



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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

WARNING LETTER  
2000-DT-33

September 12, 2000

Mr. Michael H. Lalley, President  
Living Foods, Inc.  
1900 W. Main Street  
Ionia, MI 48846

Dear Mr. Lalley:

On June 5 and 6, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1900 W. Main Street, Ionia, Michigan. The inspection was conducted to determine compliance with The Federal Food, Drug and Cosmetic Act (hereafter referred to as "The Act") and to determine if your sprout processing operations were conducted under sanitary conditions.

During the inspection, the FDA investigator observed significant shortcomings in your operations that are not in compliance with The Act. The FDA investigator presented your firm with a list of inspectional observations (form FD-483) which presents the investigator's evaluation of your firm's performance with respect to compliance with The Act.

The inspection determined among other things, that although your firm was analyzing the spent irrigation water for the alfalfa sprout operation, your firm was not doing microbiological testing for the other sprouts you process. These included clover sprouts, broccoli sprouts, radish sprouts, spicy sprouts, 7-sprouts, garlic sprouts, and onion sprout. Further, it was determined that no microbiological testing of mung bean sprout production was being done, as this testing had been discontinued by your firm at the first of the year.

As such, these non-tested 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 the 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.

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

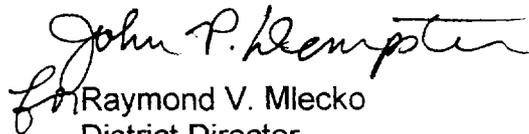
You should take prompt measures to correct this deviation. Failure to promptly correct the deviation noted may result in regulatory action without further notice. Such action includes seizure and or injunction.

We acknowledge your phone call of June 7, 2000, to Investigator Clark regarding your plans for microbial testing. During that phone conversation you indicated you would now test (spent irrigation water) for all sprouts that you decide to continue to grow. It was indicated you would continue to grow alfalfa and mung bean sprouts, but that decisions on which other sprouts would be produced had not yet been made. Although we appreciate your prompt phone call, we request your response in writing.

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