



Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER

2000-DT-16

March 29, 2000

Mr. Alejo Pizarro
President
Cedar Lake-MGM Foods
5293 Peacock Lane
Riverside, CA 92505

Dear Mr. Pizarro:

An inspection of your low acid food canning firm located at 5333 Quarter Road, Cedar Lake, MI was conducted on December 7-10, 1999 by Investigators Michael V. Owens and Sally S. Eberhard. At the conclusion of the inspection you were presented with a Form FDA-483, Inspectional Observations, listing serious deviations from the Current Good Manufacturing Practice (CGMP) regulations for low acid food manufacturers [Title 21, Code of Federal Regulations (CFR), Parts 108.35 and 113]. These deviations cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically our investigators found:

1. Your firm has not established a process in accordance with 21 CFR 113.83 for dinner steaks in 401 x 208 cans, a product which you have produced since 1985. Your firm also has not evaluated this increase in container height as a process deviation from your existing process for this product in 401 x 205 cans in accordance with 21 CFR 113.89. Your firm also has not filed a process for this product in accordance with 21 CFR 108.35(c)(2).
2. Your firm is not recording critical factors specified in the scheduled process in accordance with 113.40(a)(13) for the following products:
 - a. Maximum fill weight for Vegi Scallops in 307x409 and 404x700 cans.
 - b. Maximum fill weight for Chops in 307x409 cans.

- c. Maximum frank diameter (1-1/4") and maximum number of franks (8 per can) for Vegi Franks in 307x409 cans.
 - d. Sausage diameter and number of links per can for Breakfast Sausage in 307x409 cans.
 - e. Consistency of product formulation for Dinner Steaks and Vegi Scallops.
3. Your firm does not use a suitable type of valve maintained in good condition for the cooling water lines leading to retorts #1,2 and 3 in accordance with 21 CFR 113.100(c). Water was observed leaking from the gate valves in these lines into the retorts. You should ask your processing authority to perform temperature distribution studies to determine the effect of leaking valves on the adequacy of the process.
 4. Your firm did not record corrective action taken in accordance with 21 CFR 113.60 when out of specification can seam measurements were encountered. For example:

On 11/23/99 the products Vege Burger and Vege Scallops were processed in 307x409 cans. The seam tear down measurements for thickness reported a high result of [REDACTED] respectively. The thickness specification for these cans is [REDACTED]. The processing and can tear down record does not indicate that the operator was aware of the out-of-specification result, nor does it indicate if the closing machine was adjusted.

On 12/2/99 four lots of the product Vege Burger were processed in 404x700 cans. The thickness measurements on lots 33601 and 33602 were [REDACTED] above the [REDACTED] maximum thickness specification. The thickness measurement on both lots 33603 and 33604 was [REDACTED], within specification. There is nothing in the records to indicate the operator was aware of the two out-of-specification results, nor if any machine adjustment was performed.
 5. Failure to record, at the time of observation, the approximate number of cans per coding interval.

Example: Processing records reviewed covering December 2 and 6, 1999 and November 30, 1999 do not include the approximate number of cans per coding interval. Other records include a number determined from the labeling machine at a time one or more days after the batch was retorted.

21 CFR 113.100(a)

6. Failure to include on some of your production records the signature or initials of the retort operator, and failure to always include the actual date the records were reviewed by a qualified management individual.
21 CFR 113.100(b)

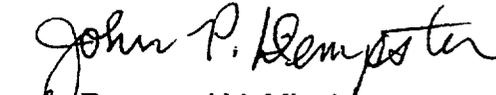
The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Mr. Melvin O. Robinson, Compliance Officer. (313) 226-6260 Extension 128

Sincerely yours,


Raymond V. Mlecko
District Director
Detroit District

Cc: Mr. John R. Sias
Production Manager
Cedar Lake-MGM Foods
5333 Quarter Road
Cedar Lake, MI 48846