SEP 5 1990

REGULATORY LETTER

Mr. Edward Parker
Chief Executive Officer
Pacific Rice Products, Inc.
PO Box 2060
Woodland, California 95695

Dear Mr. Parker:

It has come to our attention that you are marketing a product called "Vita Fiber Rice Bran." The product's label contains statements addressed in the Food and Drug Administration's health messages interim enforcement policy expressed in the Federal Register of February 13, 1990, pages 5176-5191 (55 FR 5176). The statements are in violation of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

Section	Brief Description
403(a)(1)	The label statements "WHEN PART OF A LOW FAT DIET, CAN HELP REDUCE CHOLESTEROL", "Nature's Cholesterol Fighter", and "Recent medical research shows that eating Rice Bran every day ...can reduce cholesterol levels. ...one can reduce the risk of heart disease" are false and misleading in that they are not adequately supported by the consensus document cited in the health messages proposal (1988 Surgeon General's Report on Nutrition and Health and the 1989 National Academy of Sciences Report on Diet and Health).
	The label statement "4 Tablespoons, Daily of Vita Fiber Provides 50% of the Surgeon General's Recommendations for Dietary Fiber Intake" is false and misleading because the referenced report does not provide a quantitative recommendation for the amount of dietary fiber needed for reduction of serum cholesterol.

Currently available consensus documents discuss in their supporting texts the potential hypocholesterolemic effects associated with intakes of dietary fibers. These effects are generally limited to the soluble components of dietary fibers when consumed by hyperlipidemic individuals at very high levels as part of a low fat, low saturated fatty acid and low cholesterol total diet. Although these research findings are discussed in the text of the consensus documents, none of these reports has chosen to target recommended quantities of intakes for total dietary fibers or soluble dietary fibers for the U.S. population relative to reduction in risk of coronary heart disease. This caution is apparently partially based on lack of knowledge of the mechanism of action and also on difficulties in interpreting study results since other components of the diet that affect risk of coronary heart disease were altered in addition to dietary fiber. To date the Food and Drug Administration has not made an independent determination as to whether there is an adequate scientific basis to support label claims that soluble fiber or the type of fiber found in rice bran is effective in lowering serum blood cholesterol and risk of coronary heart disease in the U.S. population.

This letter includes only the food misbranding charges related to the health messages on this product. It does not address the possible regulation of your products on other grounds, including as drugs, and is not an all inclusive list of regulatory deficiencies for this product or, for your firm's other products. It is your responsibility to assure that all of your firm's products comply with all aspects of the Act. We, therefore, suggest that you review all similarly labeled products to determine compliance with the Act. Your review should include consideration of the Food and Drug Administration's interim enforcement policy on health messages (55 FR 5176).

We request that you take prompt action to correct the above violations. The FDA would be happy to discuss with you any other potential label deficiencies prior to the time that any corrective actions are taken on the cited violations so that you can assure yourself that all necessary label changes are made in concert. If such action is not taken, FDA is prepared to seek regulatory sanctions provided under the law, which include seizure and/or injunction, on all applicable statutory grounds.

Please notify us within ten (10) days of the steps you have taken to correct these label claims. If corrective action cannot be completed within ten days, please provide the reason for the delay and the time within which the corrections will be completed. Your response should be directed to:

Janice F. Oliver
Director, Division of Regulatory Guidance
Food and Drug Administration
200 C. Street, S.W., (HFF-310)
Washington, D.C. 20204

Sincerely,

L. Robert Lake
Director, Office of Compliance
Center for Food Safety
and Applied Nutrition
Food and Drug Administration