DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	6/1/2026-6/5/2026
	FEI NUMBER 3004967045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Koji Ukai, General Manager of Kawashima Site

FIRM NAME	STREET ADDRESS
Eisai Company Ltd.	1 Kawashimatakehaya-Machi
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kakamigahara, Gifu, 501-6024 Japan	Drug Manufacturer

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) (WE) OBSERVED:

OBSERVATION 1
Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,
On 06/01/2026, I observed (b) (4) and dust on the floors around the (b) (4) in the (b) (4) (machine room) in Pharmaceutical Manufacturing Building (b) (4) The (b) (4) is located directly above the manufacturing space, including the (b) (4) room. The air handling units supplying the manufacturing space were also located in this area. Your firm stated (b) (4) falls out of the (b) (4) when they are emptied. Your firm's SOP (number MJ302-01-EG0001) for cleaning the machine room instructs employees to promptly clean up after working with the (b) (4) This SOP also instructs the person in charge to conduct (b) (4) patrols of the machine room and look for dust. Pharmaceutical Manufacturing Building (b) (4) is used to manufacture (b) (4) mg (b) (4) tablets for the US market.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	WAYNE MCGRATH -S Digitally signed by WAYNE MCGRATH -S Date: 2026.06.05 11:55:30 +09'00'	Wayne D. McGrath, CSO	06/05/2026