DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Dr, Rm 2037 HFC-130 Rockville, MD 20857 FDA483responseinternational@fda.hhs.gov	3/12/2026-3/13/2026 FEI NUMBER 3004323569

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Yoshiya Tomita, Factory Manager

FIRM NAME	STREET ADDRESS
Kibun Foods Inc. Funabasi Factory	44, Takase-Cho
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Funabashi, Chiba, Japan, 273-0014 Japan	Steamed and frozen processed egg products, fish based surimi products

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 OBSERVED:
OBSERVATION 1
You did not identify an allergen preventive control for a hazard when one was needed.

Specifically,

The hazard analysis listed allergens as a potential hazard at the labeling step however, the labeling step was not identified as a preventive control. The products shipped to the US include egg containing product as well as a mixed tray of finished products (steamed fish cake, sweetened chestnut, baked fish cake with egg, sweetened, black soybeans, seasoned kelp) which contain allergens such as wheat, fish, soy and egg.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Deborah K Richardson, Investigator

X Deborah K Richardson Investigator Signed By: Deborah K. Richardson -S Date Signed: 03-13-2026 01:00:30

DATE ISSUED
3/13/2026

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."