U.S. FOOD & DRUG ADMINISTRATION

BIORESEARCH MONITORING
INVESTIGATIONS BRANCH 2
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BANNOCKBURN, IL 60015
847-249-8632 101

03/25/2025

Dilawar Ajani, M.D., P.I.
10101 Bissonnet Street, Suite 105-A
Houston, TX 77036
US

Reference: Inspection Date(s):12/10/2024 - 12/16/2024

Location: Dilawar Ajani, M.D., P.I.
7777 Southwest Fwy
Houston, TX 77074-1802
US

Dear Ajani Dilawar MD, PI:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that was conducted by or on behalf of the U.S. Food and Drug Administration (FDA) at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. Visit the FDA website at (www.fda.gov) and search for 'FOIA Request' to submit a FOIA request.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Lisa Hayka via telephone at 312-259-4008 or email at Lisa.Hayka@FDA.HHS.GOV.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Lisa Hayka -S

Digitally signed by Lisa Hayka -S
Date: 2025.03.25 13:33:16 -05'00'

FEI:3007134943
Enclosure: Establishment Inspection Report (EIR)

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SUMMARY

This FY'25 High Priority [redacted] surveillance inspection for a review of an [redacted] was accomplished using the Bioresearch Monitoring Compliance Program (CP 7348.811). It was assigned by the Center for Drug Evaluation and Research (CDER), Office of Scientific Investigations (OSI) under eNSpect Operation ID # 304024.

This is one of several FDA inspections for this Clinical Investigator, Dilawar Ajani, MD. There were 2 discussion items discussed with Dr. Ajani's prior inspections conducted 07/17/2017 and 10/16/2008: one subject took more than the allowed doses of rescue medication and 6 subjects were non-compliant with

their diary or IP. Dr. Ajani promised corrections. All previous inspections were classified as No Action Indicated (NAI).

This inspection was pre-announced and conducted from 12/10/2024 to 12/13/2024 and 12/16/2024. The focus of this inspection was on Good Clinical Practices (GCPs). This inspection covered an audit of such relevant records as protocols with their amendments, deviation reports, serious adverse event (SAE) and adverse event (AE) reporting, signed investigator statements, clinical source data accuracy, study drug accountability, safety reporting, training, adherence to the study protocols, IRB documentation, subject records, financial disclosures, study monitoring, primary efficacy, and major secondary efficacy assessments.

Additionally, a review of subject records was compared for accuracy [redacted] that matched the site's source data for the Protocol Study Protocol #212390," A Phase III, Randomized, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study in Adolescent and Adult Female Participants Comparing the Efficacy and Safety of Gepotidacin to Nitrofurantoin in the Treatment of Uncomplicated Urinary Tract Infection (Acute Cystitis)."GlaxoSmithKline, LTD (GSK) is the sponsor.

The following information was gathered from the site at the time of the inspection:

Number Subjects Screened = 65
Number Subjects Enrolled =62
Number Subjects Screen failed = 3
Number Subjects Lost to follow-up= 2
Number of Subject Withdrawals of consent= 2
Number of Subjects Completing Study = 58

There was no Form FDA 483, Inspectional Observations, issued. The discussion items brought to the attention of Dr. Ajani in the previous inspections were not observed during the current inspection. During this inspection, there were no additional items discussed. There were no refusals encountered or samples collected.

ADMINISTRATIVE DATA

On Wednesday, 11/27/2024, I, Investigator Anya D. Lockett-Evans, pre-announced this Phase III, Randomized, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study in Adolescent and Adult Female Participants Comparing the Efficacy and Safety of Gepotidacin to Nitrofurantoin in the Treatment of Uncomplicated Urinary Tract Infection (Acute Cystitis)" to commence on Tuesday morning of 12/10/2024.

On the morning of 12/10/2024, I was met at the lobby of Dr. Ajani's Katy Office by Mrs. Shamim Memon, VP/Budgets and Contracts for Synergy Groups Medical. I presented my credentials to her and I

was led to an empty patient examining room with 3 large bins/red tubs of yellow enveloped subject folders.

Upon arrival to the designated audit room area, I met Ms. Arsheen Memon, CEO and Founder of Synergy Group Medical. I presented my credentials to Ms. Arsheen Memon, and I issued to her an FDA 482, Notice of inspection. An exchange of business cards ensued.

At the onset of the inspection, Dr. Ajani was seeing patients at another one of his three offices. He made himself available by phone at any time during this inspection. He scheduled an interview for study purposes later in the week.

Inspected firm:	Dilawar Ajani, M.D., P.I.
Location:	7777 Southwest Fwy Houston, TX 77074-1802
Phone:	832-287-0200
FAX:	(713)776-3367
Mailing address:	10101 Bissonnet Street, Suite 105-A Houston, TX 77036
Email address:	
Website:	
Dates of inspection:	12/10/2024-12/13/2024, 12/16/2024
Days in the facility:	5
Participants:	**Anya D Lockett-Evans, Investigator**

Hours of Operation are Monday through Friday from 9AM to 5 PM.

HISTORY

Dr. Ajani was the clinical investigator for the study Protocol #212390, "A Phase III, Randomized, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study in Adolescent and Adult Female Participants Comparing the Efficacy and Safety of Gepotidacin to Nitrofurantoin in the Treatment of Uncomplicated Urinary Tract Infection (Acute Cystitis)."

INTERSTATE (I.S.) COMMERCE JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Dr. Ajani conducted the clinical research study that is regulated by part 21 CFR 312, 50, 56 and

other applicable regulations. The investigational product used in the study was shipped via interstate by the sponsor to the firm.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Dr. Dilawar Ajani, Clinical Investigator, reported that his general responsibilities as an investigator included but were not limited to full and complete oversight of the study, informed consenting, determining subject eligibility, physical examinations, health assessments, safety report evaluation, review of study related reports from sponsor, and evaluation/determination of all adverse and serious adverse event reporting.

The signed copies of the 1572 are included as **Exhibit 1.** Dr. Ajani completed an Internal Medicine residency at the VA Hospital in Pennsylvania. He has been involved in medical research for over 15 years. An updated CV for Dr. Ajani was supplied as **Exhibit 2.**

He states that 50% of his time is spent in treating patients and the other 50% of the time is involved in research. Initially study subjects were seen at Dr. Ajani's Katy, Tx office location. But study subjects were later changed to his Bissonnet office location for the convenience of subject visit commutes.

A list of Dr. Ajani's FDA regulated studies was supplied by the firm as **Exhibit** 3.

The research personnel at the time of this study were approximately 7. in number. All have since relocated. There was no organizational chart available.

Arsheen Memon, CEO and Founder of Synergy Groups Medical has been assisting with Dr. Ajani's studies for the past 2 years. Her research facility is listed on the FDA 1572 signed by Dr. Ajani in 2021. Ms. A. Memon assisted in supplying documents and requested records.

Shamim Memon, VP/Budgets & Contracts of Synergy Groups Medical has additionally assisted with the study and supplied documents and subject records requested.

CLINICALTRIALS.COM

I observed the registration and submission results information for the study were found on https://ClinicalTrials.gov in accordance with federal regulations. During the inspection, I verified the sponsor was responsible for updating the information on the site.

AUTHORITY AND ADMINISTRATION

At the start of the inspection, Dr. Ajani stated he accepts ultimate responsibility for the conduct

of this study. I informed Dr. Ajani that my inspection was a high priority clinical surveillance inspection to determine if the study was conducted in accordance with GCP and FDA regulations. Dr. Ajani was the Clinical Investigator for the study. I further emphasized to Dr. Ajani that I was auditing him as the PI of the study, and that he bore all responsibility for the data. A list of FDA regulated studies conducted by the firm is included as **Exhibit 3.** According to the list with Dr. Ajani as the CI, he did not conduct any opioid-related studies.

PROTOCOL

I verified that the protocol used was the same protocol that subjects were randomized under. The protocols reviewed on site were included as part of the background materials.

All subjects who were enrolled into the study did so under protocol and amendments approved by the IRB. **Exhibit 5** summarizes the protocol amendments. I found no issues.

Protocol Deviations

The firm used a protocol deviation log. I reviewed the deviations and verified them with their source documents. No discrepancies nor additional deviations were noted.

INSTITUTIONAL REVIEW BOARD (IRB)/INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

The IRB with oversight of the study was a central IRB, Advarra, located at 6940 Columbia Gateway Drive, Columbia, Maryland 21046.

The protocol, and all versions of the informed consent form (ICF) were approved prior to any subject being enrolled.

The IRB conducting continuing reviews.

I found no issues.

SUBJECT'S RECORDS

Informed consent

I confirmed that before subjects could participate in the study, the investigator obtained IRB approval of the study protocol, all modifications to the various protocol versions, and human subject consent forms. An IRB approved assent form was appropriately obtained for a 13 year old subject.

The consent form contained all 8 basic elements. I reviewed all 65(100%) of all the randomized and 3 screen failed subject's Informed Consent Forms. A copy of the most recent informed consent was a requirement of this assignment. The site provided this request as **Exhibit 6 (**Subject 101707**).**

I found no issues with the consenting process and documentation.

According to Dr. Ajani all subjects in this study were recruited by flyers in the community, various clinics, health fairs, radio stations (95.1 FM, 102.5, 105.1), AM 10.40 broadcasting, clinical trials.com, and/or from the in-house data base by chart review.

Source Records

There was adequate documentation to show that all subjects were alive (refer to **Exhibit 7,** Screening and Enrollment Log). Most of the subjects were available for the duration of their participation in the study (apart from those who were discontinued). All subject records were available in electronic and in paper format. I used the paper sources for report exhibits. The source documents were attributable, legible, contemporaneous, organized, and accurate. I found no issues.

During this inspection I reviewed subject source documentation to include laboratory results, concomitant medications as well as regulatory documents, i.e., 1572's and Financial Disclosure forms. My review of the various documents was without issues.

I compared the primary efficacy endpoint data in the source documents with the data [redacted] and also compared protocol deviations, subject discontinuations, lab work, concomitant medications, and AEs in 15/58 (~30%) subjects completing study.

All subjects reviewed were found to have met eligibility criteria. There were no issues.

Case report forms

The source information was documented on paper, and then entered into the electronic case report form by data entry personnel. The firm used the sponsor provided EDC. The firm entered the source data into the sponsor provided EDC, Medi-data. No issues were noted.

Adverse Events SAEs/AE's

There were no SAEs associated with this site. I reviewed enrolled subjects for adverse events against source data. There were no issues.

OTHER STUDY RECORDS

During this inspection, no other records were reviewed outside of the study's subject records and drug accountability records.

INTERVIEWS OF SUBJECTS/PERSONNEL

There were no interviews of study personnel outside of those mentioned in the Individual Responsibility and Persons Interviewed section of the report.

FINANCIAL DISCLOSURE

I reviewed signed copies of Dr. Ajani's Financial Disclosure forms as well the disclosures for his sub-investigators. There was no indication of any conflicts of interests noted.

ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES

All source and regulatory documents were made available in paper format. The beginning of the study began with paper documents. Later study documents were electronically formatted. However, the firm printed out paper records of the source from the EMR.

CONTROL OF INVESTIGATIONAL PRODUCT

According to Ms. Arsheen Memon dispensing and return of investigational product were documented as per protocol and the clinic's SOPs. When a shipment was received, the date received, the lot number of each drug, and verifying receipt was recorded. The packing list was also signed and dated.

The identification number of the subject that received the drug was recorded on the drug accountability log. **Exhibit 8** is a copy of the Drug Accountability Log supplied by the firm. Investigational drug accountability was adequately documented with no discrepancies.

There were no reported temperature excursions.

RECORDS CUSTODY AND RETENTION

According to Ms. Shamim Memon all study records are maintained at their storage facility within 2 weeks of study closing. **Exhibit 9 is** a NTF from the site's Regulatory Binder with the address 0789 Cubesmart 19840 FM 1093 Rd., Richmond, TX 77407 where records are retained indefinitely.

REPORTS TO SPONSOR

There were no additional study related reports reviewed during the inspection.

MONITORING

The sponsor's CRO was responsible for monitoring the study. On-site monitoring was conducted during Covid-19 and recently remote monitoring has taken place.

The monitor would query the study site via the EDC if there were any issues noted and not addressed during the monitoring visits. The study site would respond to the query in the EDC.

Dr. Ajani confirmed that the monitoring logs at the firm were documented in the site's regulatory binder. The study appeared adequately monitored. I found no issues.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

Close-out occurred on the afternoon of Monday, 12/16/2024. Present at the time of close-out was Dr. Ajani, Ms. Arsheen Memon, and Mrs. Shamim Memon.

There was no FDA 483, objectionable findings issued. There were no items for discussion. A review of what transpired during the 5 Day course of the inspection was provided to those in attendance.

An updated FDA contact list was provided to the firm.

The site was informed that the Agency would be the one to make the final classification for this high priority establishment inspection.

ADDITIONAL INFORMATION

I collected exhibits on hard copy. Some pdf files collected were combined for clarity.

SAMPLES COLLECTED

There were no samples taken.

EXHIBITS COLLECTED

1 CI 1572's, 5 pages
2 CI's CV, 6 pages

3 Listing of CI Studies the past 5 years, 3 pages
4 DOA, 3 pages
5 Summary of Protocol Changes, 2 pages
6 ICS for most recent Subject, 20 pages
7 Ajani Enrollment and Screening Log, 5 pages
8 Drug Accountability Log, 21 pages
9 Address for Record Retention, 1 page

ATTACHMENTS

1 FDA Notice of Inspection, 3 pages
2 Assignment Memo Dr. Ajani, 6 pages

Anya D. Lockett-evans -S

Digitally signed by Anya D. Lockett-evans -S
Date: 2024.12.27 15:45:21 -06'00'

Anya Lockett-Evans, Investigator
Food and Drug Administration
Office of Bioresearch Monitoring Inspectorate
Division of Bioresearch Monitoring Inspectorate III
Bioresearch Monitoring Investigations Branch 3