure, Investigator Janet B. Abt, Investigator Michael S. Kopf, Investigator	02/27/2013

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	02/12/2013 - 02/27/2013* FEI NUMBER 3004839646

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brian D. Williamson, President & CEO

FIRM NAME	STREET ADDRESS
JCB Labs LLC	7335 W 33rd. St. N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wichita, KS 67205-1225	Producer of Sterile Drug Products

OBSERVATION 3

Deviations from written production and process control procedures are not recorded and justified.

Specifically, your firm's batch record for Propoven (propofol) 1%, Lot 121108@4, revealed the following written process directions: (b) (4) [redacted].

However, on 2/12/13, your firm's President/CEO stated you are not following the written directions on the batch record; he described the actual procedure used to repackage Lot 121108@4 and all subsequent batches of propofol is as follows: (b) (4) [redacted].

Furthermore, you deviated from your established process during the repackaging of Propoven (propofol) 1%, Lot 121108@4, by venting the source vial to the pharmacy atmosphere without adequately determining what effects this has on finished product quality attributes. In addition, your firm's President/CEO stated the need to vent vials is common during the repackaging process of Propoven (propofol) 1%, and the venting process is not routinely recorded on batch records when it occurs.

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Your firm has not established a stability testing program for repackaging Propoven (propofol) 1%. In addition, you have set a Beyond Use Date of 45 days for repackaged Propoven (propofol) 1% using an unvalidated analytical method, which has not been shown to be stability indicating.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Monica M McClure, Investigator Janet B. Abt, Investigator Michael S. Kopf, Investigator	02/27/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax:(913) 495-5115 Industry Information: www.fda.gov/oc/industry	02/12/2013 - 02/27/2013* FEI NUMBER 3004839646

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brian D. Williamson, President & CEO

FIRM NAME	STREET ADDRESS
JCB Labs LLC	7335 W 33rd. St. N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wichita, KS 67205-1225	Producer of Sterile Drug Products

*** DATES OF INSPECTION:**
02/12/2013(Tue), 02/15/2013(Fri), 02/19/2013(Tue), 02/27/2013(Wed)

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Monica M McClure, Investigator Janet B. Abt, Investigator Michael S. Kopf, Investigator	02/27/2013