



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

03-BLT-13

May 14, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Leslie V. Issenock, President
M&I Seafood Manufacturers, Inc.
8805 Kelso Drive
Baltimore, Maryland 21221

Dear Mr. Issenock:

The Food and Drug Administration (FDA) conducted an inspection of your seafood processing firm located at 8850 Kelso Drive, Baltimore, Maryland 21221 on March 18-24, 2003. Review of labels collected during the inspection revealed that your label for "chesapeake bay Brand JUMBO gulf shrimp" is misbranded within the meaning of Section 403(q)(1) of the Food, Drug and Cosmetic Act (FD&C Act) in that the label bears the nutrient content claim "LOW IN CALORIES" and fails to bear the nutrition information required by Title 21, Code of Federal Regulations (CFR), Part 101.9.

The label for this product does not qualify for an exemption from nutrition labeling per Section 403(q)(5) and 21 CFR 101.9(j)(10) since the label contains the nutrient content claim "LOW IN CALORIES".

This same violation was brought to your attention in a Warning Letter sent to your firm from the Baltimore District Office on December 19, 1997.

The above violations are not intended to be an all-inclusive list of the labeling deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with the laws and regulations enforced by the FDA. You should take prompt action to correct the labeling violations and prevent their recurrence. Failure to promptly do so may result in regulatory action without further notice, such as seizure or injunction.

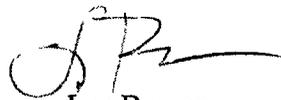
We would also like to advise you that use of the product name "chesapeake bay ...JUMBO gulf shrimp" may be in conflict with Title 21 CFR 101.3 – Identity labeling of food in packaged form, since the shrimp was received from Indonesia.

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Please respond in writing to this office within 15 working days of receipt of this letter. Your response should outline the ~~steps you~~ steps you have taken to correct the noted violations. An original label, if revisions to the label are made, should be included with your response. If corrective action cannot be completed within 15 working days, you should state the reasons for the delay and the time frame in which the corrections will be made.

Your reply should be addressed to Ms. Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions regarding the issues set forth in this letter, you may contact Ms. Bucey at (410) 779-5417.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Bowers', with a long horizontal flourish extending to the right.

Lee Bowers
Baltimore District Director