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	11/3/2025-11/14/2025* FEI NUMBER 3022483154

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sushil (NMI) Sharma, Associate Vice President of Quality

FIRM NAME	STREET ADDRESS
Tailstorm Health Inc dba Medivant Health	24416 N 19th Ave Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-1400	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:

LABORATORY SYSTEM

OBSERVATION 1

Established laboratory control mechanisms are not followed.

Specifically,

Your firm does not have an established system suitability procedure. Your firm performs the Light Obscuration Particle Count Test using your (b) (4) Particle Count ((b)(4) PC) for finished drug product release testing. However, your firm has not conducted method suitability testing for bevacizumab (Avastin) sterile intravitreal pre-filled syringes.

Your firm utilizes the (b) (4) Technique to test for particulate matter for sterile intravitreal injectables, including bevacizumab (Avastin) pre-filled syringes, lot D25110 (BUD: 17/SEP/2026).

OBSERVATION 2

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

Your firm does not have an established procedure for the review of audit trails to ensure the reliability of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Cecilia H Kieu, Investigator	X Cecilia H Kieu Investigator Signed By: Cecilia H. Kieu -S Date Signed: 11-14-2025 11:44:55	11/14/2025

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Mr. Sushil (NMI) Sharma, Associate Vice President of Quality	
FIRM NAME Tailstorm Health Inc dba Medivant Health	STREET ADDRESS 24416 N 19th Ave Ste 200
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-1400	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

your analytical testing data. Your Quality unit did not review audit trails. Your batch record checklist does not include confirmatory documentation that audit trails in your analytical instruments and software were reviewed and evaluated as part of batch release.

Your firm utilizes the (b) (4) Particle Count ((b) (4) PC) to test for particulate matter for your finished sterile drug products.

Since October 2024, your Quality unit released at least (b) (4) batches of bevacizumab (Avastin) pre-filled syringes, tirzapetide pre-filled syringes, and semaglutide pre-filled syringes.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 3

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

On 11/11/2025, during the filling of bevacizumab (Avastin), lot D25120, I observed an unidentified white string on the ceiling of the ISO (b) (4) filling room. The condition of the ceiling surface presents a potential source of particulate contamination within the classified area used for aseptic processing.

***DATES OF INSPECTION**

11/03/2025(Mon), 11/04/2025(Tue), 11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri)

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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."