DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	12/7/2015-12/9/2015 FEI NUMBER 1371719

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Robert R. Mayo, M.D. , Chief Medical Officer

FIRM NAME	STREET ADDRESS
Rochester General Hospital	1425 Portland Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, NY 14621-3001	User 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Written MDR procedures have not been implemented .

Specifically, written MDR procedures have not been fully implemented in that MDR event files do not include complete documentation of your deliberations and decision making process including documentation required for your MDR Decision pathway. For example, MDR events referencing patient identifier b(6) and patient identifier b(6) Additionally, you have not demonstrated that your procedures are providing for timely and effective identification, communication and evaluation of events that may be subject to MDR requirements. For example, this includes events referenced under incident reports (b) (6), (b) (6), (b) (6) and (b) (6).

Annotations to Observations

Observation 1: Promised to correct

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nicholas C Mendiola, Investigator 12/9/2015 X Nicholas C Mendiola Nicholas C Mendiola Investigator Signed by: Nicholas C. Mendiola -S	12/9/2015

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."