

**NOTIFICATION PURSUANT TO**  
**SECTION 6 OF DSHEA**

RECEIVED  
12/15/97

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™ Diabetic Support Formula Product #12895 bearing the statements set out below:

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

The text of each structure-function claim is as follows:

- (Statement 1) The REGENEX™ Diabetic Support Formula, when used in conjunction with the REGENEX™ Multi Formula, provides a complex of nutrients to support diabetics.
- (Statement 2)
- (Statement 3)
- (Statement 4)

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 9<sup>th</sup> day of December, 199 7.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

DR. LUKE R. BUCCI

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Vice President of Research

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The text of each structure-function claim for *Gymnema sylvestre* is as follows:

- (Statement 1)      Recent clinical studies have shown *Gymnema*'s active constituent, Gymnemic acid, provides nutritional support for pancreatic cells and normal carbohydrate metabolism.
- (Statement 2)
- (Statement 3)
- (Statement 4)

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The text of each structure-function claim for **Ginkgo biloba** is as follows:

- (Statement 1) Most Ginkgo products on the market contain high levels of this particular substance that can cause allergy reactions.
- (Statement 2) Ginkgo biloba has a number of benefits such as supporting blood circulation to the brain and extremities by vasodilation of blood vessels.
- (Statement 3) Ginkgo biloba has been shown to support mental function.
- (Statement 4) Ginkgo biloba has potent antioxidant activity, protecting blood vessels by supporting their selective permeability.
- (Statement 5) The ginkgolides from Ginkgo biloba are the active ingredients that provide nutritional support for circulatory health, helping to promote normal, non-adhesive platelet activity in the arteries.

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The text of each structure-function claim for Quercetin is as follows:

- (Statement 1) Quercetin belongs to a larger family known as flavonoids, which are found in plants. It is a powerful antioxidant, scavenging free radicals.
- (Statement 2) Flavonoids such as quercetin have been found to moderate aldose reductase.
- (Statement 3)
- (Statement 4)
- (Statement 5)

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The text of each structure-function claim for **Momordica charatia** is as follows:

**(Statement 1)** Charantin, a crystalline fraction from the fruit, is the active constituent shown to nutritionally support the pancreatic cells.

**(Statement 2)**

**(Statement 3)**

**(Statement 4)**

**(Statement 5)**

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

- (Statement 1) Magnesium is an important mineral in the body, with a significant role in cellular chemical reactions and provides support to the cardiovascular system.
- (Statement 2) Diabetics are one group of individuals that have been shown to have low levels of magnesium, possibly due to insulin resistance.
- (Statement 3) Magnesium provides nutritional support for beta cells of the pancreas.
- (Statement 4)
- (Statement 5)

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The text of each structure-function claim for Zinc is as follows:

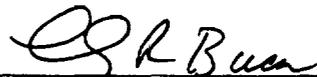
- (Statement 1) Zinc is a mineral, which is part of the structure of over 200 enzymes in the body.
- (Statement 2) It is involved in the manufacturing of protein and DNA and is essential for immune system function.
- (Statement 3) Diabetics who have immune cell abnormalities are noted for having low blood zinc levels.
- (Statement 4) Normal levels of zinc are essential to the proper manufacture, secretion and use of pancreatic hormones by the body.
- (Statement 5)

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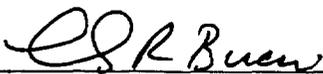
The text of each structure-function claim for **Chromium** is as follows:

- (Statement 1)**            Chromium is a trace mineral and cofactor essential for normal protein, fats and carbohydrate metabolism.
- (Statement 2)**            Chromium provides nutritional support for the beta cells of the pancreas.
- (Statement 3)**
- (Statement 4)**
- (Statement 5)**

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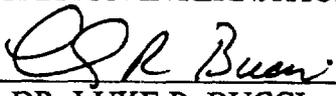
The text of each structure-function claim for Bis(maltolato)oxovanadium (BMOV) is as follows:

- (Statement 1) BMOV is an organic complex of the mineral vanadium that has been shown to be more readily absorbed through the gastrointestinal tract than other vanadium sources.
- (Statement 2) Vanadium helps to stimulate glucose to move into the tissue from the blood and enhances glucose metabolism.
- (Statement 3)
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The text of each structure-function claim for **Biotin** is as follows:

- (Statement 1)      Biotin is a B vitamin that is involved in carbohydrate metabolism.
- (Statement 2)      Normal levels of biotin helps to maintain normal levels and functioning of an enzyme called pyruvate carboxylase that regulates blood pyruvate levels.
- (Statement 3)
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- (Statement 5)

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The text of each structure-function claim for **Alpha lipoic acid** is as follows:

- (Statement 1)           It supports cellular utilization of nutrients and inhibits glycosylation.
- (Statement 2)           It is considered an ideal antioxidant preventing free radical damage.
- (Statement 3)
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The text of each structure-function claim for **Fructooligosaccharides (FOS)** is as follows:

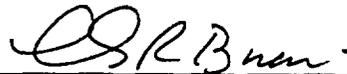
- (Statement 1) FOS is a form of sugar which supports the "friendly" bacteria found in the intestinal tract.
- (Statement 2) The friendly bacteria help to improve digestion and the utilization of carbohydrates.
- (Statement 3)
- (Statement 4)
- (Statement 5)

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