DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	05/20/2014 - 05/28/2014* FEI NUMBER 3010768898

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Norman E. Lepor, Principal Investigator

FIRM NAME	STREET ADDRESS
Norman Lepor	99 North La Cienega Blvd. #203 Westside Medical Associates of LA
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Beverly Hills, CA 90211	Clinical Investigator

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 OBSERVED:

OBSERVATION 1

Investigational drug disposition records are not adequate with respect to dates and quantity.

Specifically, the date returned and quantity returned is not available for the following subjects for study (b) (4) :
Subject (b) (6), (b) (7)(C)
Subject
Subject

*** DATES OF INSPECTION:**
05/20/2014(Tue), 05/21/2014(Wed), 05/22/2014(Thu), 05/23/2014(Fri), 05/28/2014(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Comyar Shoghi, Investigator 	05/28/2014