



OCT 23 1997

0793 '97 DEC 16 P1:41

Ms. Karen A. Weaver
Dilling and Dilling
150 North Wacker Drive
Chicago, Illinois 60606

Dear Ms. Weaver:

This is in response to your letter of October 20, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), on behalf of Natren, Inc., Westlake Village, California. Your submission states that Natren, Inc. is making, among other claims, the following claims for the products:

Healthy Trinity

"Helps prevent yeast over-growth (candida)..."
"...may help alleviate intestinal upsets such as constipation and diarrhea."

Megadophilus

"...inhibit the growth of disease-causing bacteria..."
"Helps reduce cholesterol levels."

Bifido Factor

"Helps to minimize the effect of constipation and/or diarrhea."

Digesta-Lac

"Rids the digestive tract of pathogens..."
"May help alleviate the need for laxatives..."

Mega Vegi-dophilus

"Defends the small intestine against harmful bacteria"

975-0163

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Page 2 - Ms. Karen A. Weaver

Life Start

“Helps prevent a predisposition to allergies and encourages the formation of antibodies against undesirable bacteria and viruses.”

Digesta-Lac Wafers

“...creating a hostile environment for harmful bacteria.”

“May be a good preventive measure for food poisoning.”

Section 403(r)(6) of the act 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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases, including bacterial, viral, and yeast infections, constipation, diarrhea, food poisoning, and hypercholesterolemia. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are 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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, Los Angeles, Office of Compliance, HFR-PA240

DILLING AND DILLING
ATTORNEYS AT LAW
150 NORTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
(312) 236-8417

KIRKPATRICK W. DILLING
KAREN A. WEAVER, R.P.H.
RAKESH M. AMIN, R.P.H.

ESTABLISHED 1917

ALBERT W. DILLING
1892 - 1969
JOHN M. MANN

PATENT AND TRADEMARK
COUNSEL

0794 '97 DEC 16 P
October 20, 1997
RECEIVED
OCT 21 1997

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

Via Overnight Delivery

Re: Notification of Statements of Nutritional Support

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

If necessary, please address future correspondence to our firm.

Sincerely yours,

DILLING AND DILLING

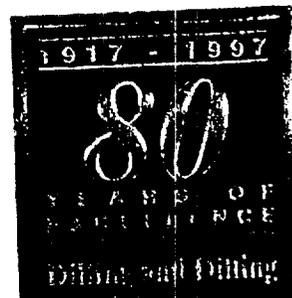
Karen A. Weaver
Karen A. Weaver

Enclosure

NOTE: Also see docket
975-0163

75560 CALLE DEL SUR
INDIAN WELLS, CALIFORNIA 92210
(619) 568-1924
TELEFAX NO
(619) 341-1045

CALIFORNIA LEGAL ASSOCIATE
R. CHANDLER MYERS
301 NORTH LAKE AVENUE
PASADENA, 91101
(818) 792-0007



55312
TELEFAX NO
(312) 236-8418
CABLE ADDRESS
DILGRON

October 20, 1997

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

0795 '97 DEC 16 P1:41

Re: Statements of Nutritional Support

Dear Sir:

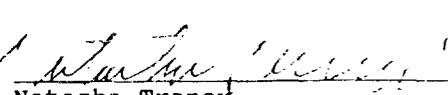
Consider the following as notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: Natren, Inc.
3105 Willow Lane
Westlake Village, California 91361

| <u>Statement Text</u> | <u>Name of Subject Dietary Ingredient(s)</u> | <u>Brand Name</u> |
|---|--|-------------------|
| 1) "Helps prevent yeast over-growth (candida) in both men and women, detoxifies the G.I. tract and may help alleviate intestinal upsets such as constipation and diarrhea". | Lactobacillus acidophilus, Bifidobacterium bifidum and Lactobacillus bulgaricus | Healthy Trinity |
| 2) "This beneficial bacteria produces lactic acids that inhibit the growth of disease-causing bacteria by lowering the pH in the small intestine". "Maximizes food absorption by producing enzymes which aid digestion". "Helps reduce cholesterol levels". | Viable culture containing non-fat milk, Whey and Lactobacillus bifidum, super strain DDS-1 | Megadophilus |
| 3) "Works in the large intestine to keep it healthy". "Bifidobacteria live on the intestinal wall, discouraging bad bacteria from taking up residence and helping the large intestine dispose of unused foods from the body". "Helps to minimize the effect of constipation and/or diarrhea". "Gives benefits all throughout the digestive tract as well as the large intestine". "German studies show B. bifidum bacteria is the most effective agent in reducing stress on your liver functions". | Viable culture containing non-fat milk, whey and Bifidobacterium bifidum, super strain Malyoth | Bifido Factor |

| <u>Statement Text</u> | <u>Name of Subject Dietary Ingredient(s)</u> | <u>Brand Name</u> |
|--|---|--------------------|
| 4) "Rids the digestive tract of pathogens and helps the body digest foods more efficiently". "Naturally aids digestion while getting rid of unfriendly bacteria that want to take up residence in the digestive tract". "May help alleviate the need for laxatives and maintain our natural electrolyte balance". | Viable culture containing non-fat milk, whey and Lactobacillus bulgaricus, super strain LB-51 | Digesta-Lac |
| 5) "Defends the small intestine against harmful bacteria". | L. acidophilus, super strain DDS-1 | Mega Vegi-dophilus |
| 6) "Stimulates better weight gain through nitrogen retention." "Helps prevent a predisposition to allergies and encourages the formation of antibodies against undesirable bacteria and viruses". | Viable culture containing non-fat milk, whey and Bifidobacterium infantis, super strain NLS | Life Start |
| 7) "Helps lower the pH in the intestines, creating a hostile environment for harmful bacteria". "Facilitates better digestion, and is a good appetite suppressor". "Helps the body digest carbohydrates and proteins". "Helps improve the bioavailability and absorption of required minerals, especially calcium". "Designed to aid digestion naturally". "May be a good preventive measure for food poisoning". "Provides a convenient way to promote good digestion and a healthier digestive tract." | Viable culture containing non-fat milk, whey and Lactobacillus bulgaricus, super strain LB-51 | Digesta-Lac Wafers |

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.



Natasha Trenev
President
Natren, Inc.