

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

6313 '98 SEP 21 P1:55

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® REGENEX™ Cardio Formula Product #12890** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

RECEIVED
9/15/98

The text of each structure-function claim for **Cardio Formula** is as follows:

(Statement 1) The REGENEX™ Cardio Formula is a combination of vitamins, minerals, amino acids, herbs, and advanced nutrients to support the heart and cardiovascular system. This formula was developed in cooperation with Nutritional Scientists from the American Academy of Anti-Aging Medicine (A4M) to provide a nutritional component to those concerned with cardiovascular health.

(Statement 2) The REGENEX™ Cardio Formula, when used in conjunction with the REGENEX™ Multi Formula, provides a complex of nutrients to support the heart and its blood vessels. For example, Pantetheine and carnitine are important constituents for normal metabolism of fat in cardiovascular health. Vitamins, mineral, herbs, and other ingredients have been added to support the heart, coronary arteries and other elements of the cardiovascular system.

(Statement 3) Coenzyme Q10 -- A fat soluble, powerful antioxidant, that protects the heart muscle cells against free radical damage. Coenzyme Q10, known as ubiquinone, is an important part of the electron transport chain, found in cells. It is responsible for producing large amounts of energy needed by cardiac muscle tissue. In the mid 1960's, scientists found that a high concentration of Coenzyme Q10 was found in the myocardium (heart muscle) and is important for proper heart function. Coenzyme Q10 has been found to decline with age.

(Statement 4) Hawthorn -- An herb that has been used for centuries. It is included in Germany's Commission E Monograph for cardiovascular health. The active flavonoids and proanthocyanidins were found to support blood flow to the heart and heart muscle contraction which promotes proper cardiac rhythm.

(Statement 5) Pantetheine -- The stable, coenzyme form of the B vitamin pantothenic acid. Pantetheine is a part of coenzyme A, a component within the cell that plays a role in fat transport in and out of cells. Pantetheine blood levels have been shown to support oxygen and nutrient flow through coronary arteries.

(Statement 6) L-Carnitine -- An amino acid that is required for transporting long chain fatty acids across the mitochondria. Once fatty acids are transported, they are converted to energy. The highest concentration of carnitine is found in the heart and skeletal muscle tissue. When carnitine levels are elevated, cardiac muscle tissue is more efficient in metabolizing fat. With improved energy production, the heart muscle can function more efficiently.

(Statement 7) Taurine -- An amino acid, synthesized in the body from cysteine. Taurine has been shown to play a role in electrolyte balance within cells. Taurine has an effect on the membrane of cardiac muscle tissue cells. It stimulates transport enzymes that remove calcium ions from cells during diastole (the relaxation phase of the heart and increases the release of calcium during systole (the contraction phase). Taurine has antioxidant properties, protecting lipids of the cell membrane from peroxidation.

(Statement 8) Vitamin E -- A powerful free radical scavenger which fights against the oxidation of cholesterol. Clinical studies have shown vitamin E, in higher levels than the RDA, is important in cardiovascular health. The form of vitamin E used in this product, tocopherol acetate, has been shown to be a highly bioavailable form.

(Statement 9) Vitamin B12, Folic Acid and B6 -- Vitamin B12, folic acid and B6 are B vitamins that have been shown to reduce negative by-products of amino acid metabolism, thus supporting healthy arteries and homocysteine levels.

(Statement 10) Magnesium -- An important mineral required for over 300 metabolic reactions in the body. It is essential for cardiac rhythm of the heart and blood pressure. Magnesium is an important nutrient to support the functioning of cardiac muscle. Magnesium has been shown to support arterial wall tone.

(Statement 11) Selenium -- An essential trace mineral that has strong antioxidant protection for the heart.

(Statement 12) Garlic -- From a perennial plant that has been shown to have a number of benefits for cardiovascular health. It has antioxidant properties, and plays a role in healthy platelet activity.

(Statement 13) Ligusticum wallichii -- An herb that has been traditionally used in China for centuries. The active components from this herb are the alkaloids which have been shown to support arterial wall tone and non-adhesive platelet activity.

(Statement 14) Alpha Lipoic Acid -- A potent free radical scavenging agent against superoxide, hydrogen peroxide and other free radicals.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 8th day of September, 1998.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: 
DR. LUKE R. BUCCI
Vice President of Research