



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-35

August 1, 2000

Ms. Susan L. Boyd, President
Sun Sprouts of Traverse City
6447 Boyd Road
Williamsburg, Michigan 49690

Dear Ms. Boyd:

On June 29, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 6447 Boyd Road, Williamsburg, Michigan. The inspection was conducted to determine compliance with the current Good Manufacturing Practice requirements (cGMP's) for foods (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the cGMP's for foods (21 CFR 110). The FDA investigator presented your firm with a list of inspectional observations (FD-483) which presents the investigator's evaluation of your firm's performance regarding various aspects of the current Good Manufacturing Practice requirements for foods (21 CFR 110).

During the inspection, it was determined among other things that your firm is not analyzing the spent irrigation water for your sprout operation.

As such, these sprout products are adulterated within the meaning of 402(a)(4) of the Act because they are being produced under insanitary conditions that may render sprouts injurious to health. The conditions under which these sprout products are being produced are considered unsanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility.

*Redacted
8-2-00
CL*

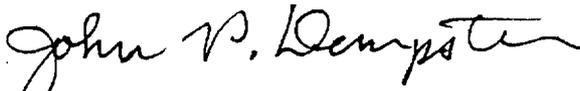
The above is not intended to be an all inclusive list of deviations at your facility. It is your responsibility to assure that your establishment is in full compliance with all requirements of the federal regulations.

You should take prompt measures to correct this deviation. Failure to promptly correct the deviation noted may result in regulatory action without further notice. Such action includes 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 this violation, including an explanation of each step taken to prevent its recurrence. If corrections 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 written reply should be directed to Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Avenue, Detroit, MI 48207, telephone 313-226-6260, extension 135.

Sincerely yours,


for Raymond V. Mlecko
District Director