DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	3/22/2021-4/12/2021
	FEI NUMBER 3018101540

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael H. Brookins, Director of Operations

FIRM NAME	STREET ADDRESS
Age Management Institute Santa Barbara	533 E Micheltorena St. Suite #203
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Santa Barbara, CA 93103-2200	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
You did not have a HEPA filter over the area to which sterile product was exposed.
Specifically,

You did not have a HEPA filter in the (b) (4) (b) (4) hood which sterile products were exposed to, nor did you have a HEPA filter in the IV storage and mixing room. A (b) (4) was used in the (b) (4) hood. As such, your sterile drug products were produced in an unclassified area. During the period of 1/13/2021 to 2/25/2021, you produced (b) (4) purportedly sterile drug products in the (b) (4) hood by combining multiple individual sterile drug products to prepare bags intended for intravenous (IV) infusion and IV (b) (4) syringes based on doctor's prescriptions for IV therapy, listed as follows:

(b) (4)

OBSERVATION 2
Non-microbial contamination was observed in your production area.
Specifically,

Non-microbial contamination was observed in your IV storage and mixing room for the following:

A. You used a (b) (4) dated 08/28/2008 in the (b) (4) hood to produce purportedly sterile drug products. The

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	Taichun Qin	Taichun Qin, Investigator	4/12/2021

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back of the (b) (4) was observed to be dirty.

B. You used a (b) (4) refrigerator for the storage of both opened and unopened sterile vials; however, it was observed that water drips remained on the cap of sterile vials and in the bottom of a refrigerator tray where vials were placed, and that ice buildup and frost remained under the bottom of the freezer directly above those vials.

C. The working surface of the (b) (4) hood used in producing purportedly sterile drug products had unknown stains and the paint peeled off non-working surfaces.

D. Two sinks with brownish stains on (b) (4) were located in the IV storage and mixing room approximately three feet from the (b) (4) hood.

E. The air condition vent located in the IV storage and mixing room above the door was covered with dust and grime.

F. There was a carpet covering part of the floor in the IV storage and mixing room, making it difficult to clean.

G. An artificial plant was placed inside the IV storage and mixing room.

H. The table used to hold the (b) (4) hood had unknown stains.

I. Two rows of cabinets were installed in the IV storage and mixing room approximately one foot apart from the ceiling, making the top difficult to clean.

OBSERVATION 3

The aseptic processing areas had difficult to clean equipment or surfaces.
Specifically,

Your (b) (4) hood used in producing purportedly sterile drug products is not designed in a way so as to be cleaned

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easily.

A. The (b) (4) located inside the (b) (4) hood was unsealed, making it difficult for cleaning and disinfection of the unsealed area.

B. There was a gap between the irregular screw hinges used to fix the (b) (4) inside the hood and the top interior surface in the hood, making it difficult for cleaning and disinfection.

OBSERVATION 4

Sporicidal agents were not used in your production area.
Specifically,

You used non-sterile (b) (4) Disinfectant Wipes from (b) (4) containing (b) (4) and sterile wipes saturated with (b) (4) from (b) (4) for cleaning and disinfection in your (b) (4) hood. The (b) (4) Disinfectant Wipes were expired on 7/30/2020. According to your purchase invoices, no sporicidal agent was purchased from October 1, 2020 to March 31, 2021. During the period of 1/13/2021 to 2/25/2021, you produced (b) (4) purportedly sterile drug products for IV therapy.

Observation 5

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.
Specifically,

You used an individual drug product that was expired to produce purportedly sterile drug products for IV therapy.

On 2/22/2021, you produced (b) (4) for IV therapy that consisted of (b) (4) and an IV (b) (4)

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(b) (4)
however, (b) (4) used in producing this (b) (4) was expired on 2/20/2021.

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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 judgement, 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."