



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

93712d

November 25, 2002

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-3-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ira A. Gitlin, President
Milfico Foods, Inc.
2500 Lunt Avenue
Elk Grove Village, IL 60007

Dear Mr. Gitlin:

The Food and Drug Administration (FDA) conducted inspections of your firm on June 6, 2002, and on July 23 and 24, 2002, and found serious deviations from Title 21, Code of Federal Regulations, (21 CFR), Part 101-Food Labeling and Part 123-Hazard Analysis and Critical Control Point (HACCP) System/Fish and Fishery Products. These deviations cause the batter-breaded seafood products that you manufacture to be in violation of Sections 402(a)(4) and 403(k) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your batter-breaded seafood products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. Further, based on FDA analytical findings, your Gourmet Deluxe Breaded Shrimp product is misbranded within the meaning of Section 403(k) of the Act. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at <http://www.fda.gov>.

Our determinations, in regard to the deviations we found during the current inspection, are as follows:

LABELING

- The Gourmet Deluxe Breaded Shrimp that your firm manufactures is misbranded under Section 403(k) of the Act for failing to declare sulfites in the list of ingredients as required by 21 CFR 101.22(j) and 101.4(b)(1). FDA analysis of a sample (Sample #179214), collected from your firm on June 6, 2002, confirmed that this product contains sulfites at levels greater than 10 ppm.

SEAFOOD HACCP

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for batter-breaded shrimp does not list the food safety hazard of sulfites.

Sulfiting agents must be declared on the product label of a finished food unless they are exempt from labeling because they are considered incidental additives under §§ 101.100(a)(3) and (4). A sample of GOURMET DELUXE BREADED SHRIMP, collected during our inspection, was analyzed by our Arkansas Regional Lab, and was found to contain greater than 10 ppm sulfiting agents in the original and check analyses. Although you have indicated to our investigators that you do not add sulfiting agents to the shrimp that you bread, your firm is, however, required to declare the presence of sulfiting agents already present in shrimp, and in other products, that you receive, process and distribute, when the level of these sulfiting agents is at or above 10 ppm.

You may refer to Chapter 19 of the FDA Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001, for recommendations on how to control sulfites in your finished product. This Guidance provides information on control of sulfites through labeling, testing of incoming shrimp for residues of sulfiting agents, receipt of a supplier's certification that sulfiting agents were not used on incoming lots of shrimp, and reviewing the labeling (or accompanying documents) on shipments of shrimp received from another processor for the presence of sulfite declaration.

At the close of our inspection of June 2002, your firm's Secretary, Mr. Tod M. Gitlin, was issued a Form FDA 483, which is a list of our investigators' observations of deviations noted during our inspection. (A copy of the FDA 483 is enclosed.) Before our investigators' inspectional report was forwarded to our compliance office, your firm faxed our lead investigator for that inspection a copy of revised labels to include the whey ingredient, for your GOURMET DELUXE BREADED TAIL ON SHRIMP IN A BASKET, and for your GOURMET DELUXE BREADED MINI TAIL ON SHRIMP POUCH PACK. Your firm also faxed him a certificate of calibration for a digital thermometer.

During our inspection of July 2002, your firm's Secretary provided our investigator with a copy of revised labels to include both the dried whey and the hydrolyzed soy protein ingredient. The products for which you provided revised labels included the following: ROYAL CHOICE BREADED ROUND TAIL OFF SHRIMP, BOSTON PRIDE FANTAIL BREADED SHRIMP, GOURMET DELUXE BREADED TAIL ON SHRIMP IN A BASKET, GOURMET DELUXE BREADED MINI TAIL ON SHRIMP POUCH PACK, PRIME BRAND LARGE GOURMET BUTTERFLY BREADED SHRIMP, ABS BREADED POPCORN SHRIMP, OPEN SEA BREADED SEA SCALLOPS, and OPEN SEA RAW BREADED NATURAL OCEAN PERCH FILLETS.

While we acknowledge these corrective actions, your response to sulfite declaration, labeling and seafood HACCP deficiencies in the current inspection should include a specific, comprehensive approach to monitor and prevent these defects from recurring.

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence to each requirement of the Act, and its implementing regulations, including being vigilant that products received, manufactured, stored and distributed meet all requirements. 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 provide this office, within 15 working days from your receipt of this letter, a detailed response stating the actions you plan to take, or have taken, to correct and prevent the objectionable conditions we have cited. (It is not necessary to report the corrections we have noted above, unless you have additional relevant information.) Provide the specific time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made.

Your reply should be directed to James T. Karpus, Compliance Officer, at the address listed in the letterhead.

Sincerely,


Arlyn H. Baumgarten
District Director

Enclosure: Form FDA 483