DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	6/1/2026-6/5/2026 FEI NUMBER 1000517901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Edna J. Glaza, Director of Quality Assurance and US Quality Control

FIRM NAME	STREET ADDRESS
Access Business Group LLC	7575 Fulton St E
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ada, MI 49355-0001	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 and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

On 6/01/2026, during a walkthrough of the (b) (4) Manufacturing building (Building (b) (4)) encompassing room (b) (4) and room (b) (4) which houses the (b) (4) system and associated (b) (4) ((b) (4)), and Mixing Rooms (b) (4) and (b) (4) ((b) (4) level), the following conditions were observed:

a) Active (b) (4) were observed (b) (4) from (b) (4) at their (b) (4) on the (b) (4) system skid, under or around sample ports on the (b) (4) system, and from an undetermined source beneath the (b) (4) system. Active (b) (4) were also observed under (b) (4) .

b) Water was pooling inside a light fixture and dripping onto the floor near (b) (4) .

c) Two hoses associated with Mixing Tanks (b) (4) , located on the (b) (4) level ((b) (4)) of the mixing room ((b) (4)), were observed stored with their open ends in direct contact with the floor. Additionally, two transfer hoses, one connected to Mixing Tank (b) (4) and the other connected to Mixing Tank (b) (4), were found with their ends, although capped, resting on the floor.

(b) (4) generated by this system is used as a component in the manufacture of (b) (4) -

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shannon L Maisano, Investigator Eric D Bowles, Investigator	X Shannon L Maisano Investigator Signed By: SHANNON L MAISANO -S Date Signed: 06-05-2026 11:48:18	6/5/2026

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(b) (4) and (b) (4). The hoses described above are used in the cleaning and sanitization of equipment used to manufacture these products and in the transfer of product to associated fill lines.

(b) (4), Lot # (b) (4), released 5/05/2026, and (b) (4), Lots # (b) (4) and # (b) (4) released 4/29/2026, were manufactured using (b) (4) from this system.

OBSERVATION 2

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,

Access Business Group LLC does not perform second-person verification during microbial plate reading and counting of environmental monitoring plates, raw material plates, finished product plates, and water samples. A single analyst reads and records colony counts without independent verification by a second person.

There is no assurance that microbial plate counts are accurately read and recorded, which could result in unreported excursions, inaccurate environmental monitoring data, or the release of drug product that does not conform to established microbiological specifications.

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X Eric D Bowles
Investigator
Signed By: 2004433695
Date Signed: 06-05-2026 11:49:33

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Shannon L Maisano, Investigator
Eric D Bowles, Investigator

X Shannon L Maisano
Investigator
Signed By: SHANNON L MAISANO -S
Date Signed: 06-05-2026 11:48:18

DATE ISSUED
6/5/2026

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."