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	10/23/2023-10/27/2023
	FEI NUMBER 3004967045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Fumiyasu Kojima, Group Officer & General Manager

FIRM NAME	STREET ADDRESS
Eisai Company Ltd.	Kawashimatakehaya-Machi 1, Kawashimatakehaya-Machi
CITY, STATE, ZIP CODE, COUNTRY Kakamigahara, Gifu, 501-6024 Japan	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A) Your Quality Unit does not control the issuance of batch manufacturing records. QA approved master batch records are stored electronically in the MAQS software system, and according to SOP # MJ203-01-PM0021, Revision: 04, the production planning group can directly print the batch manufacturing records from MAQS, without any QA oversight.

B) According to SOP # MJ301-01-DW0002, Revision: 14, the warehouse temperature monitoring data is to be reviewed by the warehouse personnel (b) (4) However, QA does not verify if the production personnel performed the (b) (4) review, and QA does not perform periodic spot checks of the recorded warehouse temperature data.

OBSERVATION 2

Drug products are not stored under appropriate conditions of humidity so that their identity, strength, quality, and purity are not affected.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bijoy Panicker, Investigator Ankur C Patel, Investigator	X Bijoy Panicker Investigator Signed By 2001996716 Date Signed 10-27-2023 03 58 12	10/27/2023

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	10/23/2023-10/27/2023 FEI NUMBER 3004967045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Fumiyasu Kojima, Group Officer & General Manager

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

Your firm stores capsules (e.g.: (b) (4) Capsules, Size #(b) (4) Lot #(b) (4) used for the manufacture of (b) (4) Capsules in Warehouse 2, where humidity is not controlled and there are no predefined specification limits for the humidity. Your capsule supplier recommends a storage condition of (b) (4) °C and (b) (4) % RH for the (b) (4) capsules.

X Ankur C Patel
Investigator
Signed By: 2003087186
Date Signed: 10-27-2023 03:58:54

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Bijoy Panicker, Investigator
Ankur C Patel, Investigator

X Bijoy Panicker
Investigator
Signed By: 2001996716
Date Signed: 10-27-2023
03:58:12

DATE ISSUED
10/27/2023