

NEWAYS INTERNATIONAL

0093 6 JUN -3 P2:28

November 21, 2005

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

VIA FACSIMILIE

212

Subject: Notification for Statements on Dietary Supplement Labeling
Product: Cal-Sea-Um

Dear Sir/Madame:

This notification is being submitted on behalf of Neways International, Inc., 2089 Neways Drive, Springville, UT 84663, a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the *Dietary Supplement Health and Education Act of 1994*, 21 U.S.C. 343 (r) (6), and in accordance with the provisions of 21 CFR 101.93 (a), your Agency is hereby notified that Neways International, Inc. has made structure function claims as described in 21 U.S.C. 343 (r) (6) (A), for its dietary supplement *Cal-Sea-Um*, as follows:

- Statement 1: Supports...maintains...optimal...bone health.
Dietary Ingredient(s): Calcium, Magnesium, Vitamin D
- Statement 2: Contributes to normal bone health and development.
Dietary Ingredient(s): Calcium, Magnesium, Vitamin D
- Statement 3: Includes a vegetable source of Vitamin D to further support bone tissue.
Dietary Ingredient(s): Vitamin D
- Statement 4: Maintains...Contributes to bone density.
Dietary Ingredient(s): Calcium, Magnesium, Vitamin D
- Statement 5: Essential in...maintain(ing)...bone mass...and...strength.
Dietary Ingredient(s): Calcium, Magnesium, Vitamin D
- Statement 6: Provides minerals necessary for healthy bone matrix.
Dietary Ingredient(s): Calcium, Magnesium, Vitamin D

979 0162

LET 17071

Office of Special Nutritionals/CFSAN (HFS-450)

November 21, 2005

Page 2

Statement 7: Facilitates... absorption of calcium..., magnesium..., and other minerals.

Dietary Ingredient(s): Vitamin D

Statement 8: Cal-Sea-Um's combination of magnesium with vitamin D helps boost calcium's effectiveness....

Dietary Ingredient(s): Magnesium, Vitamin D

Statement 9: Supports healthy bones and teeth....

Dietary Ingredient(s): Calcium, Magnesium, Vitamin D

Statement 10: Research indicates... calcium... can even help maintain healthy weight when combined with exercise and a low calorie diet.

Dietary Ingredient(s): Calcium

The undersigned certifies that the information contained in this notice is complete and accurate, and that Neways International has substantiation that these statements are truthful and not misleading.

Sincerely,



Richard A. Evans

Sr. Vice President of Communications and Technology
Neways International, Inc.