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

PURGED

November 21, 1996

cc: HFI-35/FOI Sta
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-13

Gordon E. Marks
President
Marks Brothers Pickle Company, Inc.
Route 2, County F
Wautoma, Wisconsin 54982

Dear Mr. Marks:

An inspection of Marks Brothers Pickle Company, Inc., Wautoma, WI, by FDA Investigator Jon C. Polzine on October 15 and 23, and November 1, 1996, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for acidified food manufacturers [Title 21, Code of Federal Regulations (CFR), Parts 113 and 114]. Such conditions cause the food products being manufactured at this facility to be adulterated within the meaning of Sections 402(a)(4) and 402(a)(3) of the Federal Food, Drug and Cosmetic Act (the Act).

Objectionable conditions found during the current inspection were cited on a form FDA-483, Inspectional Observations. They were discussed with you at the close of the inspection.

Specifically, our investigator found:

1. Processing records for all acidified foods are inadequate to permit a health hazard evaluation of the manufacturing processes for each

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batch of product. The processing records do not include all the following items (21 CFR 114.100):

- Documentation of the pH values for all batches of acidified foods; and
 - Documentation that the packaging and raw material has been examined prior to use.
2. Failure to document that the pH is checked on each lot of finished product in accordance (21 CFR 114.80).
 3. Processes have not been filed for acidified foods manufactured at your firm [21 CFR 108.25(c)].

This letter is not meant to be an all-inclusive listing of the deficient conditions and practices at your food facility. As president, the most responsible individual at Marks Brothers Pickle Company, Inc., it is ultimately your responsibility to ensure that the relish and pepper products manufacturing operation in Wautoma, WI, is operating in compliance with the Federal Food, Drug and Cosmetic Act and associated regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action including seizure and/or injunction without further notice.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the measures you intend to take to correct the cited violations. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612) 334-4100 ext. 156.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Feldman". The signature is fluid and cursive, with a large, stylized initial "J".

John Feldman
Director
Minneapolis District

HEM/ccl