DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	4/14/2026-4/24/2026* FEI NUMBER 3017618045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tuochuan Dong, Director of Business and Operations

FIRM NAME	STREET ADDRESS
Avotres Inc.	140 East Hanover Ave, Suite 140
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cedar Knolls, NJ 07927-2070	Corporate Headquarters

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:
The following observation(s) are applicable to the protocol entitled:

A Phase 1 / 2 (b) (4) Study of Safety, Tolerability and Potential Efficacy of AVOTRES Cell-Based Therapy (AVT001) in Patients with Type 1 Diabetes

OBSERVATION 1

Failure to ensure proper monitoring of the study.

Specifically,

1. You did not conduct or oversee any of the activities delegated to your investigational product (IP) manufacturer throughout the study, which is your delegated responsibility as per the quality agreement. You did not ensure proper monitoring of the investigational product at different phases of development including, but not limited to, (b) (4) (b) (4) This contributed to missing elements in the Chain of Custody forms that were required to be completed.

2. Study monitors failed to ensure that the Chain of Custody (CoC) form, which documents investigational product accountability, contained the required elements during subject source record review.
   For example:
   - Subject (b) (4), (b) (6), (b) (7)(C) CoC form dated (b) (6), (b) (7)(C) did not include an expiration date or time for the investigational product.
   - Subject (b) (4), (b) (6), (b) (7)(C) CoC form dated (b) (6), (b) (7)(C) did not include an expiration date or time

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Mayar M Mussa, Investigator

X Mayar M Mussa
Investigator
Signed By: 2003950881
Date Signed: 04-24-2026
10:05:28

DATE ISSUED
4/24/2026

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for the investigational product.

The monitoring visit reports did not document these deficiencies.

***DATES OF INSPECTION**

4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri), 4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mayar M Mussa, Investigator X Mayar M Mussa Investigator Signed By: 2003950881 Date Signed: 04-24-2026 10:05:28	4/24/2026

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."