

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. MCCOLL
A. WES SIEGNER, JR.
ALAN M. KIRSCHENBAUM
DOUGLAS B. FARQUHAR
JOHN A. GILBERT, JR.
JOHN R. FLEDER
MARC H. SHAPIRO
ROBERT T. ANGAROLA
(1945-1996)

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D. C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

MARY KATE WHALEN
OF COUNSEL
JENNIFER B. DAVIS
FRANCES K. WU
DAVID B. CLISSOLD
CASSANDRA A. SOLTIS
JOSEPHINE M. TORRENTE
MICHELLE L. BUTLER
ANNE MARIE MURPHY
PAUL L. FERRARI
JEFFREY N. WASSERSTEIN
MICHAEL D. BERNSTEIN
LARRY K. HOUCHE
DARA S. KATCHER*
KURT R. KARST*
MOLLY E. CHILDS*

*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4284

2-8-93 '03 JUN -6 10:24
May 16, 2003

BY FEDEX

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (FDA)
5100 Paint Branch Parkway
College Park, Maryland 20740

Section 403(r)(6) Notification

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(6), and also pursuant to FDA regulations, 21 C.F.R. § 101.93(a), we hereby submit the following notification to FDA, in the form required by 21 C.F.R. § 101.93(a), concerning a statement that is to be included in the labeling of a dietary supplement product:

Name and address of the manufacturer of the dietary supplement that bears the statement:
Calpis Co., Ltd., 20-3, 2 Chome, Ebisu-Nishi, Shibuya-Ku, Tokyo 150-0021, Japan.

Name and address of the distributor of the dietary supplement that bears the statement:
Calpis U.S.A., Inc., 19675 Mariner Avenue, Suite 101, Torrance, California 90503.

Text of the statement that is being made: "Support for normal blood pressure; use as part of your diet to help maintain a healthy blood pressure level that is already within the normal range."

Name of the dietary supplement (including brand name) that is the subject of the statement and on whose label the statement appears: Ameal S™ Dietary Supplement.

975 0162 LET 12046

2603 MAIN STREET
SUITE 760
IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

I hereby certify that the foregoing information is complete and accurate and that it is my understanding and belief that Calpis Co., Ltd. has substantiation that the above-quoted statement is truthful and not misleading.

Sincerely yours,

A handwritten signature in black ink that reads "Stephen H. McNamara". The signature is written in a cursive style with a long horizontal line extending to the right.

Stephen H. McNamara
For Calpis Co., Ltd.