



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
2001-DT-06

December 28, 2000

Mr. Donald W. Bruning, Owner
Quality Produce
6704 Antelope Drive
Nineveh, Indiana 46164

Dear Mr. Bruning:

On May 23, 2000 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 6704 Antelope Drive, Nineveh, Indiana. 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. With respect to some of these, 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.

More importantly, the FDA Investigator discussed with you observations concerning your microbial testing procedures for the sprouts you produce. A review of the inspectional findings indicates the following significant conditions that need to be addressed and corrected:

Your firm performs microbial testing on spent irrigation water [REDACTED] As indicated in the guidance documents presented to you, microbial testing should be conducted on every batch of sprouts produced.

Your firm is not conducting routine microbial testing for *Salmonella* on the batches of sprouts you produce. Again, this should be tested for on each batch produced.

Handwritten signature
12/28/00

We acknowledge your testing of spent irrigation water from the manufacture of alfalfa sprouts and mung bean sprouts for *E. coli* using the [REDACTED]. However, we do not consider the test that you are using to be an effective equivalent to the test methods listed in the industry guidance document "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production."

The testing procedures described in the guidance are screening tests. They were chosen to give results as quickly and as simply as possible on the presence or absence of *Salmonella* and *E. coli* 0157:H7. Sprouts and their irrigation water have a high level of natural microflora that can interfere with detection.

Detection effectiveness of test kits can vary depending on multiple factors such as, but not limited to, food type, level of normal flora present and the enrichment media used. The testing procedures described in the guidance involve an enrichment step to encourage the selective growth of pathogens, if they are present, to make their detection possible.

FDA is not aware of any test kits that will detect pathogens in spent irrigation water when an enrichment step is not performed. The [REDACTED] that you are using does not contain an enrichment step. As noted in the sprout guidance, if screening methods other than those described in the guide are used, they should first be validated using spent irrigation water either by comparative studies with standard methods described in the FDA Bacteriological Analytical Manual (BAM) or by formal collaborative studies. However, your firm has not provided our investigator with data demonstrating the equivalency of the kit being used to standard BAM methods for detecting *E. coli* 0157:H7 and *Salmonella* in spent irrigation water.

Because of the above, your sprout products are considered 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 adequate 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 these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and or injunction.

We note that during the inspection, you asked for exemptions from the above based on several factors. Please understand Mr. Bruning that we can grant no exemptions in these instances in that that proper microbial testing procedures must be followed in order to assure the product produced is not adulterated within the meaning of The Act. We recognize that the findings now being presented to you in this letter are dated, but nevertheless believe it important to bring these deficiencies to your attention so that you have an opportunity to take appropriate actions to assure your products are in compliance.

Please notify this office in writing, within thirty (30) working days of your receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. If corrections cannot be completed within 30 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
Detroit District