DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787)729-8500 Fax:(787)729-6809 orabioinspectionalcorrespondence@fda.hhs.gov	9/9/2024-9/18/2024* FEI NUMBER 2627511

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Alvin Peralta Faulkner, General Manager Puerto Rico Operations

FIRM NAME	STREET ADDRESS
Fenwal International, Inc.	Rd 357, Km 0.8
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Maricao, PR 00606	Manufacturer

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

Equipment used in the manufacture, (b)(4) of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, the (b)(4) is not adequately qualified to produce (b)(4) (b)(4) for (b)(4) products such as red cell preservation solution and anti-coagulant.

a. On 11 SEP 24, we observed unknown white material (b)(4) is (b)(4) pieces of equipment producing (b)(4) for (b)(4) product formulation.
b. (b)(4) is (b)(4) and used to clean (b)(4) equipment. (b)(4) and (b)(4).
c. (b)(4) equipment create (b)(4) long (b)(4) not used since 4 JUL 2024
d. Equipment connected to the (b)(4) such as (b)(4) (b)(4) (open to environment), (b)(4) and (b)(4) connections not represented on approved drawings.
e. Approved Drawing (b)(4) for product (b)(4) module (b)(4) does not show product solution (b)(4) from (b)(4). This module is used for Alyx, Amicus, and Intersol products.

Red cell preservation solution and anti-coagulant solutions formulated with (b)(4) are used to manufacture Alyx, Amicus, Intersol, and Blood Pack Units.

***This is a repeat observation from the previous inspection in September**

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	Scott T Ballard, Investigator Cody D Rickman, Investigator Lizaida Perez, Investigator - Team Biologics	X Cody D Rickman Investigator Signed By: Cody D. Rickman -S Date Signed: 09-18-2024 11:55:50	9/18/2024

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2022*

OBSERVATION 2

Equipment and (b)(4) are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the environment of solution (b)(4) is not adequately controlled with (b)(4). For example:

a. On 12 SEP 2024 and 14 SEP 2024, we observed the (b)(4) showed apparent biological growth on (b)(4) and (b)(4) from (b)(4) (b)(4) along with (b)(4) distributed through the equipment. This (b)(4) controlled as Grade (b)(4) environment.
b. On 12 SEP 2024 and 14 SEP 2024, we observed the (b)(4) showed apparent biological growth and (b)(4) on supply (b)(4). This (b)(4) controlled as Grade (b)(4) environment.
c. On 12 SEP 2024, we observed approximately (b)(4) removed from (b)(4) showed apparent biological growth. Fill (b)(4) is controlled as Grade (b)(4) environment.
d. On 10 SEP 2024, we observed (b)(4) in (b)(4) showed apparent biological growth. (b)(4) is not a classified/controlled environment.
e. On 13 SEP 2024, we observed a yellow/brown stain on (b)(4) in (b)(4) (b)(4) with unknown cause. (b)(4) is controlled as a Grade (b)(4) environment.

(b)(4) is used in formulating solutions for Amicus, Alyx, and Intersol solutions. (b)(4) is used in the manufacture of Blood Pack Units.

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This is a repeat observation from the previous inspection in September 2022

OBSERVATION 3

Buildings used in the of a drug product are not maintained in a good state of repair.

Specifically, manufacturing equipment and facilities showed disrepair that creates difficult to clean surfaces and difficulty in maintaining clean equipment. For example:

a. On 10 SEP 2024, we observed a (b)(4) sagging from apparent saturation with rain water.
b. On 9 SEP 2024, we observed (b)(4) were not covered/closed after cleaning in (b)(4) (b)(4)
c. On 10 SEP 2024, we observed peeling paint on (b)(4).
d. On 10 SEP 2024 and 13 SEP 2024, we observed cracked and peeling floor surfaces with (b)(4) (b)(4). Additionally, we observed (b)(4) with peeling (b)(4) near the (b)(4).
e. On 10 SEP 2024, we observed white crystal formations on (b)(4) in the (b)(4) (b)(4).

(b)(4) is used in formulation of fluids for Blood Pack Units. (b)(4) is used in formulation of Alyx, Amicus, and Intersol products.

This is a repeat observation from the previous inspection in September 2022

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that in-process materials conform to appropriate standards of identity, strength, quality and purity.

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Specifically, lab methods not adequately performed or scientifically valid to produce accurate results, for example:

f. On 10 SEP 2024, we observed (b)(4), used in bioburden testing circumferentially taped to reportedly prevent drying of (b)(4). This practice is not included in the written instructions #12-04-03-001, SOLUTION BIOBURDEN TESTING. Additionally, the growth promotion testing (Protocol # (b)(4) 202023F27 rev A, dated 18 APR 2024) does not include the practice of completely (b)(4).

g. (b)(4) study ((b)(4) dated 3 AUG 2016) using (b)(4) of multiple representative surfaces such as (b)(4) and others shows recoveries between (b)(4) for (b)(4). These (b)(4) with (b)(4) are used to sample product (b)(4) surfaces such as (b)(4). Your (b)(4) Lab supervisor stated there is no correction factor used in reporting routine monitoring with this method.

h. Observed (b)(4) with aberrant missing pattern of growth around (b)(4) where instrument is heated by (b)(4) and used to (b)(4), creating inaccurate total bioburden counts. This (b)(4) is documented with total count (b)(4) ((b)(4) unit lot # (b)(4)).

i. Bioburden (b)(4) for batch # (b)(4) was observed with total count documented as (b)(4). One of two technicians counted (b)(4); where counts are more than 10 different, SOP # MA-02-02-062 rev E instructs to notify a supervisor, but no additional action was taken. This (b)(4) was not counted for all (b)(4), but instead split into (b)(4).

j. Written procedure (SOP #MA-02-02-062 rev E) is not followed to indicate "TNTC" when counting of bioburden using (b)(4) methods where colonies are found above (b)(4) (b)(4).

Solution bioburden test method is applicable to Blood Pack Units, Alyx, Intersol, and Amicus Products.

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OBSERVATION 5

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, (b)(4) of a drug product.

Specifically, your firm does not adequately monitor areas of distinct environmental classification.

Environmental air samples are collected (b)(4) which does not provide adequate data on Grade (b)(4) rooms where blood pack unit and apheresis component products are (b)(4) For example, (b)(4) for Alyx, Amicus, and Intersol; as well as (b)(4) for Blood Pack Units.

Additionally, there is no continuous monitoring of differential pressures between rooms of differing classifications. For example, (b)(4) (Grade (b)(4)) to (b)(4) (Grade (b)(4)) where the differential pressure is documented once per day of production.

OBSERVATION 6

Washing and toilet facilities lack hot and cold water.

Specifically, your hand washing facilities for employees entering manufacturing and lab areas are deficient as follows:

a. On 10 SEP 2024 and 13 SEP 2024, we observed cold water for hand washing in (b)(4) for (b)(4).
b. On 10 SEP 2024 and 11 SEP 2024, we observed cold water for hand washing in (b)(4) for (b)(4).
c. On 10 SEP 2024 and 13 SEP 2024, we observed hand (b)(4) cold air in (b)(4) for (b)(4). (b)(4) in (b)(4) and (b)(4) (b)(4) before employees enter production areas.
d. We observed no hand washing stations for employees entering the (b)(4) lab. The firm does not have a procedure instructing employees to wash hands before entering the (b)(4)

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lab.

OBSERVATION 7

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, Annual product reviews fail to include data regarding (b)(4) components used in manufacturing of blood pack units and apheresis components (Alyx, Amicus, and Intersol). For example APRs do not include defect rates, testing summaries, or supplier qualification status.

Annual product reviews for BPU, Alyx, Amicus, and Intersol products for the calendar year 2023 were significantly delayed until being signed and approved on 12 SEP 2024.

*DATES OF INSPECTION

9/09/2024(Mon), 9/10/2024(Tue), 9/11/2024(Wed), 9/12/2024(Thu), 9/13/2024(Fri), 9/16/2024(Mon), 9/17/2024(Tue), 9/18/2024(Wed)

X Scott T Ballard
Investigator
Signed By: Scott T. Ballard -S
Date Signed: 09-18-2024 11:56:20

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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 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."