

8379 '97 AUG 12 AIO :04

APR - 4 1997

Jonathan W. Emord, Esq.
Claudia A. Lewis, Esq.
Emord & Associates, P.C.
1050 Seventeenth Street, N.W.
Washington, D.C. 20036

Dear Mr. Emord and Ms. Lewis:

This is in response to your letter of February 11, 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 The Health Connection, Limited. Your notification submitted on behalf of The Health Connection, Ltd. Inc. states that the firm intends to make the following statement for the product SPV-30.

SPV-30 enhances immune system function by increasing CD4 and CD8 counts.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that 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 statement that the firm is making for this product suggests that it is intended to treat, mitigate or cure immune deficiency diseases that are characterized by a reduction in the levels of circulating CD4 and CD8 cells. A product that claims to treat, mitigate, or cure immune deficiency diseases is a drug within the meaning of section 201(g)(1)(B) of the act, and is subject to regulation under the drug provisions of the act. If you intend to make a claim 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.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

978-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, New York District Office, Compliance Branch, HFR-NE150

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W.

SUITE 600

WASHINGTON, D.C. 20036

TELEPHONE: (202) 466-6937

TELECOPIER: (202) 466-6938

March 14, 1997

VIA UPS OVERNIGHT

Dr. Elizabeth Yetley
Officer of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

*Re: Fulfillment of Reporting Obligation
under 21 U.S.C. § 343(r)*

Dear Dr. Yetley:

The Health Connection, Limited ("HC"),¹ by counsel, hereby submits an original and two copies of its notice of statements of nutritional support in accordance with 21 U.S.C. § 343(r). HC does so within thirty days of first marketing the product SPV-30 with the statements. Under 21 U.S.C. § 343(r) HC retains substantiation for each of the statements listed below. In accordance with the requirements of § 343(r), HC includes the following disclaimer in boldface type, prominently displayed on each piece of literature that bears the statements listed below: **This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Product Name: SPV-30

Product Ingredient: Extract of the Boxwood Evergreen Tree

Statements of Nutritional Support:

1. SPV-30 provides nutritional support for the body's immune system.

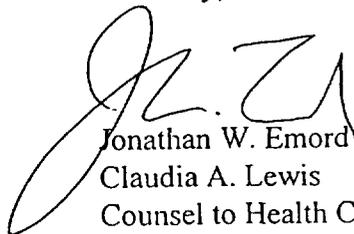
¹ The address for Health Connection, Limited is 105 Ralph Avenue, Copiague, New York 11726.

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Drs. Yetley and Moore
March 14, 1997
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2. SPV-30 provides nutritional support for the body's natural defense system.
3. SPV-30 enhances immune system function by increasing CD4 and CD8 counts.

Sincerely,



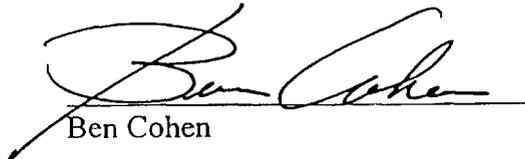
Jonathan W. Emord
Claudia A. Lewis
Counsel to Health Connection, Limited

cc: Diana Amador
Bruce A. Goldwitz

Certification

I, Ben Cohen, President of Health Connection, Limited, hereby certify that the information contained in the foregoing notice is complete and accurate and that Helath Connection, Limited has substantiation that the above-listed statements of nutritional support are truthful and non-misleading.

Executed on: 3-17-97


Ben Cohen