



December 4, 2000

WARNING LETTER
CHI-6-01

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Guadalupe J. Zurita, President
Chilemex, Inc.
2354 S. Ashland Avenue
Chicago, IL 60608

Dear Mr. Zurita:

On September 13, 14 and 25, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, as a follow-up to our inspection of June 23 and 24, 1999. The purpose of these inspections was to determine both compliance with the FDA Hazard Analysis and Critical Control Point (HACCP) Regulations for seafood, implemented in December of 1997, and compliance with the Good Manufacturing Practice (GMP) Regulations for foods. Subsequent to the June 1999 inspection, we sent you a letter dated August 6, 1999, notifying you of serious HACCP deficiencies observed during that inspection. In that letter, we requested a response from you, but none was received. At the conclusion of the September 2000 inspection, the investigator issued an FDA 483 (Inspectional Observations), listing observations that included continued serious deficiencies in relation to HACCP requirements, as well as including GMP deficiencies.

The deficiencies identified in these inspections include deviations from FDA's Seafood HACCP Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and deviations from FDA's Good Manufacturing Practice Regulations for Human Food (21 CFR 110). These violations cause your products to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at <http://www.fda.gov>.

Specifically, our investigator found the following violations in the current inspection:

- In regard to your Import Seafood Operation:
 - Your firm has failed to develop and implement a list of written product specifications that are designed to ensure that the product you import is safe, and is processed in accordance with Seafood HACCP Requirements. [See 21 CFR Part 123.12(a)(2)(i).] This deviation was also brought to your attention in our letter, dated August 6, 1999, pursuant to our previous inspection of June 1999.
 - Your firm has failed to perform one or more of the importer's affirmative steps, which are identified in 21 CFR 123.12(a)(2)(ii). This deviation was also brought to your attention in our letter, dated August 6, 1999, pursuant to our previous inspection of June 1999.

Additionally, our laboratory tested a sample of ground shrimp collected during the current inspection, and found an ammoniacal odor indicative of decomposition in all subsamples. The lab also detected and confirmed the presence of FD&C Red No. 40, which is not declared in your product labeling. This color is permitted in foods only if it is added from a certified lot; the color must be declared on the product label, according to 21 CFR 101.22(k)(1).

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Federal 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, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct and prevent the recurrence of these objectionable conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also, provide documentation, relating to the affirmative step(s) and to product specifications, that all corrections have been made.

In addition to the deviations described on page one, and continuing into page two, of this letter, the following observations were made during the current inspection:

- In regard to your Domestic Seafood Operation:
 - Your firm has failed to adequately monitor and correct pest (rodent) conditions, as well as to develop HACCP Sanitation Monitoring Records and Corrective Action Records for Exclusion of Pests, in accordance with 21 CFR 123.11.

- Your failure to control rodent activity at your firm causes your products to be adulterated under Section 402(a)(4) of the Act, in that they are stored under conditions whereby they may become contaminated:
 - Rodent excreta pellets were observed along the North, South and West walls that delineate the internal perimeter of your food-storage warehouse.
 - Rodent excreta pellets were observed on the base of a pallet of seasonings, and near pallets of peppers.
 - A dead rodent was observed on a glue board, near broken peppers and seeds, in a room adjacent to the food storage warehouse.
 - Openings, which could contribute to a rodent infestation, were noted in the East and West doors of the food-storage warehouse.

Your reply relating to all of these concerns should be directed to the Food and Drug Administration, Attention: James Karpus, Compliance Officer, (312) 353-5863, ext. 199.

Sincerely,

\s\
Raymond V. Mlecko
District Director