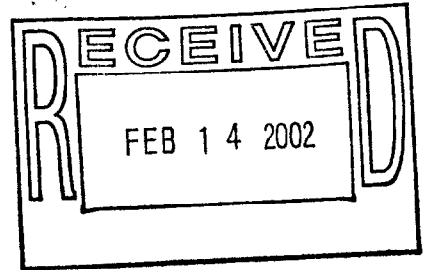


DELOIS L. SHELTON  
OFFICE OF REGULATORY AFFAIRS  
WEIDER NUTRITION INTERNATIONAL, INC.  
2002 SOUTH 5070 WEST  
SALT LAKE CITY, UTAH 84104-4836  
TELEPHONE (801) 975-5031  
FACSIMILE (801) 972-6532

January 21, 2002



Lynne A. Larsen, Ph.D.  
Acting Director, Division of Programs and Enforcement Policy  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington DC 20204

*Re: Submission of Structure/Function Claims*

Dear Dr. Larsen:

Enclosed are the structure/function claims for the following products, as generated by Dr. Luke Bucci, one original signature and two copies of each:

- 1) Schiff® Immunolin Tablets, product #11533
- 2) Schiff® Immunolin Daytime Formula Drink Mix, product #11531
- 3) Schiff® Immunolin Nighttime Formula Drink Mix, product #11532

We welcome the opportunity to communicate with your office as we continue to submit structure/function claims as allowed by the Dietary Supplement Health and Education Act.

Please feel free to contact this office if you have further questions or comments regarding this submission.

Respectfully,

A handwritten signature in cursive script that reads "DeLois L. Shelton".

De Lois L. Shelton, Director of Regulatory Affairs

975 0162 LET 9379

**NOTIFICATION PURSUANT TO**  
**SECTION VI OF DSHEA**

In compliance with Section VI 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® Immunolin (60 tablets) Product #11533, Schiff® Immunolin Daytime Formula Drink Mix Product #11531, and Schiff® Immunolin Nighttime Formula Drink Mix Product #11532** bearing the statement(s) 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)** Supports your immune system.
- (Statement 2)** These nutrients [immunoglobulins, Vitamin C, Echinacea, Inulin] promote optimal immune system function.
- (Statement 3)** Schiff® Immunolin supplements your body's immune system with one of its natural defenses --- immunoglobulins.
- (Statement 4)** In this way, oral IgG can promote healthy immune functions throughout the whole body.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc., am authorized to certify this Notification on 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 21<sup>st</sup> day of January, 2002

**WEIDER NUTRITION INTERNATIONAL, INC.**

**BY:**



**DR. LUKE R. BUCCI**



## STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Immunoglobulins / Vitamin C / Echinacea

DATE: October 16, 2001

BY: Luke Bucci

Document Name: Schiff Immunolin 11533 Oct01.doc

BRAND, CODE # & PRODUCT NAME(S): Schiff 11533 Immunolin (60 tablets)

NUTRIENT AMOUNT: Immunoglobulin G 500 mg; Vitamin C 60 mg; Proprietary Blend  
(*Andrographis paniculata* extract leaf 120 mg, *Echinacea purpurea*  
extract herb 12.5 mg) 132.5 mg per serving (two (2) tablets)

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**STRUCTURE/FUNCTION CLAIM:**

Supports your immune system\*

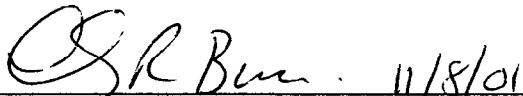
As a dietary supplement, take two (2) tablets daily for on-going immune support.\*

These nutrients [immunoglobulins, Vitamin C, Echinacea, Andrographis] promote optimal immune system function.\*

Schiff Immunolin supplements your body's immune system with one of its natural defenses – Immunoglobulins.\*

In this way, oral IgG can promote healthy immune functions throughout the whole body.\*

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Approved by / Date

**SUBSTANTIATION:**

Echinacea – Immune Health

Vitamin C – Immune

Andrographis – Immune

Immunoglobulins

Vitamin C – Reviews



**weider**  
NUTRITION GROUP

## STRUCTURE / FUNCTION CLAIMS

**NUTRIENT:** Immunoglobulins / Vitamin C / Echinacea

**DATE:** October 16, 2001

**BY:** Luke Bucci

Document Name: Schiff Immunolin 11531 11532 Oct01.doc

BRAND, CODE # & PRODUCT NAME(S): Schiff 11531 Extra Strength Daytime Formula Immunolin; 11532 Extra Strength Nighttime Formula Immunolin Lemon Drink Mix (5 packets, 20 g each)

**NUTRIENT AMOUNT:**

**Daytime Formula:** (11531) Immunoglobulins 1000 mg; Vitamin C 60 mg; Proprietary Blend (Inulin 1000 mg, Echinacea purpurea herb 13 mg) 1013 mg per serving (one (1) packet)

**Nighttime Formula:** (11532) Immunoglobulins 1000 mg; Vitamin C 60 mg; Proprietary Blend (Inulin 1000 mg, Echinacea purpurea herb 13 mg, Melatonin 1 mg) 1014 mg per serving (one (1) packet)

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**STRUCTURE/FUNCTION CLAIM:**


Supports your immune system\*

These nutrients [immunoglobulins, Vitamin C, Echinacea, Inulin] promote optimal immune system function.\*

Schiff Immunolin supplements your body's immune system with one of its natural defenses – Immunoglobulins.\*

In this way, oral IgG can promote healthy immune functions throughout the whole body.\*

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Approved by / Date

**SUBSTANTIATION:**

Echinacea – Immune Health  
Melatonin – Sleep  
Vitamin C – Immune  
Inulin

Immunoglobulins  
Melatonin – Reviews  
Vitamin C – Reviews