



g130d

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

August 22, 2001

WARNING LETTER
CHI-44-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Patrick A. Bruno, President
Gourmet Express Marketing, Inc.
26 W. 333 St. Charles Road
Carol Stream, IL 60188

Dear Mr. Bruno:

On May 2 and 10, 2001, the Food and Drug Administration (FDA) conducted an inspection of your firm, as a follow-up to our inspection of October 3, 4, 10 and 12, 2000. The purpose of these inspections was to determine compliance with the FDA Hazard Analysis & Critical Control Point (HACCP) regulations for seafood, implemented in December 1997, and with FDA's labeling requirements.

The deficiencies identified during and as a result of these inspections include a serious deviation from FDA's seafood processing (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). This deviation, which was previously brought to your attention, causes your vacuum-packed raw seafood to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. (You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.)

Specifically, the following violation existed during both of the above-referenced inspections:

- Your HACCP Plan fails to control the hazard of Clostridium botulinum.

Your HACCP Plan for controlling pathogens must list an appropriate monitoring procedure(s), to comply with 21 CFR 123.6(c)(4). Your firm's HACCP Plan for frozen seafood products lists a monitoring procedure for controlling microbiological hazards at the vacuum-packaging storage and distribution Critical Control Points (CCPs) that is not adequate to control the food safety hazard of C. botulinum growth and toxin formation.

Page 2

Since your firm has chosen not to appropriately label individual product packages of frozen seafood products with sufficient handling instructions, your HACCP Plan must specifically control the hazard of Clostridium botulinum, with measures that are equivalent to the controls for vacuum-packed fresh fish.

The above-listed violation is not intended to be all-inclusive regarding deficiencies that may exist in your operations. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct this violation. Failure to promptly correct this violation 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. Include copies of any available documentation that demonstrates that corrections have been made.

In addition to the deviation described above, it was also observed during the current inspection that your HACCP Plan has not been signed and dated.

Your reply relating to all these concerns should be directed to James Karpus, Compliance Officer, at the Chicago District Office.

Sincerely,

\s\

Raymond V. Mlecko
District Director