DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	5/27/2025-6/10/2025* FEI NUMBER 3013316698

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel D. Hernandez, Director of Quality

FIRM NAME	STREET ADDRESS
MedisourceRx	10525 Humbolt St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Los Alamitos, CA 90720-5401	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 WE OBSERVED:

OBSERVATION 1

Adverse drug experience information has not been reported to FDA.

Specifically,

Your outsourcing facility has not submitted an adverse event report to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5).

For example, Complaint # C25004, was received on January 14, 2025, where a patient reported severe GI issues and three nights of hospital stay after taking an injection of Semaglutide (2.5 mg/ml) Lot Number: (b) (4), BUD: 6/10/2025.

This serious and unexpected adverse event was not reported to FDA within 15 calendar days after first receiving the information regarding this event.

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sangeeta M Khurana, Investigator-GDUFA
Tareq W Haddad, Investigator

X Sangeeta M Khurana Investigator-GDUFA Signed By: SANGEETA M. KHURANA -S Date Signed: 06-10-2025 13:38:23

DATE ISSUED
6/10/2025

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On 05/27/2025, Investigators observed a live spider in the production area where all Active Pharmaceutical Ingredients (APIs) used for the manufacture of human drugs are stored in the refrigerators including API Semaglutide injection.

Additionally, a dead cricket was observed in the middle of the incubator room. These incubators are used for the incubation of media fill vials, environmental and personnel monitoring samples collected during the production of compounded human drugs.

***DATES OF INSPECTION**
5/27/2025(Tue), 5/28/2025(Wed), 5/29/2025(Thu), 5/30/2025(Fri), 6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu), 6/06/2025(Fri), 6/09/2025(Mon), 6/10/2025(Tue)

X Tareq W Haddad
Investigator
Signed By: TAREQ W. HADDAD -S
Date Signed: 06-10-2025 13:39:21

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sangeeta M Khurana, Investigator-GDUFA Tareq W Haddad, Investigator	X Sangeeta M Khurana Investigator-GDUFA Signed By: SANGEETA M. KHURANA -S Date Signed: 06-10-2025 13:38:23	6/10/2025

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."