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SEP 5 1990

REGULATORY LETTER

Mr. Gerald Shreiber
President
J & J Snack Foods Corp.
5353 Downey Rd.
Vernon, CA 90058

Dear Mr. Shreiber:

It has come to our attention that you are marketing a product called "Toasted Oat Bran Shake". 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 "REDUCING CHOLESTEROL It's no secret that scientific tests have conclusively proved that adding oat bran to your diet can -and does- significantly reduce cholesterol. ... the results are unanimous. ... ingesting 3 1/2 ounces of oat bran per day may reduce cholesterol by as much as 25%" represent and suggest that when used as directed the product provides a nutritionally significant amount of soluble dietary fiber. These representations and suggestions are false and misleading because they are contrary to fact.

403(a)(1)

The label statement "Pride O' The Farm Oat Bran Shake is 88% pure Oat Bran, the best source of dietary fiber you can buy" is false and misleading because it is contrary to fact. (cont. next page)

COPY FOR YOUR
INFORMATION

Although oat bran fiber is commonly used as a source of fiber, (particularly soluble fiber) in clinical trials, we are unaware of any data which compare all fiber sources to define the "best" source.

403(a)(1)

These label statements are further misleading since they represent and suggest that the ingredient "Oat Bran" (rather than soluble dietary fiber) is the substance of dietary significance relative to claims for lowering 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 for reduction in the 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 as found in oat bran and other dietary sources is effective in lowering serum blood cholesterol and risk of coronary heart disease in the U.S. population.

403(a)(1)
201(n)

The label states "Oat Bran Fiber Rich" and makes cholesterol-reducing claims, but the label fails to provide nutrition labeling and fails to reveal the material fact as to how much fiber is contained in one serving of the product.

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 appl'cable 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