DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration, ORA, NYK-DO 158-15 Liberty Avenue, Jamaica, NY 11433, USA Phone: 718-340-7000 Fax: 301-662-5651 Email: ORANYKFirmResponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	December 6, 7, 8 19 & 22, 2016
	FEI NUMBER 3012729025

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Hans G. Go, Director, Pharmacy Operations

FIRM NAME	STREET ADDRESS
Magellan Rx Pharmacy, LLC	31-75 23rd Street, Suite 410
CITY, STATE AND ZIP CODE Astoria, NY 11106	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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
Inadequate aseptic practices were observed. Specifically,

(A) Personnel were observed donning sterile gloves in the non-classified anteroom.
(B) Personnel failed to disinfect or change gloves frequently enough to prevent contamination between the compounding of each chemotherapy prescription.
(C) Personnel engaged in aseptic processing were observed leaving and re-entering the cleanroom from the non-classified anteroom without first replacing gowning apparel.
(D) Personnel were observed using a non-sterile (b) (4) inside the ISO 5 (b) (4) hood which could come in contact with any sterile components of the IV delivery system.
(E) Personnel were observed touching equipment or other surfaces located outside of the ISO 5 (b) (4) hood with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.
(F) Failure to remove jewelry, such as earrings, prior to entering the cleanroom according to Policy and Standards# OP.353.03-2015, entitled, "Compounding", effective April 11, 2015. An operator was observed wearing a loop earring in the cleanroom not covered by any gowning apparel or bouffant cap on December 8, 2016.

Observation 2
There is an inadequate facility design and equipment use for sterile operation. Specifically,

(A) The facility design was observed to allow the influx of non-classified quality air from the anteroom into the ISO 7 cleanroom.
(B) A sink is present in the cleanroom located approximately 12 feet away from the ISO 5 (b) (4) hood.
(C) Failure to operate the ISO 5 (b) (4) hood continuously according to Policy and Standards# OP.354.04.1, entitled, "Equipment and Sanitizing", effective July 10, 2014.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Alice S. Tsao, CSO Mindy Chou, Investigator Rachael Moliver, Investigator	12/22/2016

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Observation 3
Your firm fails to have adequate cleaning and disinfecting practices in the aseptic processing areas. Specifically,

(A) Failure to clean ISO 5 (b) (4) hoods before its use according to Policy and Standards# OP.354.04-1, entitled, "Equipment and Sanitization" effective June 10, 2014.
(B) Cleaning wipes used in the ISO 5 (b) (4) hoods are not sterile and lint free.
(C) Sporicidal agents are not used in your facility's cleanroom and the ISO 5 (b) (4) hoods.
(D) Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

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		Alice S. Tsao, CSO Mindy Chou, Investigator Rachael Moliver, Investigator	12/22/2016