



PURGED

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

cc: HFI-35/FOI Staff
DWA

February 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-29

Ryan A. Downs
Vice President/Co-owner
David D. Flanagan
Vice President/Co-owner
Flanagan Brothers Inc.
400 Clark Street
Bear Creek, Wisconsin 54922

Dear Mr. Downs and Mr. Flanagan:

An inspection of your firm on January 6-9, 1997, by Investigator Kathy Clark-Girolamo revealed an acidified food product, pickled red cabbage, is processed at your facility under serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Parts 108 and 114. By virtue of these deficiencies this product is adulterated within the meaning of Section 402(a)(3) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Deviations noted include the following:

1. Your pickled red cabbage does not have a filed process with FDA [21 CFR 108.25(c)(2)].
2. Operators of processing and packaging systems are not under the supervision of a person who has attended a school approved by the Commissioner (21 CFR 114.10).

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3. Lack of sufficient control to assure that the finished equilibrium pH values for the acidified foods are not higher than 4.6 in that batch records, lot numbers 110896 and 110897, indicate finished pH values above 4.6 [21 CFR 114.80(a)(2)].
4. Product codes do not identify the establishment where this product is packed, the actual year it was packed, and the period during which it was packed [21 CFR 114.80(b)].

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

Within 15 days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the correction will be completed. Your response should be sent to the attention of Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Our investigator collected a sample of your "Old Bavarian Red Cabbage" (97-079-059) and a sample of your "Pickled Red Cabbage with Apples" (97-079-060). Six cans of each sample were examined for filth and pH determination. The following results are included for your information: One whole thrip (0.64mm) and 1 unidentified insect fragment (0.62mm) were found in sample 97-079-059; the average pH was 3.93. Seventeen unidentified insect fragments (0.1 - 0.52mm) were found in sample 97-079-060; the average pH was 3.44.

Sincerely yours,



John Feldman
Director
Minneapolis District

JEH/ccl