DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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OCT 19 2001

Mr. Don Brucker
Senior Vice President of R&D
NatureWell, Inc.
7855 Ivanhoe Avenue
Suite 322
La Jolla, California 92037

Dear Mr. Brucker:

This is in response to your letter of October 4, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that NatureWell, Inc. is making the following claim for the product **MigraDaily**:

> "...support normal cerebrovascular tone and resolve cerebral tension and pressure."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, in conjunction with the name of the product (i.e., MigraDaily), suggest that it is intended to treat, prevent, or mitigate a disease, namely migraine headaches. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

# NatureWell INC.

OCT - 3 2001

Office of Special Nutritionals
(HFS-450)
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

78041

Dear Office of Special Nutritionals:

Notice pursuant to 21 U.S.C. 343 (r) (6)

NatureWell, Inc. makes the following notification:

1. Name and Address of Distributor:

   NatureWell, Inc.
   7855 Ivanhoe Avenue, #322
   La Jolla, CA 92037

2. Text of Statement Being Made:

   Studies indicate that the ingredients in MigraDaily can support normal cerebrovascular tone and resolve cerebral tension and pressure.

3. Name of Dietary Ingredient:

   Thiamin Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Calcium (as Dicalcium Phosphate), Magnesium (as Magnesium Oxide), Feverfew extract (chrysenthemum parthenium) (Leaf) (Standardized to 0.8% Parthenolide), White Willow Extract (Selic alba) (bark) (Standardized to 15% Salacin).

4. Name of Dietary Supplement:

   MigraDaily™

I, Don Brucker, certify that the information contained in this notice is complete and accurate, and NatureWell, Inc. has substantiation that the statement is truthful and not misleading.

Dated: 10/4/01

By: _____
Don Brucker
Senior Vice President of R&D
NatureWell, Inc.

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