DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502 Phone: (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	9/9/2019-9/18/2019*
	FEI NUMBER 3006624492

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael J. Whyte, Owner

FIRM NAME	STREET ADDRESS
Isorx, Corp.	845 Marina Bay Parkway, Suite 9
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Richmond, CA 94804	Producer of Sterile and Non-Sterile Drugs

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

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 9/11/2019, you removed a pre-sterilized/depyrogenated syringe from the ISO 5 laminar flow hood and cleanroom, which exposed the syringe to unclassified air in your lab space. You then returned this syringe to your ISO 5 laminar flow hood. This syringe was used in the production of I-123 Metaiodobenzylguanidine (MIBG) USP, Rx (b) (6), lot I19141MIBG, a sterile drug product.

OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

On 9/11/2019, you used wipes to clean the interior of your ISO 5 laminar flow hoods that were not labeled as sterile. These wipes are used for your pre-operational cleaning of the laminar flow hood. This ISO 5 laminar flow hood was used to produce I-123 Metaiodobenzylguanidine (MIBG) Rx (b) (6), lot I19141MIBG, a sterile drug product.

OBSERVATION 3

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Andrew K. Haack, Investigator	09/18/2019

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Specifically,
You do not require a specific contact time for the (b) (4) sporicidal that you apply to your ISO 5 laminar flow hoods. This sporicidal was used to clean the laminar flow hood used to produce I-123 Metaiodobenzylguanidine (MIBG) Rx (b) (6), lot I19141MIBG, a sterile drug product.

OBSERVATION 4
Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically,
You do not maintain production records for the manufacture of drug products. Also your production records do not include a quality verification that the steps of production have been performed correctly. One example includes I-123 Caps USP, Rx (b) (6), lot I19105, made on 7/9/2019. Examples of omissions on the batch record for this product includes but is not limited to: lack of listing the steps taken to manufacture this product, the identity/ amounts of raw materials used in manufacturing, and these records are not signed and dated.

*DATES OF INSPECTION
9/09/2019(Mon), 9/10/2019(Tue), 9/11/2019(Wed), 9/12/2019(Thu), 9/16/2019(Mon), 9/17/2019(Tue), 9/18/2019 (Wed)

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	Andrew Haack	Andrew K. Haack, Investigator	09/18/2019