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November 21, 1989

REGULATORY LETTER
CHI-481-90

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven Rubin, President
Vita Food Products, Inc.
2222 W. Lake Street
Chicago, Illinois 60612

Dear Mr. Rubin:

During an inspection of your firm on August 31, 1989, and September 6-8, 12-13, 15, 22, 1989, Food and Drug (FDA) Investigator Harry B. Richmond found a serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1)	The article, "** Herring Party Snacks **", is misbranded because its labeling bears the statement, "*** Herring is also a rich source of Omega-3 Fatty Acids, which has been found to minimize the risk of heart disease..". The article is further misbranded because it fails to bear complete nutrition labeling as required by 21 CFR 101.9. The labeling bears cholesterol and fatty acid claims but fails to bear declarations of the cholesterol and fatty acid content per serving as a part of the nutrition labeling as required by 21 CFR 101.5 in the manner prescribed by 21 CFR 101.9(c)(6)(i) and (ii).

The labeling bears the claim "low cholesterol" and states that "a very small portion of it is cholesterol (20 milligrams)". In the Federal Register of November 25, 1986, we published a proposal to revise the present cholesterol labeling, 21 CFR 101.25. The proposed definition for "low cholesterol" is a term that may be used on the label of a food which contains less than 20 milligrams of cholesterol per serving. We do not object to a manufacturer using the proposed descriptors in the absence of a final rule, provided the product complies with proposed criteria. This product, however, does not comply; therefore, the term "low cholesterol" should be deleted from the label.

We request that you take prompt action to correct this violation. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under the law. These include seizure and/or injunction.

The violation referenced is not intended to be all inclusive. It is your responsibility as a manufacturer and distributor of this article to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and associated regulations are being met.

Please advise us within ten (10) days of your receipt of this letter as to further specific actions taken or intended to be taken to correct these violations and ensure lasting compliance. Your response should be directed to Jerome Bressler, Acting Director, Compliance Branch.

Sincerely,

Raymond V. Mlecko
District Director

[redacted]

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