



OCT 28 1997

0802 '97 DEC 16 P1:42

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 V.E. Irons, Inc., Kansas City, Missouri. Your submission states that V.E. Irons, Inc. is making, among other claims, the following claims for:

Vit-Ra-Tox No. 15

“To help protect against heart conditions”
“May aid in protecting our bodies by lowering triglycerides while raising HDL’s”

Vit-Ra-Tox No. 57

“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 suggest that they are intended to treat, prevent, cure, or mitigate diseases, namely, coronary artery disease and hypertriglyceridemia (Vit-Ra-Tox No. 15), and, in the context of the total claim, capillary fragility (Vit-Ra-Tox No. 57). 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.

975-0163

LET85

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

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

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

OCT 23 1997

ESTABLISHED 1917

ALBERT W. DILLING

1892 - 1969

W. M. MANN
PATENT AND TRADEMARK
COUNSEL

October 20, 1997 DEC 16 P142

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

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

RECEIVED
OCT 23 1997

0804 '97 DEC 16 P1:42

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.

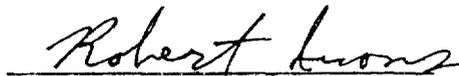
Distributor Name & Address: V. E. Irons, Inc.
705 McGee Street
Kansas City, Missouri 64106

<u>Statement Text</u>	<u>Name of Subject 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	Vit-Ra-Tox No. 15
2) "Promotes healing"; "Works as an antioxidant"; "Forms and maintains collagen"; and "Fragility of capillaries can be lessened".	Vitamin C	Vit-Ra-Tox No. 57
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) Vit-Ra-Tox No. 53

55370

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
4) "Protein digestant" and "Digestive aid".	Papain, Papaya Seed, Russian Black Radish, Betaine HCl	(Pro-Gest) Vit-Ra-Tox No. 56
5) "To aid in assimilation of proteins, carbohydrates and fats" and "Helps digest proteins".	Pepsin, Amylase, Lipase, Protease and Pancreatin	Vit-Ra-Tox No. 54
6) "To aid digestion".	Papain	Vit-Ra-Tox No. 21

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
V. E. Irons, Inc.