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	June 28 & 29; July 8, 2016
	FEI NUMBER 2434377

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William R. Grace M.D.

FIRM NAME	STREET ADDRESS
William R. Grace M.D. P.C.	945 Fifth Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
New York, NY 10021	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

The cleaning, disinfecting and upkeep of the equipment used to produce and prepare sterile drug products are inadequate. Specifically,

(A) Non sterile wipes are used to clean and wipe down the surfaces of the Class II (b) (4) at the (b) (4) regardless the number of usage throughout the day.

(B) (b) (4) at unknown concentration is used to clean the Class II (b) (4) (b) (4) .

(C) Apparent brownish soiled material was observed on the inside bottom edges of the Class II (b) (4)

(D) The (b) (4) certification of the Class II (b) (4) was not performed (b) (4) and the certification raw data from (b) (4) were not available for review.

OBSERVATION# 2

Inadequate aseptic techniques demonstrated by the operators who prepare and handle sterile drug products. Specifically, during the simulation performed by the operators on (b) (4) it was observed that

(A) Non sterile gloves were used in the preparation of sterile drug products inside the Class II (b) (4) .

(B) The operators have never received any training nor have been qualified to prepare sterile drug products.

OBSERVATION# 3

Inadequate facility design to prevent microbiological contamination of sterile drug products. Specifically,

(A) The Class II (b) (4) is located next to the main refrigerator and in close proximity of the (b) (4) area without any air quality control in the surrounding area.

(B) A sink is located approximately five feet away from the Class II (b) (4) .

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	07/08/2016

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	June 28 & 29; July 8, 2016
	FEI NUMBER 2434377

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William R. Grace M.D.

FIRM NAME	STREET ADDRESS
William R. Grace M.D. P.C.	945 Fifth Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
New York, NY 10021	Producer of Sterile Drug Products

OBSERVATION# 4

Drug products purporting to be sterile are not tested to determine conformance to such requirements. Specifically,
(A) The IV flush bag containing (b) (4) does not bear an expiration date determined by appropriate stability data to assure it meets applicable standards of identity, strength quality and purity at the time of use, which could be used on patients for over a period of (b) (4) on average until the inventory has been depleted.
(B) There is no sterility testing performed on the IV flush bag containing (b) (4) to assure sterility after multiple withdrawals from the IV bag ports.
(C) Expired sterile injectables were stored in the cabinet, including but not limited to Heparin (b) (4) Lot# (b) (4) expiry 1MAY2015; Lidocaine (b) (4) Lot# (b) (4) expiry 1JAN2016; Lidocaine (b) (4) Lot# (b) (4), expiry 1DEC2015 and (b) (4), Lot# (b) (4) expiry 10/15.

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	07/08/2016