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 www.fda.gov	5/11/2026-5/15/2026
	FEI NUMBER 3012611386

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sucai (nmi) Zhang, Test Facility Manager

FIRM NAME	STREET ADDRESS
JOINN Laboratories (Suzhou) Co. Ltd.	No. 1 Zhaoxi Road Biomedical Industrial Park, Taicang
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Suzhou, Jiangsu, 215421 China	Non-clinical Laboratory

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 WE OBSERVED:

OBSERVATION 1

Testing facility management failed to assure that all personnel clearly understood the functions they were to perform.

Specifically,

a. Section 4.3.1 of SOP ADM-027 Version 16, "Archive Administration," effective July 5, 2023, states, "The study number, archive date, specimen type, storage location, amount and other relevant information shall be documented in database (the Ziguang Archive management software)."

   For study (b) (4), the Ziguang archive management software entry listed 63 wet tissue bags on May 11, 2026; however, 62 wet tissue bags were physically verified as archived on shelves 52-1-7 and 51-3-7 in Building 8, room 8103.

b. Section 4.3.1 (Specimen Storage) of SOP ADM-027 Version 23.0, "Archive Administration," effective March 23, 2026, states, "When Document Management System (DMS) is adopted, the archive administrator shall enter the information such as the specific placement position and quantity of the samples."

   Thirty-four trays of (b) (4) blocks (e.g. (b) (4)) were temporarily stored in the Building 27 document archives (room 27104) due to space limitations in the Building 27 specimen archives (room 27102); however, DMS was not updated to reflect this temporary storage location when observed on May 11, 2026.

SEE REVERSE OF THIS PAGE		DATE ISSUED
	Julian C. Hanson, Investigator Andrew R. Wasko II, Biologist Xinguang Li, Senior Pharmacokineticist Lakecha N. Lewis, Investigator	5/15/2026

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 www.fda.gov	5/11/2026-5/15/2026
	FEI NUMBER 3012611386
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sucai (nmi) Zhang, Test Facility Manager	
FIRM NAME JOINN Laboratories (Suzhou) Co. Ltd.	STREET ADDRESS No. 1 Zhaoxi Road Biomedical Industrial Park, Taicang
CITY, STATE, ZIP CODE, COUNTRY Suzhou, Jiangsu, 215421 China	TYPE ESTABLISHMENT INSPECTED Non-clinical Laboratory

c. Section 4.2.5 of SOP PATH-020 Version 3, "Microtomy of (b) (4) Sections," effective February 2, 2023, states, "Verify the block code and record the block code on the glass slide (or verify the block code if the glass slide is printed with a block code)."

For study (b) (4), upon comparing the (b) (4) blocks to the corresponding slides, the slide generated from (b) (4) block (b) (4) code 3 (brain section 3, dorsal) was erroneously labeled as (b) (4) code 3B (brain section 3, ventral), and the slide generated from (b) (4) block (b) (4) code 3B (brain section 3, ventral) was erroneously labeled as (b) (4) code 3 (brain section 3, dorsal).

d. 21 CFR 58.83 states, "All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date."

Mobile phase for GLP study (b) (4) (b) (4) found in room 8232 was not labeled with an expiration date or storage conditions. Wrong number (b) (4)

e. Section 4.5.1.2 of SOP ADM-029 Version 15.0, "Use and Management of Equipment," effective April 2, 2026, states, "When using the following externally calibrated/verified equipment, their corrected values or error values should be introduced ***. Hygrometers used for monitoring environmental temperature and humidity (excluding EBI system monitoring probes)."

The Room Temperature and Humidity Record (Form BA-041-F03) for Room 8237 recorded temperature and humidity readings twice daily without applying the corrected values from April 2, 2026, through May 12, 2026.

OBSERVATION 2

The testing facility is not of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies.

Specifically

SEE REVERSE OF THIS PAGE		DATE ISSUED
	Julian C. Hanson, Investigator Andrew R. Wasko II, Biologist Xinguang Li, Senior Pharmacokineticist Lakecha N. Lewis, Investigator	5/15/2026

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 www.fda.gov	5/11/2026-5/15/2026
	FEI NUMBER 3012611386

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sucai (nmi) Zhang, Test Facility Manager

FIRM NAME	STREET ADDRESS
JOINN Laboratories (Suzhou) Co. Ltd.	No. 1 Zhaoxi Road Biomedical Industrial Park, Taicang
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Suzhou, Jiangsu, 215421 China	Non-clinical Laboratory

a. In Building 7, where reserve animals were being held, the floor in one area of animal room 7176 did not slope toward the drain. We observed discoloration and pooling liquid in one part of this area.

b. In Building 7, in the corridor near room 7178, we observed bubbling and cracking in the surface of the PVC floor.

c. In Building 5, near animal room 5264, the vertical locking mechanism for the door separating the silent area corridor would not stay in place. We observed non-human primates pushing this door open while undergoing observations.

SEE REVERSE OF THIS PAGE		DATE ISSUED
	Julian C. Hanson, Investigator Andrew R. Wasko II, Biologist Xinguang Li, Senior Pharmacokineticist Lakecha N. Lewis, Investigator	5/15/2026

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."