



g1223d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-54

April 19, 2001

Henry L. Rosenthal, President
Green Turtle Cannery
81219 Overseas Hwy.
P. O. Box 585
Islamorada, Florida 33036

Dear Mr. Rosenthal:

An inspection of your food manufacturing facility at the above address on February 6, 2001, by FDA Investigators Jerry H. Bridgers, Edwin J. Gorney, Clara E. Santiago, and James T. O'Neal found serious deviations from the Low Acid Canned Food (LACF) regulations in Title 21, Code of Federal Regulations, Parts 108 and 113 (21 CFR 108 and 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).

Deviations to 21 CFR Parts 108 and 113 include, but are not limited to the following:

- Your firm's vertical still retort vents were not fully open to permit rapid discharge of air from the retorts during the venting period. However, you did not have evidence on file in the form of heat distribution data to show that your venting procedure accomplishes adequate venting of air from the retorts [21 CFR 113.40(a)(12)(iii)].
- Your firm did not use the proper temperature recording chart to record your processes. As a result, contrary to the requirements of 21 CFR Part 113.40(a)(2), your temperature recording chart recorded temperatures that were higher than the known accurate mercury-in-glass retort thermometer during processing times.
- Your firm failed to test your retort mercury-in-glass thermometers for accuracy against a known accurate standard thermometer at least once a year to ensure their accuracy in accordance with 21 CFR 113.40(a)(1).

Mr. Henry L. Rosenthal
Page 2
April 19, 2001

- Your firm's recording thermometer chart records were not always identified by date, the product, and other data as necessary so that they can be correlated with the written records of lots processed [21 CFR 113.100(b)].
- Your firm's recording thermometer charts were not signed or initialed to indicate review by a representative of management within one working day after the actual process [21 CFR 113.100(b)].
- Your firm did not process your products in conformity with the scheduled process filed with FDA [21 CFR 108.35(c)(3)(i)]. We note that based on [REDACTED], the scheduled process for conch chowder in 303 x 406 cans calls for an initial temperature of [REDACTED] degrees F and for [REDACTED] minutes at processing temperature [REDACTED] degrees F. However, your firm processed conch chowder on February 6, 2001 at initial temperatures of [REDACTED] degrees F and [REDACTED] degrees F and for [REDACTED] minutes at processing temperature [REDACTED] degrees F. If this modification to your filed scheduled process is to be used on a regularly scheduled basis, you must promptly file the modified process as a scheduled process.
- Your firm has not registered or filed any processes including the scheduled processes which show the principal place of business and location of your canning establishment at the current address in accordance with 21 CFR 108.35(c)(1) and (2).

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure and/or issuance of an order of need for a Temporary Emergency Permit.

It is necessary for you to take action on this matter now. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations and prevent their reoccurrence. Any corrective actions taken should apply to all of the Low Acid Canned Foods you manufacture. You may wish to include in your response documentation such as new registration and process filing forms or the results of a temperature distribution study that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

Mr. Henry L. Rosenthal
Page 3
April 19, 2001

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is written in a cursive style with a large, stylized initial "E".

Emma R. Singleton
Director, Florida District