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	11/16/2015-12/3/2015* FEI NUMBER 3004839646

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brian D. Williamson , PharmD and President

FIRM NAME	STREET ADDRESS
JCB Laboratories LLC	7335 W 33rd St N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wichita, KS 67205-9368	503B Outsourcing Facility

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 drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, you have not validated all of the strength testing for your finished pharmaceutical products. You currently manufacture [redacted] different types of pharmaceutical products; [redacted] of these products do not have a validated strength testing method, which you perform for final release of your product(s).

OBSERVATION 2

The master production and control records are deficient in that they do not include complete manufacturing and instructions and testing .

Specifically, your Betamethasone Sodium Phosphate Injectable 6 mg/ml solution batch records do not specify if an [redacted] can be used to [redacted] in step [redacted] of their batch record. You also do not record the amount of [redacted]. In addition, you do not follow step [redacted] of this manufacturing procedure. The procedure says you will [redacted] vials, but you [redacted] the vials. Lastly, you do not record check fill volumes prior to using the [redacted] in the aseptic filling process.

Specifically, for Lidocaine Jelly a.k.a. Tropicamide 0.2% / Cyclopentolate 0.2% / Phenylephrine 0.5% / Ketorolac 0.1% / Lidocaine Jelly 0.4%, the batch record does not contain adequate detailed instructions on how to mix the product. For example in step [redacted] of your production record, it says to [redacted]. There is no time requirement and

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	Carl A Huffman, Investigator Brett R Havranek, Investigator X Carl A Huffman 12/3/2015 Carl A Huffman Investigator Signed by: Carl A. Huffman -S	12/3/2015

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there are no instructions on how to (b) (4). In addition, the procedure does not record when your employees perform check fill volumes prior to filling product. This product has had 5 batches (140827@31, 141118@12, 150305@6, 150312@1, and 150811@7) with sub-potency testing on the various API's found in this product postproduction. These are documented in your deviation reports in DEV-2015-122, DEV-2015-123 and DEV-2015-306.

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, for DEV-2015-306, discovered on 8/12/2015, you documented that you had no CAPA action planned for your latest sub-potent batch of product, except that you will continue to monitor all batch failures and note any trends. You identified "Potential human error." as a possible cause; however, there is no justification for this reason recorded in the deviation report. In addition, you did not identify or discuss that this manufacturing method is not validated, nor is the strength testing method validated. In fact, no root cause was identified, nor a CAPA initiated to try and prevent the problem from occurring again. This product, Lidocaine Jelly a.k.a. Tropicamide 0.2% / Cyclopentolate 0.2% / Phenylephrine 0.5% / Ketorolac 0.1% / Lidocaine Jelly 0.4%, has had 5 batches (140827@31, 141118@12, 150305@6, 150312@1, and 150811@7) with sub-potency testing on the various API's found in this product postproduction. These are documented in your deviation reports in DEV-2015-122, DEV-2015-123 and DEV-2015-306.

Specifically, we discovered a single vial of lot # 150518@2 of Betamethasone separated in the retain samples, that appears to have particles and a low fill, and had no investigation written up on it. This lot was implicated in DEV-2015-286, which details a complaint with five patient illnesses.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

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- The location of the settling plates is inadequate to monitor the filling of the sterile product or the (b) (4), because they are unable to indicate whether any viable organisms were released over the product during the (b) (4).

  Specifically, in your Environmental Monitoring (EM), you monitor the (b) (4) (b) (4), where your aseptic filling takes place. The settling plates for EM (b) (4) are placed (b) (4) (b) (4) to the filling area where product is filled (b) (4)(b) (4).

- You do not document that you perform EM sampling in all appropriate locations.

  In the (b) (4) you perform surface sampling (b) (4) plates) in multiple areas; however, you do not document that you perform surface sampling (b) (4) plates) on (b) (4) (b) (4) within this (b) (4).

  First, you have (b) (4) located in the (b) (4) but (b) (4) (b) (4) is listed on the EM schedule and no records exist showing the monitoring of the other (b) (4). These (b) (4) are directly behind the employees performing (b) (4) sterile filling. On 11/17/2015, we observed these employees extensively using this workspace during filling operations to (b) (4) as a writing surface to document filing, and as the surface to change sterile gloves.

  In addition, your mobile (b) (4) is located within the Aseptic Fill room. This (b) (4) is used to help (b) (4) after wiping with sterile (b) (4). Neither the (b) (4) nor (b) (4) handle are listed in your EM schedule.

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Lastly, you do not document exact locations where surface samples (b) (4) plates) are taken – only general areas such as " (b) (4) of the (b) (4) or (b) (4) (b) (4)

OBSERVATION 5

The container labels of your outsourcing facility?s drug products are deficient.

Specifically, the outer container packaging lacks route of administration for the following pharmaceuticals:

- Epinephrine 1:1000 1 mg/mL
- Lidocaine HCL 4%, Epinephrine 0.05%, Tetracaine HCL 0.5% Topical 3 ml
- Lidocaine HCL 1%, Phenylephrine HCL 1.5% 1 ml single use syringe
- Tropicamide 1%, Cyclopentolate 1%, Phenylephrine 2.5%, Ketorolac 0.5% 0.5 mL single use syringe
- Bevacizumab (Avastin) 2.5 mg/0.1mL single dose injection

For example the outer packaging for Epinephrine 1:1000 1 mg/mL is shipped in an opaque blue bag. You are unable to read the inner labeling, which contains the name of the drug and how it is used.

*DATES OF INSPECTION

11/16/2015(Mon),11/17/2015(Tue),11/18/2015(Wed),11/19/2015(Thu),11/20/2015(Fri),12/02/2015(Wed),12/03/2015(Thu)

12/3/2015

X Brett R Havranek
Brett R Havranek
Investigator
Signed by: Brett R. Havranek -S

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."