DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration/ORA/OPQO/HQ 12420 Parklawn, Room 2032 Rockville, MD 20857 Attn: Hyosum Forman Industry Information: www.fda.gov/oc/industry	8/29/2022-9/2/2022
	FEI NUMBER 3008927877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Koichi Mitomo, Plant Director, Gifu Plant

FIRM NAME	STREET ADDRESS
Meiji Seika Pharma Co., Ltd.	2890 Kitagata, Kitagata-Cho, Motosu-Gun
CITY, STATE AND ZIP CODE Gifu, 501-0431	TYPE OF ESTABLISHMENT INSPECTED API Manufacturer

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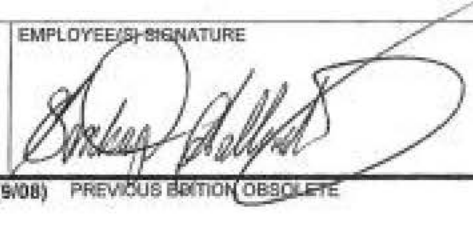
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

QUALITY SYSTEM

Observation 1
Failure to have a quality unit that is independent of production and fulfills quality assurance (QA) and quality control (QC) duties.

Specifically,
Your written procedure Roles and Responsibilities of Operations related to GMP, 40-60-018-00-00-V17, page 10 states the QA manager is responsible review of the validation protocol and reports. Page 11 of the procedure states Validation Manager is responsible for approving the validation protocol, validation report and releasing equipment for production. Validation Master Plan for the production of (b) (4) and related validation activities were approved by the Validation Manager.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Santiago Gallardo Johnson, Investigator	09/02/2022

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FACILITIES AND EQUIPMENT SYSTEM

Observation 2
Failure to exercise sufficient controls over computerized systems to prevent unauthorized printing of drug substance labels.

Specifically,
a. Computer Tag. No. 10020792 used for printing (b) (4) and (b) (4) finished product and shipping labels does not require unique username and password to access for printing labels.

b. Label room key control log did not SGS 9/2/2022 capture access to the room during label printing operations for drug substance (b) (4) Lot (b) (4) on 5/16/2022.

Observation 3
Failure to properly maintain buildings and facilities used in the manufacture and storage of intermediates and API.

Specifically,
Raw Material warehouse No. 1 used to store raw materials and intermediates for the use in production of (b) (4) has water leak damage and mold growth on ceiling tile over (b) (4) lot number (b) (4)

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		Santiago Gallardo Johnson, Investigator	09/02/2022