DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	02/02-06/2026
	FEI NUMBER 3002808534

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Seiichiro Matsumoto, President & CEO	
FIRM NAME Yuki Gosei Kogyo, Co., Ltd.	STREET ADDRESS 788, Ochiai, Joban Nishigo-machi, Iwaki-shi,
CITY, STATE, ZIP CODE, COUNTRY Fukushima 972-8316, Japan	TYPE ESTABLISHMENT INSPECTED API 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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your complaint investigations were deficient. For example,

A. Complaint Investigation 2024-39 was initiated on 10/31/2024 when your customer informed of an incident involving anaphylactic reaction followed by death of (b) (6) (b) (6) after using drug products (b) (4) This (b) (4) drug was manufactured using API supplied by your firm (Lot# (b) (4) Though this non-sterile API is used in (b) (4) drug, the investigation did not extend to raw materials used in the manufacturing process including (b) (4) water for potential endotoxin contamination. No retain samples were tested and no risk assessment was performed to the current testing frequency of (b) (4) (b) (4) for the (b) (4) water used in the production. Similar complaint was filed again on 2/19/2025 (Complaint# 2025-05) for another batch (Lot# (b) (4) and the investigation is still

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open after nearly a year. Though these lots were shipped to Europe, the same equipment and manufacturing process is applied for the API batches manufactured for the US market.

B. Complaint investigations were not completed in a timely manner by creating an investigation report and closing the investigation. The investigations were found to be open beyond the allowed time of (b) (4) for generating the report as described in the written procedure, JHA438, Quality Information Processing Procedure, version 9, section 7. Examples of open investigations include but are not limited to the following:

Complaint #	Date Opened (YYYY/MM/DD)	API Name	Lot #	Days Open
2023-04	2023/02/08		(b) (4)	1093
2023-08	2023/03/29			1044
2023-10	2023/06/09			972
2023-11	2023/06/09			952
2023-18	2023/11/02			826
2023-20	2023/11/16			812
2023-23	2023/12/26			772

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		(b) (4)	
2024-17	2024/03/22		685
2024-22	2024/05/10		636
2024-31	2024/08/09		545
2024-33	2024/09/12		511
2025-05	2025/02/19		351

OBSERVATION 2

Procedures designed to prevent objectionable microorganisms in drug substance not required to be sterile are not effective.

Specifically,

You have not established a written procedure for testing of objectionable organisms in (b) (4) water that is used in the production process of APIs that are used for the manufacturing of (b) (4) drug products. For example, (b) (4) API is used in (b) (4) drug products.

OBSERVATION 3

Your supplier qualifications are deficient.

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Specifically,

US marketed API, namely, (b) (4) uses the key starting material (b) (4) Your written procedure, SOP# JHA440, Supplier Control Procedure, dated 5/1/2025, section 3.5, requires onsite audit of main raw material supplier's site (b) (4) However, you have not conducted any onsite audit of this supplier after 3/2/2023. Also, no justification is documented to extend the onsite audit time beyond (b) (4)

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