



D1391B HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
Fax (504) 589-4657

February 10, 1998

WARNING LETTER NO. 98-NOL-17

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven R. Grinstead, President and CEO
Fresh America Corporation
6600 LBJ Freeway, Suite 180
Dallas, Texas 75240

Dear Mr. Grinstead:

An inspection of Fresh America of Louisiana, dba Bano Quality Products, Inc., 6930 South Choctaw Drive, Baton Rouge, Louisiana, a prepared cut vegetable processor, was conducted by the Food and Drug Administration on January 27-29, 1998. During that inspection, our investigators documented numerous insanitary conditions which causes your cut vegetable products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act, in that the products were prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth.

Objectionable insanitary conditions noted included: (1) shredded vegetable products in direct contact with numerous insanitary objects, including the metal hoist chain, hoist electrical cord, and the rusty welded water flume; (2) employees handling insanitary objects, such as plastic crate bottoms, rubber hose, and hoist electrical cord, then contacting shredded bell peppers; (3) employees allowing their clothing to directly contact shredded vegetables; (4) condensate dripping from plastic pipes onto shredded vegetables; (5) inadequate washing and sanitizing of processing equipment; (6) encrusted residues from previous operations on knives used to cut vegetables and in crates used to hold cut vegetables; (7) vegetables picked up from the floor and placed back into production; and, (8) perforated plastic crates containing whole peeled onions in direct contact with cooler walls and plastic curtains in cooler doorways.

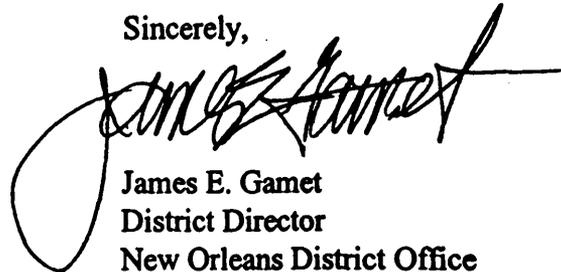
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", written over a large, stylized loop.

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

cc: Mr. Samuel J. Montalbano, Director of Operations
Fresh America of Louisiana
dba Bano Quality Produce, Inc.
6930 South Choctaw Drive
Baton Rouge, Louisiana 70806

/tjt