



December 12, 2001

02-BLT-07

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Isaac, President
Martin's Seafood, Inc.
Maryland Wholesale Seafood Market
7901 Oceano Avenue
Jessup, Maryland 20794

Dear Mr. Isaac:

The Food and Drug Administration (FDA) conducted an inspection of your breaded seafood operation located at 1618 E. Bank Street, Baltimore, Maryland, on May 2 & 4, 2001. On July 2 & 12, 2001, we conducted a follow-up inspection at your facility located at 7901 Oceano Avenue, Jessup, Maryland.

Our inspections revealed that your product "Lighthouse BRAND BREADED OYSTERS" is misbranded within the meaning of 403(i)(2) of the Food, Drug, and Cosmetic Act (FD&C Act) and Title 21, Code of Federal Regulations (CFR) 101.4(b)(2), in that the label fails to bear the common or usual name of each ingredient, including ingredients derived from the batter and the breading mixes.

Labeling for the ingredients used to produce your "Lighthouse BRAND BREADED OYSTERS" indicates that the batter mix contains, among other ingredients, bleached wheat flour, nonfat milk, and eggs, and the breading contains, among other ingredients, bleached wheat flour. Wheat, milk, and eggs are allergens and failure to declare, in the ingredients' statement of the breaded oysters, ingredients that contain these allergens is a health hazard.

This is not an all-inclusive list of the deviations at your firm. As a food manufacturer, you are responsible for assuring that your overall operations and the foods you manufacture and distribute are in compliance with the law. FDA's Compliance policy Guide 555.250 (copy enclosed) provides a "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens." Additional information, including the Code of Federal Regulations and the FD&C Act, may be obtained on the internet web-site entitled "www.fda.gov."

For your information, allergen-related hazards for seafood products should be addressed in your Hazard Analysis and Critical Control Point (HACCP) plan. Your HACCP plan provided to the investigator during the May 2 & 4, 2001 inspection does not cover this hazard. FDA's Fish and Fishery Products Hazards and Control Guidance, Third Edition, June 2001, Chapter 19, and Appendix 6, provide guidance on application of HACCP principles to allergen-related issues for seafood products. Please

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notify this office in writing what steps you have already taken or will take to cover all allergen-related hazards in your HACCP plan.

You should take prompt action to correct all these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action being taken by the FDA without further notice. Such action includes 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 the noted violations and to prevent recurrence. We also request that you provide documentation for the corrections, as they are made, including copies of any revised labels. 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.

Your response should be sent to Rosalie Bucey, Compliance Officer, Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. Ms. Bucey may be reached at (410) 779-5417.

Sincerely,



Lee Bowers

Director, Baltimore District

cc: Ms. [REDACTED] Operations Manager
Martin Seafood, Inc.
1618 E. Bank Street
Baltimore, Maryland 21231

Enclosure