DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	5/27/2025-6/2/2025* FEI NUMBER 3016599369

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brian J. Radecki, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Rapa Therapeutics LLC	12712 Rock Creek Mill Road, Suite 5B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rockville, MD 20852-2570	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:
the following observation relates to the clinical study: (b)(4) .

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,

a) You failed to implement a clinical monitoring plan and standard operating procedures (SOPs) that adequately describes the clinical monitoring procedures and risk-based monitoring approach prior to performing clinical monitoring activities. Additionally, your study protocol states: Monitoring and auditing procedures developed by the sponsor will be followed to comply with Good Clinical Practice guidelines.

b) You failed to perform source data verification (SDV) of the AE electronic case report form (eCRF) for two (2) subjects ((b) (6), (b) (7)(C)) enrolled at Site 01. I observed that no AEs were reported for either subject in the electronic data capture (EDC) system.

c) You failed to perform SDV of the concomitant medications eCRF for all subjects enrolled at Sites 01 and 02. I observed study-required prophylactic medications were not reported in the EDC system.

d) You failed to identify the underlying cause of missed study procedures to implement effective corrective and preventive actions for Site 01.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	David L Chon, Investigator	X David L Chon Investigator Signed By: 2001733875 Date Signed: 06-02-2025 14:42:41	6/2/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Brian J. Radecki, Chief Executive Officer	
FIRM NAME Rapa Therapeutics LLC	STREET ADDRESS 12712 Rock Creek Mill Road, Suite 5B
CITY, STATE, ZIP CODE, COUNTRY Rockville, MD 20852-2570	TYPE ESTABLISHMENT INSPECTED Sponsor

Specifically, I observed eight (8) protocol deviations between May 28, 2021, thru October 13, 2021 at Site 01 involving hemolyzed blood samples, which prevented the collection of key safety laboratory results, such as bilirubin, for subjects (b) (6), (b) (7)(C), and (b) (6), (b) (7)(C) at various study timepoints. In each case, re-draws were either not performed or results from re-draws were not obtained.

e) You failed to provide the data safety monitoring board (DSMB) reports dated 2/16/2021, 8/3/2021, 5/3/2022, 2/21/2023, and 11/15/2023 to Site 02 to ensure submission to the Institutional Review Board (IRB) for their review.

The initial IRB approval notice dated 1/21/2022 for site 02 states: "If this study includes data monitoring committee/data safety monitoring board, please note that the reports of all meetings of this committee should be submitted to the IRB even if the outcome of the meeting results in no changes to the study".

The protocol states: "The site Institutional Review Board (IRB), and other regulatory bodies as applicable, will review all appropriate study documentation to safeguard the rights, safety, and well-being of the subjects. This includes, but is not limited to, the Protocol, Investigator's Brochure, Informed Consent Form, advertisements (if applicable), other written information given to subjects, safety updates, annual progress reports, etc.".

***DATES OF INSPECTION**

5/27/2025(Tue), 5/28/2025(Wed), 5/29/2025(Thu), 5/30/2025(Fri), 6/02/2025(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	David L Chon, Investigator	X David L Chon Investigator Signed By: 2001733875 Date Signed: 06-02-2025 14:42:41	6/2/2025

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."