DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	12/3/2015-1/11/2016* FEI NUMBER 3005310193

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael S. Wiegel , Director of Risk Management

FIRM NAME	STREET ADDRESS
Advocate Lutheran General Hospital	1775 Dempster St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Park Ridge, IL 60068-1143	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

The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility.

Specifically, 10 of 10 deaths of patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) procedures with a potential Carbapenem-resistant Enterobacteriaceae (CRE) infected duodenoscope were not reported.

OBSERVATION 2

The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility.

A. Specifically, 39 of 39 confirmed positive cases of CRE were not reported to the manufacturer after these patients underwent an ERCP procedure with a duodenoscope.

B. Specifically, 4 of 7 mandatory reports filed in b(3) were not sent to FDA within the required 10 working days. The MDR reports did not contain the date that the user facility became aware of the event.

1. Patient Identifier: b(3) b(6) "Date of event: b(3) b(6) ; Date of This Report: b(3) "

AMENDMENT 1

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Brittani N Franklin, Investigator
Brittani N. Franklin 1/11/16

1/11/2016
X Brittani N Franklin
Brittani N Franklin
Investigator
Signed by: Brittani N. Franklin -5

DATE ISSUED
1/11/2016

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2. Patient Identifier: b(3) b(6) "Date of event: b(3) b(6) ; Date of This Report: b(3)

3. Patient Identifier: b(3) b(6) "Date of event: b(3) b(6) ; Date of This Report b(3) "

4. Patient Identifier: b(3) b(6) "Date of event: b(3) b(6) Date of This Report: b(3)

C. Specifically, 7 of 7 mandatory reports were not sent to the manufacturer, even though the manufacturer was known.

OBSERVATION 3

An MDR adverse event report was submitted on a form other than FDA Form 3500A (MEDWATCH form) or an approved electronic equivalent.

Specifically, 9 events were reported using the FDA 3500, Voluntary reporting form , for "Product Problems" between b(3) b(3) in which the "Required Intervention to Prevent Permanent Impairment/Damage ", "Hospitalization- initial or prolonged" , and "Life Threatening " boxes were checked. For example:

1. Patient Identifier: b(3) - Event description: b(3) b(3) "Life Threatening" box was checked.
2. Patient Identifier: b(3) b(6) - Event description: b(3) b(3) "Required Intervention to Prevent Permanent Impairment/Damage (Devices)" box was checked.
3. Patient Identifier: b(3) b(6) - Event description: b(3) b(3)

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OBSERVATION 4

MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable.

All reportable events are maintained together in one file, separated by the year of the event. The only information in the file is the 3500 or 3500A. No supporting documentation is included or referenced therein.

OBSERVATION 5

The user facility report submitted on FDA Form 3500A did not include all information reasonably known.

Specifically, Block F (user facility information) was omitted from all of the mandatory reports submitted in (b)(3) There were 7 mandatory reports submitted in (b)(3)

OBSERVATION 6

The written MDR procedure does not include documentation and recordkeeping requirements for all Medical Device Reports and information submitted to FDA and device manufacturers .

Specifically, the MDR site policy (policy #: LGH-061-008) does not require:

A. Documentation of all information evaluated to make a reportability decision, including patient records and laboratory results;

B. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

OBSERVATION 7

Written MDR procedures have not been developed .

Specifically, the procedure does not:

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brittani N Franklin, Investigator Brittani N. Franklin 1/11/16 X Brittani N Franklin Brittani N Franklin Investigator Signed by: Brittani N. Franklin -S	1/11/2016

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A. Require a standardized review process or procedure to determine when an event meets the criteria for reporting;

B. Deliniate specific time frames for evaluation and/or reporting an adverse event;

C. Define record retention time frames;

D. Distinguish between the use of the voluntary report (3500) and the mandatory report (3500A);

E. Define what constitutes a voluntary report vs. a mandatory report;

F. Require the use of the FDA 3500/3500A form, but rather allows reporting verbally; and,

G. Define "appropriate" in the context of, "Risk Management will send appropriate information to the FDA on an annual basis..."

Annotations to Observations

Observation 1: Not annotated
Observation 2: Not annotated
Observation 3: Not annotated
Observation 4: Not annotated
Observation 5: Not annotated
Observation 6: Not annotated
Observation 7: Not annotated

***DATES OF INSPECTION**
12/03/2015(Thu),12/07/2015(Mon),12/10/2015(Thu),12/16/2015(Wed),12/22/2015(Tue),1/08/2016(Fri),1/11/2016(Mon)

AMENDMENT 1

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	Brittani N Franklin, Investigator Brittani N. Franklin 1/11/16 X Brittani N Franklin Investigator Signed by: Brittani N Franklin -S	1/11/2016

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."