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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1121667

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Leslie V. Isennock, President
M & I Seafood Manufacturing, Inc.
3916 Old North Point Road
Baltimore, Maryland 21222

Dear Mr. Isennock:

During an inspection of your Baltimore, Maryland manufacturing facility conducted by the Food and Drug Administration (FDA) on July 14 and 15, 1997, product samples were collected for analysis and labels were collected for review.

Based on our label review, your "Jumbo Mushroom Caps Stuffed with Crab" and "Unbreaded Stuffed Flounder with Crab" are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products represent the seafood portion of the stuffing to be solely crabmeat, which is false and misleading for a product which also contains blue crab surimi. These products are also adulterated within the meaning of Section 402(b)(2) of the Act, as blue crab surimi has been substituted in part for crabmeat. Likewise, "Lobster Cakes" are misbranded and adulterated because they represent the seafood portion as solely lobster meat, which is false and misleading for a product which also contains blue crab surimi.

In addition, your products "Jumbo Gulf Shrimp" and "Peeled & Deveined Shrimp" are misbranded within the meaning of Section 403(q)(1) of the Act, in that the labels bear the nutrient content claim, "Low in Calories," but fail to bear nutrition labeling as required under Title 21, Code of Federal Regulations, Part 101.9. These products are not exempt under Section 403(q)(5) of the Act from bearing nutrition labeling because they bear a nutrient content claim.

The law requires that the net contents be declared in metric units as well as inch-pound units. However, FDA has not published final regulations on how the declaration is to be made. The agency recommends that if you wish to avoid having to change labels when the regulations on

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the metric declaration become effective, you consider adding the metric contents statement now, using the guidance published in the proposed regulations, Federal Register, December 21, 1993.

We expect that any differences between that proposal and the final regulations will be minor and will not by themselves require a label change. Enclosed is a copy of "A Food Labeling Guide" for your reference.

The above violations are not meant to be an all-inclusive list of deficiencies. It is your responsibility to assure that all of your products are labeled in compliance with all applicable regulations enforced by FDA. Failure to promptly correct these labeling deficiencies may result in regulatory action being initiated by FDA without further notice, including seizure and injunction.

Within 15 working days of receipt of this letter, you should notify this office in writing of the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of William Bargo, Acting Compliance Officer. Mr. Bargo can be reached at (410)962-3442, Ext. 140.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Enclosure