

SEP 5 1990

REGULATORY LETTER

Mr. Thomas Siplon  
President  
Select Origins, Inc.  
11-10 Old Dock Rd  
Yaphank, N.Y. 11980

Dear Mr. Siplon:

It has come to our attention that you are marketing a product called "Rice Bran Oil." This 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 "This unique oil may help reduce cholesterol as part of a low fat and low cholesterol diet" and "Rice Bran Oil...may help reduce cholesterol as part of a diet low in fat and cholesterol" and any similar statements that represent and suggest that the addition of rice bran oil to a diet low in fat and cholesterol will produce a meaningful and sustained reduction in serum cholesterol (and by implication a reduction in the risk of cardiovascular disease) is false and misleading. This relationship was not included in the recommendations of the two consensus documents published in the health messages proposal (1988 Surgeon General's Report on Nutrition and Health and the 1989 Report on Diet and Health from the National Academy of Sciences). Furthermore, the scientific data do not adequately establish the validity of this label statement at this time.

COPY FOR YOUR  
INFORMATION

The label statement "An unsaturated and no cholesterol oil, it has b-sitosterol . . . ." represents and suggests that this product is unique with respect to beta sitosterol content which is false and misleading because beta-sitosterol is common in plants and plant oils, but in inadequate amounts to have a significant effect on serum cholesterol.

This statement also represents and suggests that the amount of b-sitosterol in one serving of Rice Bran Oil is sufficient to have a significant effect on serum cholesterol, which is false and misleading because (although the amount of b-sitosterol in one serving of Rice Bran Oil is not indicated) the U.S.D.A. Handbook No. 6-4 on "Composition of Foods: Fats and Oils . . ." indicates that the total phytosterol content of rice bran oil is 162 mg/100 g. The b-sitosterol content would be expected to be lower, whereas studies showing serum cholesterol lowering effects of b-sitosterol have shown effectiveness only with multiple gram amounts, generally about 3 g or more/day.

We also point out that the claimed benefits from mono- and polyunsaturated fatty acid content are outweighed by the negative attributes of the food (i.e. total fat and saturated fatty acids) with respect to reduction in blood cholesterol and by implication reduction in risk of cardiovascular disease. Reductions are recommended for both total fat and saturated fatty acids in the diet to decrease risk for cardiovascular disease. This product is high fat and does not contribute to a low fat diet.

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 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

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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:

Junice 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