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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1099
Telephone: 612-334-4100

PURGED FAX

November 12, 1996

cc: HFI-35/FOI Staf
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-9

James Byrnes
President
J. G. Van Holten & Sons, Inc.
703 West Madison
Waterloo, Wisconsin 53594

Dear Mr. Byrnes:

During an inspection of J. G. Van Holten & Sons, Inc., Waterloo, WI, on October 15, 1996, FDA Investigator David M. Mosier and Wisconsin Department of Agriculture, Trade and Consumer Protection Inspector Chris Zabel collected a sample of Van Holten's Kosher Pickles (sample 97-079-015). Analysis of the product found unidentified striated animal hairs ranging from 5 to 10 mm in length.

Filth in your finished product causes it to be adulterated under Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act. Food that is found to be adulterated is subject to regulatory action.

It is your responsibility to review your operations, isolate possible sources from which the hair may have entered into the product, and take corrective action to prevent a recurrence of these findings.

Page Two

James Byrnes
November 12, 1996

Additionally, an employee wearing boots that had not been cleaned and sanitized was observed walking in a pickle heating tank. Mold growth was observed on walls and ceilings throughout the facility.

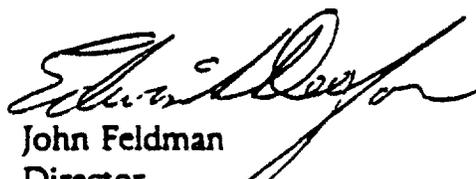
This letter is not meant to be an all-inclusive listing of the deficient conditions and practices at your food facility. As president, the most responsible individual at J. G. Van Holten & Sons, Inc., it is ultimately your responsibility to ensure that the pickle manufacturing operation in Waterloo, 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.

Your reply should be directed to Howard E. Manresa, Compliance Officer, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, MN 55401. Mr. Manresa may be reached at (612)334-4100 ext. 156.

Sincerely yours,



John Feldman
Director
Minneapolis District

HEM/ccl