DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration U.S. Embassy Shantipath, Chanakyapuri New Delhi 110 021 India Industry Information: www.fda.gov/oc/industry	16-22 August 2017
	FEI NUMBER 3006323506

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Anil Kumar Anand, Associate Director - Clinical Operations

FIRM NAME	STREET ADDRESS
Lotus Labs Private Limited	141/2, John Nagar, Koramangala III Block
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bangalore - 560 034, India	CRO

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

A. You performed study-specific screening procedures without obtaining prior informed consent.

You performed screening Fecal Occult Blood Tests (FOBT), Bleeding Tests (BT), Spirometry, and Ophthalmology Exams without obtaining prior informed consent for these procedures. For example:

- Study # (b) (4) FOBT and BT for Subjects (b) (6) and (b)
- Study # FOBT and BT for Subjects (b) (6), and (b)
- Study # BT for Subjects (b) (6), and (b). Spirometry and Ophthalmology Exams for Subjects (b) (6) and (b) (6)

The screening Informed Consent Document does not address risks/benefits or alternatives to screening, does not provide contact information for questions regarding participation in research, and does not addresss the voluntary nature of participation in screening procedures.

B. You failed to follow-up an Adverse Event until its resolution.

Study # (b) (4) Subject (b) (6) experienced adverse event (AE) Undisplaced Right Scaphoid Fracture on 3-Apr-2016. On 7-Jun-2016, a study note documented, "Recent x-ray was found to be showing 'fracture union', and wrist flexion was found to be painfully restricted terminally, and he was advised to light work for next 6 weeks." You reported this AE as resolved on 7-Jun-2016 and there was no follow-up on this AE beyond 7-Jun-2016.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Jennifer C. Adams, Assistant Country Director	22-Aug-2017

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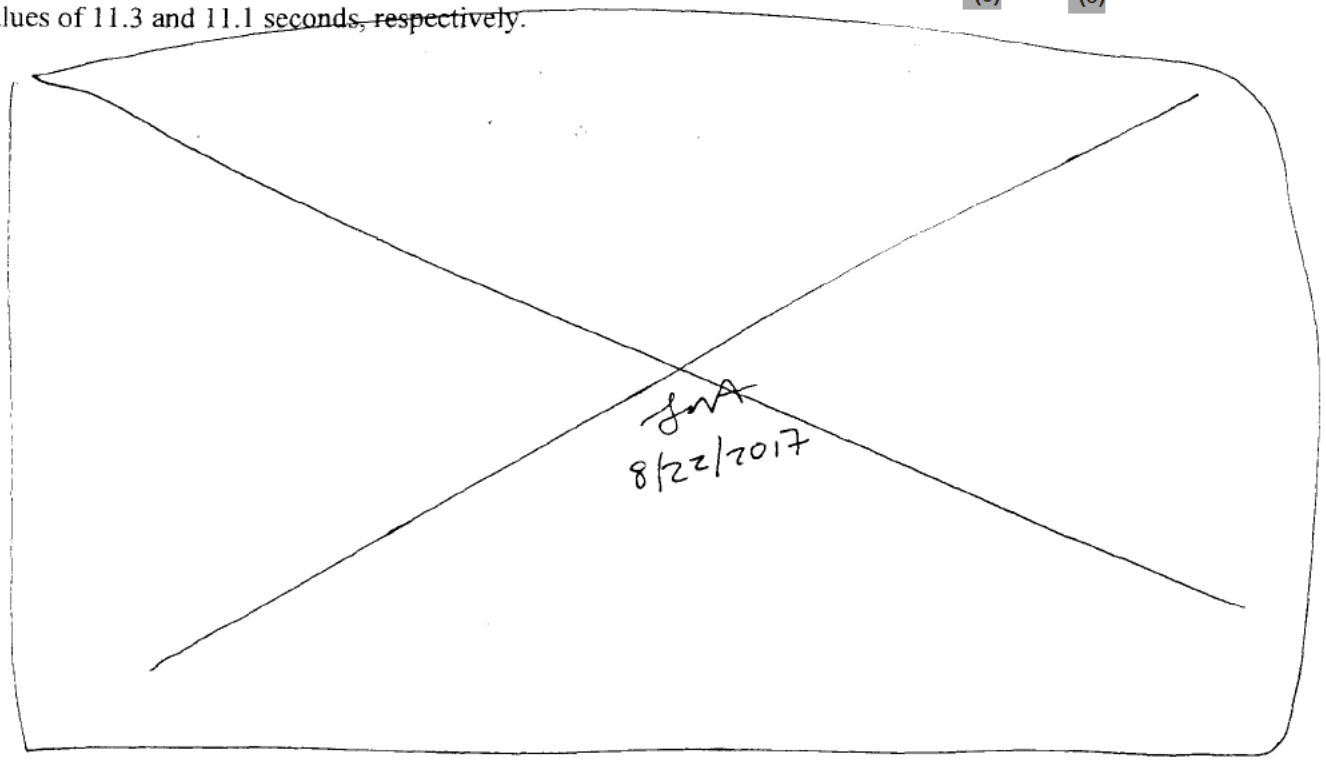
C. You enrolled subjects meeting exclusion criteria.

Study # (b) (4) Protocol excludes subjects with a history or presence of abnormal Activated Partial Thromboplastin Time (APTT). The Protocol Appendix shows the reference range for APPT as 27-37 seconds. Subject # (b) (6) had a screening APTT value of 38.4 seconds.

Study # (b) (4) Protocol excludes subjects with a history or presence of abnormal Prothrombin Time (PT). The Protocol Appendix shows the reference range for PT as 12-16 seconds. Subjects # (b) (6) and # (b) (6) had screening PT values of 11.3 and 11.1 seconds, respectively.



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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 judgement, 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."