DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M4880n

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 9, 2000

Mr. Alain Sintureil, President
Les Trois Petits Conchons
453 Greenwich Street
New York, NY 10013

Dear Mr. Sintureil:

On July 17, 18, and 20, 2000, a seafood HACCP inspection was conducted at your firm, House of Bricks, Inc., located at 625 South Main Street, Wilkes Barre, PA 18701. The inspection was conducted by Investigator Audrey T. Uy of the Food and Drug Administration (FDA), and Inspector Robert Molinaro of the Pennsylvania Department of Agriculture (PDA). The inspection revealed that your firm manufactures vacuum packaged ready-to-eat seafood pâté.

During the inspection, serious deviations from Title 21 Code of Federal Regulations (21 CFR), Part 123, Fish and Fishery Products, were documented. These deviations cause the vacuum packaged ready-to-eat seafood pâté manufactured by your firm to be adulterated within the meaning of Section 402(a)(4) of the Food Drug and Cosmetic Act (the Act) in that it has been prepared, packed, or held under conditions whereby it may have become injurious to health, as follows:

1. You continue to have no written HACCP plan when one is required for the seafood products that you process [21 CFR Part 123.6(b)].

Your firm was previously advised of this deficiency in our letter of April 9, 1999, yet you still do not have a plan. During the current inspection, you informed the FDA and PDA that you consider your "Hazard Analysis for ... Seafood Mousse/Pâté (sf7, TSF)" your written HACCP plan. A hazard analysis is not a written plan but rather a tool in determining the need for a HACCP plan [21 CFR 123.6(a)].

1. You have not adequately monitored sanitation conditions and practices during processing [21 CFR 123.11(b)].

For example, your firm does not monitor the safety of water used in processing; the prevention of cross contamination; the maintenance of hand washing/sanitizing and toilet facilities; the protection of food and food contact surfaces from adulteration; the proper labeling, storage and use of toxic compounds; and the exclusion of pests from the facility.

In addition, the inspection revealed that your firm's only preventive measure to control the food safety hazard associated with the formation of *Clostridium botulinum* toxin in finished product is by refrigeration; this measure alone is not sufficient. Critical limits for each preventive measure must be established, monitored, and verified. When your written HACCP plan is developed, you should verify that your plan is adequate to control food safety hazards, and that the plan is being effectively implemented. Currently, you are either not conducting or inadequately documenting verification activities.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific actions that you are taking to correct these deviations. You may wish to include in your response useful information 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 your 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, the Seafood HACCP regulations (21 CFR Part 123) and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be sent to Richard C. Cherry, Compliance Officer, at the address in the letterhead.

Sincerely,

W. Charles Becraft
for Thomas D. Gardine
District Director
Philadelphia District

Enclosure: FDA-483