



John Venardos Vice President  
Worldwide Regulatory & Government Affairs

2178 5 NOV 22 8:26

Herbalife International of America INC  
800 Century Park East, Century City CA 90067  
T 310.410.9600 F 310.557.3916  
e-mail. [johnv@herbalife.com](mailto:johnv@herbalife.com)

November 3, 2005

Dr. Robert J. Moore  
Branch Chief, Compliance & Enforcement Branch  
Office of Nutrition Products, Labeling & Dietary Supplements  
**FOOD & DRUG ADMINISTRATION (HFS-800)**  
5100 Paint Brush Parkway  
College Park, Maryland 20740

NOV - 9 2005

Ref: **Core Complex Dietary Supplement (N630-00)**

Dear Dr. Moore:

Pursuant to 21CFR§101.93, please be advised Herbalife International of America, Inc. has introduced Core Complex dietary supplements. Labeling includes the following structure/function claims:

Contains plant sterols which have been shown to reduce LDL and total cholesterol.\*

Supports healthy heart and blood vessel function.\*

Maintains healthy homocysteine levels already within a normal range. \*

Plant sterols and stanols, The active ingredient in Core Complex, have been shown to reduce LDL ("bad") and total cholesterol by blocking cholesterol absorption.

**Core Complex Herbalife** teamed with Nobel Laureate in Medicine, Dr. Lou Ignarro, to develop Core Complex, a multi-action, scientifically advanced daily supplement pack that targets four key indicators of cardiovascular health:\*

Cholesterol, Homocysteine, Triglycerides, Oxidant Stress  
Each of the key ingredients has been clinically shown to individually support heart and cardiovascular health.\*

**Essential Fatty Acids - Herbalifeline® Fish Oils:** Omega-3 fatty acids help to maintain a healthy cardiovascular system by maintaining cholesterol and triglyceride levels already within a normal range.\*

**Essential Fatty Acids: 100% Pure Neptune Krill Oil (NKO®)** is a proprietary natural ingredient providing three significant groups of heart-healthy compounds: Omega-3 fatty acids, phospholipids, and antioxidants. These three nutrients work together to support the heart muscle, protect the health of cell membranes, and to maintain cholesterol and triglyceride levels already within a normal range.\*

**Mixed Tocopherols and Quercetin** provide superior antioxidant protection for the heart. A balanced combination of mixed tocopherols with natural vitamin E offer stronger antioxidant protection than vitamin E alone. Antioxidants support circulation and strengthen blood vessels.\*

975 0162 LET 16 999 05-7749

