



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 21 2000

Mr. Allen K. Davis
Vice President
Neways, Inc.
150 East 400 North
Salem, Utah 84653

Dear Mr. Davis:

This is in response to your letters to the Food and Drug Administration (FDA), dated March 20, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Neways, Inc. is making the following claim for the product **Chitosorb**:

“Dietary Supplement - Fiber for Calorie and Cholesterol Management.”

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 suggests that it is intended to treat, prevent, or mitigate disease, namely hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

You also made a submission for the product **Neways Extreme Balance**. This product is claimed to be a “balanced meal replacement bar.” This product is not a dietary supplement within the meaning of 21 U.S.C. 321(ff). This product is a conventional food.

21 U.S.C. 321(ff) states, in part, that the term dietary supplement means a product that “is not represented for use as a conventional food or as a sole item of a meal or the diet.” Therefore, if you intend to market this product as a dietary supplement, it may not be represented as a meal replacement or, in any other manner, as a conventional food.

975-0163

LET 356

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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, Denver District Office, Compliance Branch, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

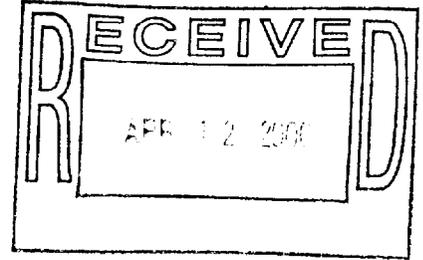
HFS-605

HFV-228 (Betz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-811:4/13/00:70195.adv:disc46

NOTICE OF STATEMENT
Pursuant to 21 CFR 101.93



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

a. Name and address of manufacturer or distributor:

Neways, Inc.
150 East 400 North
Salem, Utah 84653

b. The text of the statement:

Dietary Supplement – Fiber for Calorie and Cholesterol Management

c. The name of the dietary ingredient or supplement:

Vitamin C
Calcium
Deacetylated Chitosan

d. The name of the dietary supplement including brand name:

Chitosorb

Responsible Person

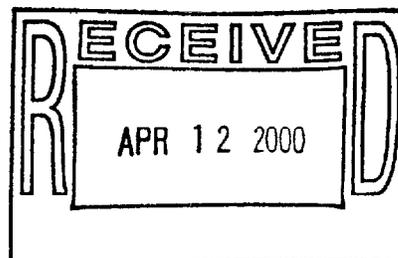
Allen K Davis
Signature

V.P.
Title

3-20-00
Date

70195

NOTICE OF STATEMENT
Pursuant to 21 CFR 101.93



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

a. Name and address of manufacturer or distributor:

Neways, Inc.
150 East 400 North
Salem, Utah 84653

b. The text of the statement:

Dietary Supplement - Balanced Meal Replacement Bar

c. The name of the dietary ingredient or supplement:

Vitamin A Acetate
Ascorbic Acid
Thiamine Mononitrate
Riboflavin
Niacinamide
D-alpha Tocopherol Acetate
Pyridoxine
Cyanocobalamin

D-Calcium Panthothenate
Cholecalciferol
Potassium Iodide
Magnesium Oxide
Ferrous Fumerate
Zinc Gluconate

d. The name of the dietary supplement including brand name:

Neways Extreme Balance

Responsible Person

Allen K Davis
Signature

VP
Title

3-20-00
Date

70195