



DEPARTMENT OF HEALTH & HUMAN SERVICES

94508d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 28, 2003

Mr. Henry O.C. Knaust, President
HK Canning, Inc.
130 North Garden Street
Ventura, CA 93001

W/L 05-04

Dear Mr. Knaust:

An inspection of your food manufacturing facility at the above address on June 2-5, 11 and 12, 2003 by FDA investigators found serious deviations from the Low Acid Canned Foods (LACF) regulations in Title 21, Code of Federal Regulations, Part 113 (21 CFR Part 113), causing your food products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). In addition, a temporary emergency permit (21 U.S.C. 344) may be required for low-acid foods in hermetically sealed containers whenever a processor has failed to fulfill the requirements of 21 CFR 108.35, including registration and filing of process information, and the mandatory requirements of 21 CFR part 113 (21 CFR 108.35(a)). You may find the Act and the LACF Regulations through links in FDA's home page at www.fda.gov.

Deviations to 21 CFR part 113 include, but are not limited to the following:

1. Your firm failed to test your retort mercury-in-glass (MIG) thermometers for accuracy against a known standard thermometer at least once a year to ensure their accuracy in accordance with 21 CFR 113.40(a)(1).
2. On 6/4/03, the temperature recording chart [REDACTED] was observed to read one degree Fahrenheit higher than the mercury-in-glass reference thermometer. Under no circumstances should a MIG thermometer read lower than a temperature recording chart [21 CFR 113.40(a)(2)].

Failure to promptly correct violations may result in regulatory action without further notice, such as seizure, injunction, and/or issuance of an order of need to obtain and hold a Temporary Emergency Permit.

We also discovered that your firm's retorts were equipped with mufflers at the air/steam injection valve. However, we were unable to determine whether retort venting was affected by the mufflers.

If mufflers are used on vent systems, you must keep evidence on file that demonstrates that the vents are operated in a manner that does not significantly impede the removal of air (21CFR113.87(g)).

We also noted that a batch of about [REDACTED] (#10) cans of red kidney beans was processed containing an undetermined quantity of peanuts, which had been unintentionally added to the red kidney beans. Your firm's scheduled process is for red kidney beans, but not for the mixture of red kidney beans and peanuts. The unintentional addition of peanuts to the kidney bean in filled containers could compromise the adequacy of the designed thermal process. Thus, there is no assurance that your current scheduled thermal process for red kidney beans would also render the mixed peanut and red kidney bean product free of microorganisms of potential health significance. You have no scheduled thermal process that has been reviewed by a competent processing authority for a mixed peanut and red kidney bean product. Further, the inadvertent addition of an allergen, such as peanuts, into a product during processing constitutes a serious concern about your manufacturing processes. The mixed peanut and red kidney bean product was still in the warehouse at the time of inspection. Please provide us with information concerning the disposition of this lot.

We also noted the following concerning your firm's retort temperature recording charts:

Your firm's retort temperature recording charts (TRCs) are not properly documented in accordance with 21 CFR 113.100(b), as evidenced by:

- TRCs do not have any signature or initial of the retort operator;
- TRCs do not have a signature or initials of a representative of management within one working day after the actual process for completeness and to ensure the product received the scheduled process.

Your firm's retort temperature recording charts do not include a means to prevent unauthorized adjustments such as a lock or notice from management [21 CFR 113.40(a)(2)].

We also noted that four of the products produced at your facility do not have their scheduled processes filed with FDA [21 CFR 108.35(c)(2)]. Specific products are identified in the FDA-483 presented to your firm on June 12, 2003. These include refried beans (pinto), vegetarian refried beans (pinto), salsa style refried beans (pinto), and refried black beans.

During the inspection, we observed facilities and equipment that could contribute to contamination of raw materials before they are canned and thermally processed.. These observations include:

- A piece of frayed, damp rope was observed directly contacting mushroom pieces on the conveyer line after these mushrooms had been washed and before being placed into cans.
- Condensate was observed dripping directly into a kettle soaking Pinto beans.
- Screening to the outside in the kettle room was found to be inadequate, allowing possible vermin and insect entry.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to

Mr. Henry O.C. Knaust, President, HK Canning, Inc.

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prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

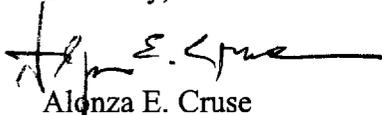
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Low Acid Canned Food Manufacturing regulations (21 CFR Part 113), and the Emergency Permit Control regulations (21 CFR Part 108) You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
19701 Fairchild
Irvine, CA 92612-2445.

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409.

Sincerely,



Alonza E. Cruse
District Director