



114084n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-81

August 18, 2000

Wong Kwok-Cheng, president
Kwok-Cheng Enterprises, Inc.
c/o: Fully Foods
400 NE 67th St.
Miami, FL 33138

Dear Mr. Kwok-Cheng:

We inspected your sprout production facility at 3785 US Alt. 19 North, Palm Harbor, FL on June 21, 2000. Our inspection found that you have failed to adopt effective preventive controls to reduce the risk of raw sprouts becoming a vehicle for foodborne illness and to ensure that your sprouts are not adulterated under the provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our inspection found that your sprouts are adulterated within the meaning of section 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 the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water has not been adopted and implemented by your sprouting facility. For example, at the time of our inspection in June, your firm had not conducted any microbial testing of spent irrigation water and no sampling method or plan for testing of spent irrigation water had been established. Daily planting/production logs were not being prepared for each date of planting and the lot numbers of seeds used for sprouting were not always identified on your production records.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as recent test results for spent irrigation water, a method/plan for testing spent irrigation water and copies of recent planting/production logs that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. You can find this Act and guidelines for the production and testing of sprout products through links in FDA's home page at www.fda.gov.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have — questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a large initial "E" and "S".

Emma R. Singleton,
Director, Florida District