DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	5/2/2022-5/20/2022* FEI NUMBER 3022076307

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lisa C. Brent, Owner	
FIRM NAME Be Well Natural Medicine	STREET ADDRESS 655 Redwood Hwy Frontage Rd Ste 200
CITY, STATE, ZIP CODE, COUNTRY Mill Valley, CA 94941-3055	TYPE ESTABLISHMENT INSPECTED Producer of 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 WE OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically,

A: We observed that the (b) (4) Laminar Flow Workstation, where sterile IV drug products are produced is located in an unclassified room.

On 05/02/2022 we observed that the room contained the following particle-generating equipment:

- Ceiling air vent located above the workstation
- Vacuum cleaner located adjacent to the workstation
- Cardboard boxes located on room shelving and under the workstation
- Paperwork and (b) (4) adjacent to the workstation
- Microwave oven
- Hand-washing sink

On 05/02/2022 we observed that the room contained the following difficult to clean surfaces:

- Porous ceiling tiles
- Textured walls
- Carpet flooring
- Fabric covered chair
- Fabric pillows

B. There is no documented assessment, or certification, of the (b) (4) Laminar Flow

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Dustin M James, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 05-20-2022 08:40:53	5/20/2022

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Workstation to assure the equipment meets operating standards and maintains an ISO 5 classified environment.

OBSERVATION 2

Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically, on 05/04/2022 we observed during preparation of sterile drug IV solution, High Dose 50 gm Vitamin C infusion 250 ml, that personnel wore (b) (4) medical scrubs and non-sterile gloves. Personnel also lacked gowning that covered wrists, hair, and mouth during sterile drug preparation.

OBSERVATION 3

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

Specifically, on 05/04/2022 during preparation of sterile drug IV solution, High Dose 50 gm Vitamin C infusion 250 ml, we observed an IV solution bag, syringes, needles, and containers of sterile drug products placed on non-sterile absorbent cloths within the (b) (4) Laminar Flow Workstation. We observed storage of uncovered absorbent cloths on open shelving in the unclassified room prior to use in the workstation.

OBSERVATION 4

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

Specifically, on 05/02/2022 personnel, responsible for (b) (4) cleaning of (b) (4) Laminar (b) (4) Flow Workstation, stated that they used non-sterile ready-to-use spray cleaner, (b) (4) (b) (4) and sterile (b) (4), to clean the workstation. These cleaning agents do not contain sporicidal agents.

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*DATES OF INSPECTION

5/02/2022(Mon), 5/04/2022(Wed), 5/09/2022(Mon), 5/11/2022(Wed), 5/13/2022(Fri), 5/18/2022(Wed), 5/20/2022(Fri)

X Dustin M James
Investigator
Signed By: Dustin M. James -S
Date Signed: 05-20-2022 08:41:26

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EMPLOYEE(S) SIGNATURE
Jolanna A Norton, Investigator
Dustin M James, Investigator

X Jolanna A Norton
Investigator
Signed By: Jolanna A. Norton -S
Date Signed: 05-20-2022 08:40:53

DATE ISSUED
5/20/2022

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."