DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/18/2025-3/25/2025* FEI NUMBER 3033709371

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pamela R. Contag, CEO

FIRM NAME	STREET ADDRESS
BioEclipse Therapeutics, Inc.	319 Bernardo Ave
CITY, STATE, ZIP CODE, COUNTRY Mountain View, CA 94043-5225	TYPE ESTABLISHMENT INSPECTED Sponsor

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:
OBSERVATION 1
Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.

Specifically, as a sponsor you failed to adequately conduct monitoring of the study.

a. Per the monitoring plan, routine monitoring for sites with subjects on study or in follow up is required. As the sponsor, you have placed the study on an enrollment pause since 8 May 2024. During the enrollment pause, monitors have been instructed by the sponsor not to conduct monitoring activities, including those related to safety and protocol compliance.

[redacted] out of [redacted] subjects that received treatment with the investigational product remained on study following the enrollment pause at Sites [redacted] and [redacted]. At Site [redacted], between the cessation of monitoring and the last subject follow-up, [redacted] elapsed.

b. Per the monitoring plan, verification of protocol compliance is a required task to be performed at interim monitoring visits. I observed 13 unresolved protocol deviations at Site [redacted], of which three were deemed [redacted], which included non-compliance with study drug dosing requirements, efficacy assessments, and a missed visit. I observed 32 unresolved protocol deviations at Site [redacted], with one protocol deviation deemed [redacted] for protocol-defined baseline evaluations not performed [redacted], and one unresolved protocol deviation at Site [redacted] for safety assessments not performed as per protocol.

c. Per the monitoring plan, 100% of adverse events (AEs)/serious adverse events (SAEs) are to be source data verified for all subjects.

Subject [redacted] remained on study following the enrollment pause, and experienced multiple SAEs, including [redacted]. The following are examples of AEs for Subject [redacted] deemed related and unexpected yet were never monitored.

Adverse Event	Date of Adverse Event
(b)(6) (b)(7)(C)	

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kristin M Abaonza, Investigator

X Kristin M Abaonza
Investigator
Signed By: Kristin M. Abaonza -S
Date Signed: 03-25-2025
16:09:36

DATE ISSUED
3/25/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/18/2025-3/25/2025*
	FEI NUMBER 3033709371

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pamela R. Contag, CEO

FIRM NAME	STREET ADDRESS
BioEclipse Therapeutics, Inc.	319 Bernardo Ave
CITY, STATE, ZIP CODE, COUNTRY Mountain View, CA 94043-5225	TYPE ESTABLISHMENT INSPECTED Sponsor

***DATES OF INSPECTION**
3/18/2025(Tue), 3/19/2025(Wed), 3/20/2025(Thu), 3/21/2025(Fri), 3/24/2025(Mon), 3/25/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kristin M Abaonza, Investigator	X Kristin M Abaonza Investigator Signed By: Kristin M. Abaonza -S Date Signed: 03-25-2025 16:09:26	DATE ISSUED 3/25/2025

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."