



g 3110 d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone 612-334-4100

February 15, 2002

WARNING LETTER**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 23

William Gollnick
Tribal General Manager
Tsyunhehkwa
7201 Seminary Road
P.O. Box 365
Oneida, Wisconsin 54115

Dear Mr. Gollnick:

An inspection of your low acid canned food and acidified food processing plant, Tsyunhehkwa (FCE 02469), was conducted by an investigator of the Food and Drug Administration from August 15 - 20, 2001. At the conclusion of the inspection Ms. Carol Elm was presented with a form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations, Parts 108, 113 and 114 (21 CFR 108, 113, and 114). These sections cover cannery Emergency Permit Control (108), the Good Manufacturing Practices for Low-Acid Canned Foods (113), and Good Manufacturing Practices for Acidified Foods (114). By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Specifically, our investigation found:

1. Failure to handle deviations less than scheduled processes per 21 CFR 113.89. Records reviewed for production on 12/14/00 (Retort #1, ~ minutes short), 3/13/01 ~ degrees low), and 3/29/01 ~ minutes short) revealed processing deviations. Your firm did not have these deviations evaluated by a processing authority nor were the products appropriately reprocessed. In addition, processing deviations occurred on 10/18/00, 11/6/00, 11/15/00, 1/9/01, 3/28/01 and 6/15/01 when the retort temperature dipped below ~° F.
2. Failure to file a process for a low-acid food, Corn Soup with Pork in pint jars, or for acidified foods such as dill pickles, hamburger dills, bread-and-butter

Page Two

William Gollnick
February 15, 2002

- pickles and pickle relish as required by 21 CFR 108.35(c)(2) and 108.25(c)(2), respectively.
3. Failure to test and record equilibrium pH in acidified foods according to 21 CFR 114.80(a)(2).
 4. Failure to follow the process times specified in the filed process required by 21 CFR 108.35(c)(3).
 5. Failure to maintain required thermal records required by 21 CFR 108.35(h) and 21 CFR 113.100.
 6. Failure to measure and record initial temperatures for the thermal process required by 21 CFR 108.35(h) and 21 CFR 113.87(c).
 7. Failure to maintain a deviation file or log as required by 21 CFR 108.35(d) and 21 CFR 113.89.
 8. The process used to produce Corn Soup with Pork on March 13, 2001, was not established by a qualified expert according to 21 CFR 108(c)(2)(ii) and 21 CFR 113.83.
 9. Failure to establish and maintain container closure examination records required by 21 CFR 108.35(h) and 21 CFR 113.60.
 10. Thermal processing records have not been reviewed consistently by management for completeness within one working day as required by 21 CFR 113.100(b).
 11. Failure to take measures to prevent unauthorized changes in adjustment of the temperature recording charts as required by 21 CFR 113.40(a)(2).
 12. Identification codes on thermally processed low-acid canned foods and acidified foods do not identify the location where produced nor the contents as required by 21 CFR 113.60(c).
 13. Temperature recording charts are not always properly marked with identifying data such as cooker number, lot number, date of cook, etc., as required by 21 CFR 113.100(b)

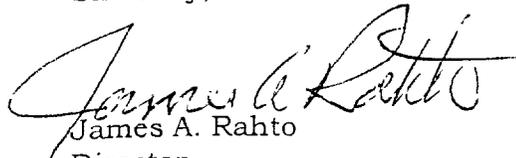
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice such as seizure and/or injunctive relief.

Page Three

William Gollnick
February 15, 2002

You should notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

TSW/ccl


xc: Jeffrey Metoxin
Facility Manager
Tsyunhehkwa
N7201 Seminary Road
P.O. Box 365
Oneida, WI 54155