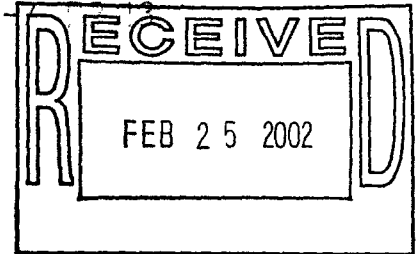


December 18, 2001

Robert Moore, Ph.D.
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

1703 12 18



RE: DSHEA – Section 6 Notification

Dear Dr. Moore:

This letter is to advise the Food and Drug Administration that within the past 30 days Nichi Nichi Pharmaceutical Co., Ltd., has commenced marketing a dietary supplement which bears one or more of the following statements of nutritional support;

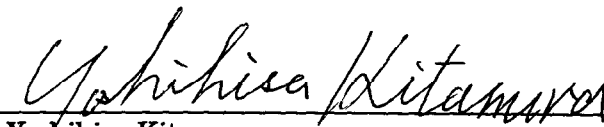
- 1) Supports the health of the digestive tract.
- 2) Promotes a healthy digestive system by providing healthy bacteria to the body.
- 3) Increases and maintains the intestinal micro flora in the body, which supports good health.

These statements are accompanied by the required disclaimer as mandated by Section 6 of DSHEA and in accordance with FDA's final regulation with respect to Section 6 notices.

The name of the product is "Protesun" and is composed of the old dietary ingredient, *Enterococcus faecalis*.

These statement have been reviewed by competent scientific experts who have advised the company that these statements are, in their opinion, truthful, not misleading, and substantiated.

Sincerely,



Yoshihisa Kitamura
C.E.O
Nichi Nichi Pharamceutical Co., Ltd.
239-1 Tominaga, Ohyamada-mura,
Ayama-gun, Mie-ken 518-1417 Japan
Phone (81)595-48-0201
Fax (81)595-48-0209

97S 0162

LET 9351

79375