DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 301-796-3150 Fax:(301)594-1204	3/9/2026-3/20/2026* FEI NUMBER 3020982471

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jing Ji, Chief Medical Officer

FIRM NAME	STREET ADDRESS
Abbisko Therapeutics Co., Ltd.	12B Floor, Building 1, Lane 515, Huanke Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pudong New Area, Shanghai China	Commercial 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 the study is conducted in accordance with the protocol and/or investigational plan.

Specifically,

Review and evaluation of information regarding the safety of the drug used in study (b) (4) was a responsibility maintained by your firm and was not transferred to a third party. You did not ensure adequate oversight of the vendor responsible for serious adverse event (SAE) case review and reporting.

This vendor made an error while updating permissions for user roles for the study which granted the blinded PV staff access to potentially unblinded safety information for subjects in this study.

This access was granted in May 2023 to five blinded PV staff on the study at the time and lasted over 7 months until January 2024. Two blinded PV staff members at your firm accessed suspect adverse reaction reports for study (b) (4) during this period, and did not report the access issue internally per quality procedures.

You remained unaware of this access permissions issue until August 2024, and unaware of the full scope of the access permissions granted until November 2025. A corrective and preventive action (CAPA) plan was not initiated by your firm until January 2026.

***DATES OF INSPECTION**
3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri)

SEE REVERSE OF THIS PAGE	Richard W. Berning, Investigator – Dedicated International Cadre	RICHARD W. BERNING -S Digitally signed by RICHARD W. BERNING -S Date: 2026.03.20 00:18:08 -04'00'	DATE ISSUED 03/20/2026

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."