DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	9/24/2024-10/10/2024* FEI NUMBER 3022483154

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Viraj Gandhi, CEO	
FIRM NAME Tailstorm Health INC	STREET ADDRESS 24416 N 19th Ave Ste 200
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-1400	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm released sterile drug product, Bevacizumab (Avastin) Lot# (b) (4), BUD: 21 Feb 2025, Batch size: (b) (4) Pre-Filled Syringes, after a positive microbial growth was detected during the personnel monitoring of aseptic personnel that performed a non-routine intervention on the filling line where (b) (4) (Equipment ID: PE001) doors were opened to adjust the filling needles and (b) (4) . 1cfu was observed from the right forearm on 04 Mar 2024, however investigation into the excursion was not initiated until 15 Mar 2024. Your Quality Unit did not expand the investigation to include a retrospective evaluation. Additionally, there is no evidence that the open Pre-Filled Syringes that were exposed during the intervention were investigated or discarded. Your investigation stated that the root cause is due to "the ISO-7 environment the operator occupies prior to entering the ISO-5 environment".

B. Your firm released sterile drug product Bevacizumab (Avastin) lots (b) (4) without thoroughly investigating out-of-specification results of particulate matter. No lab error was found at the conclusion of the investigation opened by your contract testing lab. Your firm opened an investigation into these results, but the investigation failed to determine what these particles were. Your firm re-tested these lots and released them into the U.S market without identifying

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	Dogbeda F Mackenzie, Investigator X Dogbeda F Mackenzie Investigator Signed By: Dogbeda F. Mackenzie -S Date Signed: 10-10-2024 11:45:51	10/10/2024

the source of the particles found in your drug product.

C. Your firm's Quality Unit failed to thoroughly investigate, determine root causes, and implement appropriate corrective and preventative actions in response to personnel monitoring excursions. For example, your firm opened investigation into OOS.DMC.24.003 and stated the following "The contamination observed on the left forearm of the manufacturing technician is most likely attributable to sampling the gowning material which is subject to the ISO7 environment preceding entry into ISO5 environment". Out-of-Specification results in microbiological excursions were observed on four different aseptic operating personnel over the course of 04 Mar 2024 to 01 Jul 2024. The investigations you conducted did not determine why contamination in the ISO-7 would have occurred nor did it include corrective actions to mitigate it from reoccurring. The following investigations were opened into these excursions:

Investigation	Product	Lot number
OOS.DMC.24.001	Bevacizumab (Avastin) (1.25mg/0.05mL)	(b) (4)
OOS.DMC.24.003	Bevacizumab (Avastin) (1.25mg/0.05mL)	
OOS.DMC.24.005	Bevacizumab (Avastin) (1.25mg/0.05mL)	
OOS.DMC.24.008	Bevacizumab (Avastin) (1.25mg/0.05mL)	
OOS.DMC.24.012	Semaglutide (5mg/mL)	

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

A. Your firm failed to adequately simulate your aseptic filling process of your drug product

AMENDMENT 1

Bevacizumab (Avastin) in the media fill you conducted. The media fill your firm conducted to validate the aseptic filling process of drug product Bevacizumab included an additional (b) (4) step that occurred inside of the filling machine (Equipment ID: PE001). However, the current process used to perform aseptic filling of Bevacizumab (Avastin) vials does not include a (b) (4) step inside the filling machine (Equipment ID: PE001).

B. Sterilized filling components are routinely moved from ISO-7 filling room (room # PR 003) and introduced into the ISO-5 (b) (4) (Equipment ID: PE001) without being disinfected. On 09/27/2024, during the assembly of the filling machine for Semaglutide (8mg/mL) Lot# (b) (4), your Aseptic Operators were observed placing (b) (4) filling components into ISO-5 classified (b) (4). Your Head of Quality stated that employees are not required nor trained to disinfect filling components before introducing them into the ISO-5 classified (b) (4).

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. Your smoke studies are inadequate. The smoke studies your firm conducted to simulate aseptic processes did not demonstrate the impact of the airflow during line interventions, equipment manipulations, and machine assembly. The videos did not show the airflow reaching all work surfaces and exiting your (b) (4) filling equipment.

B. Your firm does not adequately capture the environmental conditions in which aseptic processes are conducted. Your procedure SOP.DQC.007, Environmental Monitoring, Effective date: 11 Mar 2024, Revision: 03 instructs personnel performing filling machine assembly to be sampled after set-up. Your firm failed to (b) (4) sample personnel conducting filling machine setup

for about (b) (4) lots that have been released from your facility. For example:

i. On 19 Mar 2024, your technician completed setup of the filling machine (Equipment ID: PE001) for aseptic filling of drug product Bevacizumab (Avastin) Lot# (b) (4) at 07:07am, however environmental monitoring of the employee who performed setup was performed at 07:50am on 19 Mar 2024.

ii. On 26 Apr 2024, your technician completed setup of the filling machine (Equipment ID: PE001) for aseptic filling of drug product Bevacizumab (Avastin) Lot# (b) (4) at 08:01 am, however environmental monitoring of the employee who performed setup was performed at 08:34 am on 26 Apr 2024.

iii. On 01 Jul 2024, your technician completed setup of the filling machine (Equipment ID: PE001) for aseptic filling of drug product Semaglutide Lot# (b) (4) at 08:51 am, however environmental monitoring of the employee who performed setup was performed at 09:35 am on 01 Jul 2024.

C. On 27 Sep 2024, during aseptic filling of Semaglutide (8mg/mL) Lot# (b) (4), your employee was seen rubbing excess (b) (4) on gloved hands prior to being sampled.

D. Your firm performs aseptic filling of drug products using (b) (4). On 24 Sep 2024, aseptic personnel's head to mid trunk of body exposed to ISO-5 classified (b) (4) during machine assembly for Bevacizumab (Avastin) Lot# (b) (4). Your Head of Quality was unable to provide scientific justification to why personnel monitoring of aseptic personnel forehead and chest are not sampled.

OBSERVATION 4

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

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Specifically,

Your firm failed to establish a procedure for cleaning of aseptic filling equipment with sporicidal. Your environmental and personnel monitoring program has recovered spore-forming microorganisms while performing aseptic operations of sterile drug products, however there is no documentation to show that sporicidal wipes are being used during cleaning of your aseptic filling equipment.

OBSERVATION 5

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

The statement "Office Use Only" if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient.

Examples of your drug product labels that do not contain this information, include, but are not limited to:

- Semaglutide 1mg/0.2mL

*DATES OF INSPECTION

9/24/2024(Tue), 9/25/2024(Wed), 9/26/2024(Thu), 9/27/2024(Fri), 9/30/2024(Mon), 10/01/2024(Tue), 10/02/2024(Wed), 10/03/2024(Thu), 10/04/2024(Fri), 10/09/2024(Wed), 10/10/2024(Thu)

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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."