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Chicago District
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Chicago, Illinois 60661
Telephone: 312-353-5863

April 14, 2004

WARNING LETTER
CHI-6-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Yolanda Dominquez, President
Yoli, Inc. dba Mi Costenita
7647 South Kedzie Avenue
Chicago, IL 60652

Dear Mrs. Dominquez:

On November 4, 5, 10, and 13, 2003, the Food and Drug Administration (FDA) conducted an inspection of your facility. The inspection was conducted to determine your firm's compliance with FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123), "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," and the Good Manufacturing Practices (GMP) regulations for food, 21 CFR Part 110. The seafood HACCP regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated under the Act, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as HACCP. HACCP involves:

1. identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and
2. having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrate to us, to your customers, and to consumers that you are routinely practicing food safety by design. Seafood processors with fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety-oriented workforce, less product waste, and fewer problems generally.

During our inspection, the FDA investigators provided you with a Form FDA 483 (Inspectional Observations), which present their evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements.

Serious deviations that concern us are as follows:

- The violative observations, rodent and insect activity, was observed throughout the facility. 21 CFR 110.35(c)
 - Dead rodent like animal in trap # 2 along the east wall of the candy packaging area.
 - Dead rodent like animal in trap #21 along southwest wall of the warehouse.
 - Approximately 10 rodents like fecal pellets were found on the floor next to a steel beam along the central portion of the south wall of the warehouse.
 - Approximately 26 rodents like fecal pellets were found on the floor along the west wall, near the warehouse cooler.
 - Approximately 10 rodents like fecal pellets were next to a burrow like hole in the northeast corner of the warehouse.
 - Approximately four rodents like fecal pellets were found on a slip sheet on a pallet in the southwestern central portion of the warehouse.
 - Approximately 15 rodents like fecal pellets were found along the southwestern wall of the warehouse.
 - Approximately five live moths like insects were observed flying in and out of cases of dried peppers in the south portion of the warehouse.
 - Approximately four larvae like casing were observed on a case of dried chili peppers located in the south portion of the warehouse.

- Your firm has failed to maintain your facility in sufficient repair. 21 CFR 110.35 (a).
 - Gap approximately 3 feet in length and 2 inches in height was observed in dock door #2 in the south docking area, providing entryway for pests into your facility.
 - Approximately 2 foot long and 2 foot wide gaps were found in the west dock door pedestrian doorway, providing entryway for pests into your facility.
 - A water leak was observed on the floor along the northwestern portion of the warehouse, causing a puddle approximately 12 foot long and 6 feet across.

- A PVC pipe in the exterior north wall of the herb packaging room had a gap surrounding it, providing a pest entry point into the facility.
 - A city drain with large open slots located in the dock staging area is providing an entry way for pests.
 - A burrow like hole was observed in the south wall of the warehouse that provides an entry way for pests.
- You must have a written HACCP plan which adequately identifies each food hazard that is reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). Your firm does not have a HACCP plan to identify sulfites as a hazard which is likely to occur in your repackaging of dried shrimp products. This issue was brought to the firm's attention from the previous inspection conducted on 01/30/03.
- You must declare sulfites on shrimp product label to comply with 21 CFR 101.100(a)(4). During this inspection, a sample (255028) of your bulk whole dried shrimp was collected, and was found to contain sulfites above the detectable amount limit of 10 ppm.
- An employee was observed sneezing on their hands then resumed packing chilies without first washing or otherwise sanitizing her hand. 21 CFR 110.10(b)(3).
- Your firm failed to adequately calibrate and maintain thermometer used in recording temperatures for cooler used to hold dried seafood and produce. This does not comply with 21 CFR 110.40(f).
- Your firm failed to maintain smoothly bonded seams on food contact surfaces to comply with 21 CFR 110.40(b). For example, in the herb and snack processing area, tape covers the crease joint between the two tables. That does not allow for the food contact surface of the two tables to be properly maintained and sanitized. This is a repeat observation from the previous inspection conducted on 01/30/03.
- Your firm failed to hold and store cleaning and sanitizing agents in a manner that protects against contamination of food, and food contact surfaces, necessary to comply with 21 CFR 110.35(b)(2). For example, open cleaning and sanitizing agents were stored approximately one foot from finished product in the herb and snack packaging room.

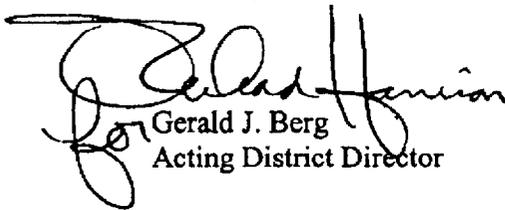
- Your firm failed to provide sufficient space for stored product and packaging material, as necessary for maintenance of sanitary operations and the production of safe food. For example, in the southwest portion of the warehouse, dried chilies and excess packaging materials were stored in a manner such that inspection for rodents can not be done. The pallets were packed tightly together, providing no room to conduct routine inspection for rodents or other pests. 21 CFR 110.20(b)(1).

- Your firm failed to have an automatic temperature alarm system for freezers and cold storage compartments to indicate if and when significant temperature changes had occurred. 21 CFR 110.40(e).

The above is not intended to be an all inclusive list of deficiencies at your facility. Several of the deficiencies noted in this letter are similar to deficiencies that were documented in our January 2003 inspection and described in the letter issued to you dated April 16, 2003. You are reminded that it is your responsibility to assure adherence to each requirement of the Act, and its implementing regulations. We request that you take prompt action to correct all violations. Failure to promptly correct these violations may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to correct these violations, including an explanation of steps that will be taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your written reply should be sent to Matthew Sienko, Compliance Officer, at the address listed in the letter head.

Sincerely,


for Gerald J. Berg
Acting District Director