



OCT 28 1997

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

0811 '97 DEC 16 P1:43

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 Sonne's Organic Foods, Inc., Kansas City, Missouri. Your submission states that Sonne's Organic Foods, Inc. is making, among other claims, the following claims for:

**Sonne's No. 5**

"To help protect against heart conditions"  
"May aid in protecting our bodies by lowering triglycerides while raising HDL's"

**Sonne's No. 17**

"Promotes healing"

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 suggests that they are intended to treat, prevent, cure, or mitigate diseases, namely, coronary artery disease and hypertriglyceridemia (Sonne's No. 5), and, in the context of the total claim, capillary fragility (Sonne's No. 17). 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 a drug 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.

975-0163

LET88

Page 2 - Ms. Karen A. Weaver

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, Kansas District Office, Office of Compliance, HFR-SW340

claims

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

RECEIVED  
OCT 23 1997

ESTABLISHED 1917

ALBERT W. DILLING  
1892 - 1969

JOHN M. MANN  
PATENT AND TRADEMARK  
COUNSEL

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

October 20 08 1997 '97 DEC 16 P1:43

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

Enclosure

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



TELEFAX No.  
(312) 236-8418

CABLE ADDRESS:  
DILGRON

October 20, 1997

~~OCT 23 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

0813 '97 DEC 16 P1:43

**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.

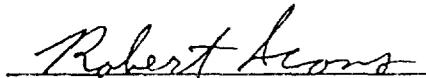
Distributor Name & Address:                      Sonne's Organic Foods, Inc.  
705 McGee Street  
Kansas City, Missouri 64106

| <u>Statement Text</u>   | <u>Name of Subject</u><br><u>Dietary Ingredient(s)</u> | <u>Brand Name</u> |
|---|--|-------------------|
| 1) "To help protect against heart conditions"; "May aid in protecting our bodies by lowering triglycerides while raising HDL's"; "Has anti-inflammatory agents which can have positive effects on the immune system"; and "Effective source of Vitamin A and Vitamin D to utilize calcium and phosphorus in building bone structure and healthy teeth". | Cod Liver Oil  | Sonne's No. 5     |
| 2) "Promotes healing"; "Works as an antioxidant"; "Forms and maintains collagen"; and "Fragility of capillaries can be lessened".   | Vitamin C  | Sonne's No. 17    |
| 3) "Functions as an antioxidant which stabilizes cell membranes and protects the cells and tissues important for muscles, eyes, liver, skin and nerves"; and "Protects red blood cells from damage".  | Vitamin E & Flax Seed Oil (Wheat Germ Oil)             | Sonne's No. 3     |

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| <u>Statement Text</u>  | <u>Name of Subject<br/>Dietary Ingredient(s)</u>       | <u>Brand Name</u>           |
|--|--|-----------------------------|
| 4) "Protein digestant" and "Digestive aid".  | Papain, Papaya Seed, Russian Black Radish, Betaine HCl | (Pro-Gest)<br>Sonne's No. 6 |
| 5) "To aid in assimilation of proteins, carbohydrates and fats" and "Helps digest proteins". | Pepsin, Amylase, Lipase, Protease and Pancreatin       | Sonne's No. 4               |
| 6) "To aid digestion".   | Papain   | Sonne's No. 12              |

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



Robert Irons  
Vice President  
Sonne's Organic Foods, Inc