



SEP 30 1999

John P. Venardos
Vice President, Regulatory Affairs
International Product Management
Herbalife International of America, Inc.
P.O. Box 80210
Los Angeles, California 90080-02 10

Dear Mr. Venardos:

This is in response to your letter of September 8, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Herbalife International of America, Inc. is making the following claims, among others, for the product "Joint Support-Glucosamine with Herbs:"

"...lifting an arm, bending a knee or even wiggling a toe may cause agonizing pain"

"The aches and discomfort may be caused by arthritis, an injury..."

"...three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by the breakdown in the cartilage between bone joints."

"...causing pain, tenderness, swelling, stiffness, and sometimes deformity."

"...people of all ages are affected by arthritis - with about 12 related disorders..."

"...provide support to aching joints which may be subject to arthritis,...injury."

"...all known to benefit aching joints and muscles"

21 U.S.C. 343(r)(6) 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 statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, namely, arthritis and related joint disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 303

Page 2 - Mr. John P. Venardos

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

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

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

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-3 10 (BWilliams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF- 1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:9/29/99:docname:67163.adv:disc41



67163

HERBALIFE INTERNATIONAL OF AMERICA, INC.
9800 La Cienega Blvd., Inglewood, CA 90301
Mailing Address: P.O. Box 802 10, Los Angeles, CA 90080-0210
(310) 410-9600 • FAX: (310) 258-7124

JOHN P. VENARDOS
Vice President, Regulatory Affairs
International Product Management

September 8, 1999



Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
200 C Street, SW.
Washington, DC. 20204

Ref.: **Joint Support – Glucosamine with Herbs**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Joint Support – Glucosamine with Herbs dietary supplement in the United States.

Joint Support – Glucosamine with Herbs will be labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

1. **LABEL**

Suggested Serving: Take one tablet two times a day.

A unique formulation of high-quality, natural herbs and enzymes with Glucosamine and MSM intended to enhance flexibility and promote healthy joints and muscles. **(Note: the DSHEA disclaimer box immediately follows the proceeding statement on the printed label.)**

2. **HERBALIFE FACT SHEET**

(Note: the asterisks appearing in the copy shown below relate to the DSHEA disclaimer box which appears on product labeling and in literature.)

Joint Support – Glucosamine with Herbs
Dietary Supplement for Joints and Muscles

Many of us take mobility for granted. However, millions of people find the simple act of lifting an arm, bending a knee or even wiggling a toe may cause agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer than our ancestors.

With average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity. According to the Arthritis Foundation, people of all ages are affected by arthritis-with about 120 related disorders-and it is the No. 1 cause of limitation of movement in the United States.

Herbalife has formulated an herbal-based product, **Joint Support – Glucosamine with Herbs**, which can help to provide support to aching joints which may be subject to arthritis, excessive wear-and-tear or injury. Taken twice daily, you can experience the benefits of six of the most widely used herbs, enzymes and nutritional factors, all known to benefit aching joints and muscles.*

Discussion Points

- Can help provide nutritional support to diminish joint swelling or wear-and-tear joint problems.*
- Helps promote healthy joints and slows the effects of aging on joints.*
- Used by athletes to help improve post-workout muscle soreness.*

Did You Know?

The connective tissue and cartilage in your body includes a natural compound called Glucosamine. The cartilage important for cushioning the joints can lose its ability to support healthy cellular growth as one ages. The body's production of Glucosamine – which is an amino sugar synthesized in the body from glucose – decreases with age, reducing new growth of cartilage destroyed through normal wear-and-tear.

Fast Facts:

- **Glucosamine Sulfate**, a natural compound produced by the body, that contributes to the natural cushioning effect of cartilage.*
- **MSM** (Methylsulfonylmethane), a naturally occurring organic sulfur compound, found in living plant and animal tissues. Known for enhancing flexibility.*
- **Turmeric** and **Boswellia**, frequently used to aid the body in the healing process.*
- **Bromelaio**, an enzyme found in pineapple, and **Peptizyme®**, a purified enzyme complex, each of which are known to provide nutritional support to joints and muscles.*

3. *HERBALIFE TODAY NEWSLETTER*

(Note: the asterisks appearing in the copy shown below relate to the DSHEA disclaimer box which appears on product labeling and in literature.)

Joint Support -- Glucosamine with Herbs.
Dietary Supplement for Joints and Muscles.

Millions of people **find** the simple act of lifting an **arm**, bending a knee or even wiggling a toe may cause agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer.

With the average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity.

Herbahfe has formulated an herbal-based product, Joint Support – Glucosamine with Herbs, which can help provide support to aching joints that may be subject to excessive wear-and-tear or injury. Taken twice daily, you can experience the benefits of six of the most widely used herbs, enzymes and nutritional factors known to benefit aching joints and muscles.*

- Glucosamine Sulfate, a natural compound produced by the body that contributes to the natural cushioning effect of cartilage.*
- MSM (Methylsulfonylmethane), a naturally occurring organic sulfur compound found in living plant and animal tissues. It's known for enhancing flexibility.*
- Turmeric and Boswellia, which frequently are used to aid the body in the healing process.*
- Bromelain, an enzyme found in pineapple, and **Peptizyme®**, a purified enzyme complex, each of which help support the **health** of joints and muscles.*
- Easy-to-swallow tablets.

4. **MINI PRODUCT INSERT**

(Note: the asterisks appearing in the copy shown below relate to the DSHEA disclaimer box which appears on product labeling and in literature.)

Joint Support – Glucosamine with Herbs
Dietary supplement for Joints and Muscles.

Many of us take mobility for granted. However, millions of people find the simple act of lifting an arm, bending a knee or even wiggling a toe may cause agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer than our ancestors.

With average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity.

Herbalife has formulated an herbal-based product, Joint Support – Glucosamine with Herbs, which can help to provide support to aching joints that may be subject to arthritis, excessive wear-and-tear or injury. Taken twice daily, you can experience the benefits of six of the most widely used herbs, enzymes and nutritional factors, all known to benefit aching joints and muscles.*

- Glucosamine Sulfate, a natural compound produced by the body, that contributes to the natural cushioning effect of cartilage.*
- MSM (**Methylsulfonylmethane**), a naturally occurring organic sulfur compound, found in living plant and animal tissues. Known for enhancing flexibility.*
- Turmeric and **Boswellia**, frequently used to aid the body in the healing process.*
- **Bromelain**, an enzyme found in pineapple, and **Peptizyme®**, a purified enzyme complex, each of which are known to provide nutritional support to joints and muscles.*
- Easy-to-swallow tablets.

5. **MINI PRODUCT BROCHURE**

Joint Support – Glucosamine with Herbs

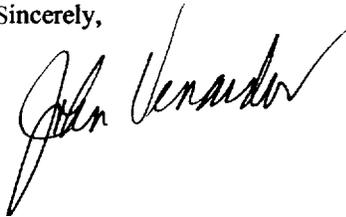
Innovative supplement provides support to aching joints, thanks to a unique blend of herbs, enzymes and nutritional factors.

Product labeling and literature prominently bears the required boxed statement, “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Please do not hesitate to advise should you have any questions.

Sincerely,



File: **Joint Support – Glucosamine with Herbs**



Joint Support
 Glucosamine with Herbs
 A Dietary Supplement
 for Joints and Muscles

60 TABLETS

Suggested Serving: Take one tablet two times a day. A unique formulation of high-quality, natural herbs and enzymes with Glucosamine and MSM intended to enhance flexibility and promote healthy joints and muscles.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Herbalife products are available only through Herbalife Independent Distributors.

30-day money back guarantee.
 Recycle this bottle.

Formulated exclusively for:
HERBALIFE INTERNATIONAL OF AMERICA, INC.
 LOS ANGELES, CA 90080-0210, U.S.A.
 MADE IN U.S.A.

307-DUS-00 © 1999 HERBALIFE INTERNATIONAL, INC., U.S.A.

Supplement Facts

Serving Size: 1 Tablet
 Servings Per Container: 60

	Amount Per Serving	% Daily Value*
Glucosamine Sulfate	500 mg	
Potassium Salt		
Methylsulfonylmethane (MSM)	250 mg	1
Dried Boswellia Extract (Boswellia serrata) (gum)	75 mg	1
Phytolyme SP (Endo-polyphosphate)	20 mg	1
Branched Chain Amino Acids	20 mg	1
Dried Turmeric Extract (root)	20 mg	1
Bioperine® (Black Pepper Extract) (fruit)	1 mg	1

* Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.
 Other Ingredients: Cellulose, Stearic Acid, Methylcellulose, Croscarmellose Sodium, Silicon Dioxide, Dextrin, Magnesium Stearate, Dextrose, Lecithin, Sodium Carboxymethylcellulose and Sodium Citrate.

#1

Joint Support – Glucosamine with Herbs

Dietary Supplement for Joints and Muscles

Many of us take mobility for granted. However, millions of people find the simple act of lifting an arm, bending a knee or even wiggling a toe may cause agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer than our ancestors.

With average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity. According to the Arthritis Foundation, people of all ages are affected by arthritis-with about 120 related disorders-and it is the No. 1 cause of limitation of movement in the United States.

Herbalife has formulated an herbal-based product, Joint **Support-Glucosamine** with Herbs, which can help to provide support to aching joints that may be subject to arthritis, excessive wear-and-tear or injury. Taken twice daily, you can experience the benefits of six of the most widely used herbs, enzymes and nutritional factors, all known to benefit aching joints and muscles.*

Discussion Points

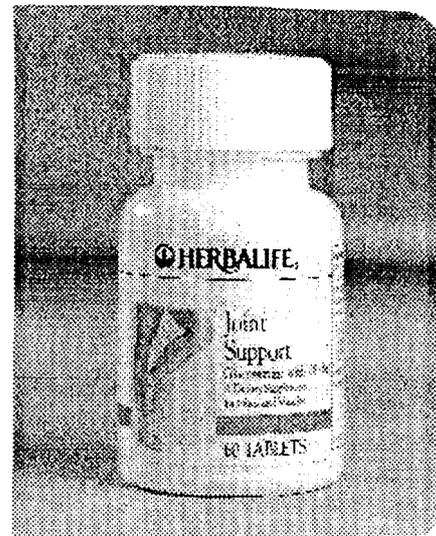
- Can help reduce the pain and swelling associated with arthritis or wear-and-tear joint problems.*
- Helps promote healthy joints and slow the effects of joint aging.*
- Useful for athletes and helps improve post-workout muscle soreness and injury.*

Did You Know?

The connective tissue and cartilage in your body includes a natural compound called Glucosamine. The cartilage important for cushioning the joints can lose its ability to support healthy cellular growth as we age. The body's production of Glucosamine-which is an amino sugar synthesized in the body from glucose-decreases with age, reducing new growth of cartilage destroyed through normal wear and tear.

Fast Facts

- **Glucosamine Sulfate** is a natural compound produced by the body, that contributes to the natural cushioning effect of cartilage.*
- **MSM (Methylsulfonylmethane)** is a naturally occurring organic sulfur compound, found in all living plant and animal tissues. Known for enhancing flexibility.*
- **Turmeric** and **Boswellia**, frequently used to aid the body in the healing process.*
- Also contains **Bromelain**, an enzyme found in pineapple, and **Peptizyme®**, a purified enzyme complex, each of which are known to provide nutritional support to joints and muscles.*



SUPPLEMENT FACTS

Serving Size One tablet
Servings Per Container 60

	Amount Per Serving	% Daily Value*
Glucosamine Sulfate	500mg	†
Methylsulfonylmethane	250mg	†
Boswellia Serrolo Extract	75mg	
Peptizyme® SP	20mg	
Bromelain	20mg	
Dried Turmeric Extract	20mg	
Dried Black Pepper Extract	1mg	

** Percent Daily Values are based on a 2,000-calorie diet
† Daily Value not established

Suggested Serving:
Take one tablet two times a day

#2



*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Ordering Details:

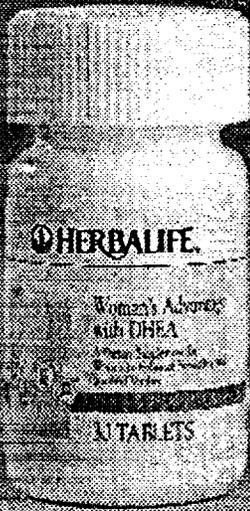
60 tablets per bottle

#3070 (case of 6)
#0261 (HAP or unit) \$18.95

“Targeted
Line”

EXPANDS
WITH

Two
Powerful
New
Products!



\$3

Woman's Advantage with DHEA and Joint Support Glucosamine with Herbs strengthen Herbalife's youthful-appearance product line.

Woman's Advantage with DHEA
Dietary supplement for women to enhance sensuality and youthful vitality.

As we age, our bodies slow the production of key hormones needed to maintain our essential youthful vitality. Throw stress into the mix and the aging process soon gets an upper hand: our appearance changes, our body shape changes and our sense of well-being decreases. This is nature's plan for us. But what if we have different plans? What if we want to feel young and look young as long as possible? Can we really help slow down or reverse the effects of aging?

Good nutrition, proper skin care and regular exercise all help us live longer, look better and feel better. But now it's possible to take a giant step forward.

Woman's Advantage with DHEA, with its proprietary blend of select herbs, contains natural hormone precursors that work in harmony with the needs of the female body. Woman's Advantage with DHEA works deep within a woman's system to help elevate sensuality, vitality and stamina as well as to create a sense of well-being.*

- DHEA is a natural hormone precursor that helps normalize the key female hormones contributing to feelings of sensuality and youthful vitality.*
- Damiana and Tribulus Terrestris are two natural herbs that work to help increase the natural sex drive.*
- Cocoa Extract, a form of chocolate, supplies an energy boost and helps provide a sense of well-being.*
- Siberian Ginseng and L-Arginine help improve stamina and endurance and maintain a more youthful muscle tone.*

#3080 (case of 6) \$119.70
#0269 (HAP or unit) \$19.95

*All statements have not been evaluated by the FDA and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Joint Support Glucosamine with Herbs
Dietary supplement for joints and muscles.

Millions of people find the simple act of lifting an arm, bending a knee or even wiggling a toe may cause agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer.

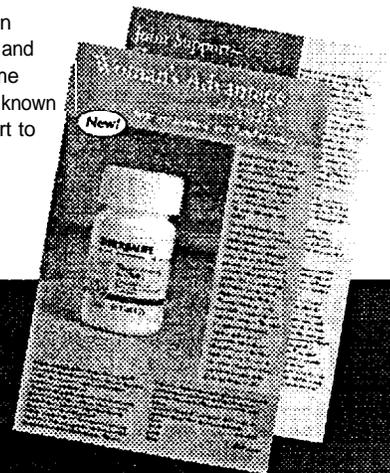
With average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity.

Herbalife has formulated an herbal-based product, Joint Support-Glucosamine with Herbs, which can help provide support to aching joints that may be subject to excessive wear-and-tear or injury. Taken twice daily, you can experience the benefits of six of the most widely used herbs, enzymes and nutritional factors, all known to benefit aching joints and muscles.*

- Glucosamine Sulfate, a natural compound produced by the body, that contributes to the natural cushioning effect of cartilage.*
- MSM (Methylsufonylmethane), a naturally occurring organic sulfur compound, found in living plant and animal tissues. Known for enhancing flexibility.+
- Turmeric and Boswellia, frequently used to aid the body in the healing process.*
- Also contains Bromelain, an enzyme found in pineapple, and Peptizyme*, a purified enzyme complex, each of which are known to provide nutritional support to joints and muscles.*

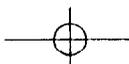
■ Easy-to-swallow tablets.

X3070 (case of 6) \$113.70
#0261 (HAP or unit) \$18.95



A special, full-color *Product Brochure Insert* is available to help you promote these great new products. Order this insert and place copies of it inside the *Product Brochures* you leave with customers and prospects.

#5975 (set of 10) \$1.00



#4

Joint Support Glucosamine with Herbs

New!



Many of us take mobility for granted. However, millions of people find the simple act of lifting an arm, bending a knee or even wiggling a toe causes agonizing pain. The aches and discomfort may be caused by arthritis, an injury or excessive wear-and-tear, but they can also occur because we are living longer than our ancestors.

With the average life expectancy on the rise, as many as three-fourths of the population over 50 will be affected by symptoms of osteoarthritis, a condition that may be accompanied by a breakdown in the cartilage found between bone joints. Without this protective padding, bones rub together, causing pain, tenderness, swelling, stiffness, and sometimes, deformity.

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- MSM (Methylsulfonylmethane), a naturally occurring organic sulfur compound found in living plant and animal tissues. Known for enhancing flexibility.*
- Turmeric and Boswellia, frequently used to aid the body in the healing process.*
- Bromelain, an enzyme found in pineapple, and Peptizyme®, a purified enzyme complex, each of which are known to provide nutritional support to joints and muscles.*
- Easy-to-swallow tablets.

#3070 (case of 6)
#0261 (HAP or unit) \$18.95



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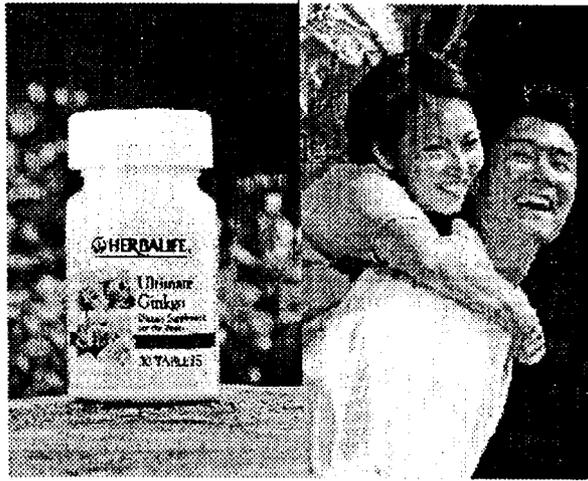
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



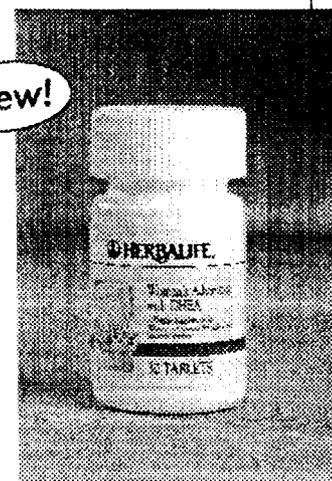
New!

Supplements for a Healthy Lifestyle

Joint Support--
Glucosamine with Herbs
Innovative supplement provides support to aching joints, thanks to a unique blend of herbs, enzymes and nutritional factors. **\$18.95**



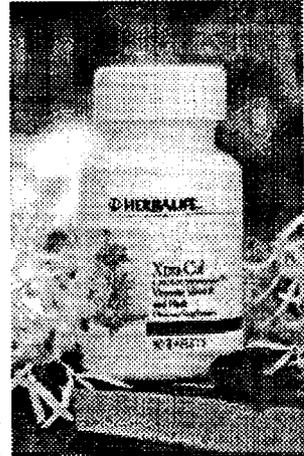
Ultimate Ginkgo
Provides flavonoid glycosides and terpenoid lactones which can help support healthy brain function. **\$15.95**



New!

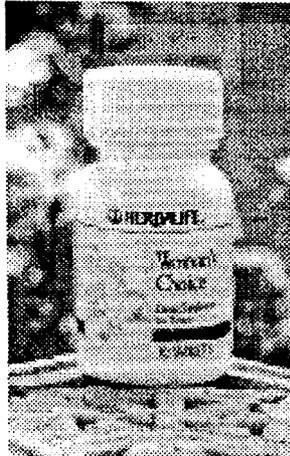
Nutritional Support for Women and Men

Woman's Advantage
with DHEA
Superior dietary supplement for women that enhances feelings of sensuality and youthful vitality. Perfect for creating a sense of well-being. **\$19.95**



Herbalife
Rich in Omega-3 fatty acids to help protect your heart. **\$24.75**

Xtra-Cal
Contains the most concentrated form of Calcium available in a tablet. **\$10.25**



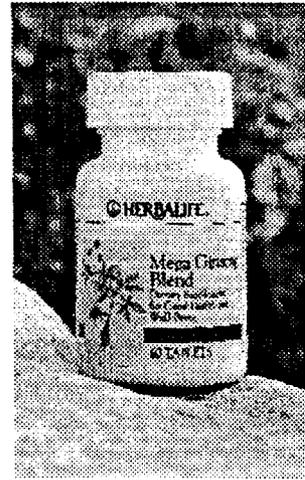
Woman's Choice
Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance. **\$22.95**

Tang Kuei Plus*
Specially formulated to normalize the challenges associated with a woman's menstrual cycle. **\$12.50**



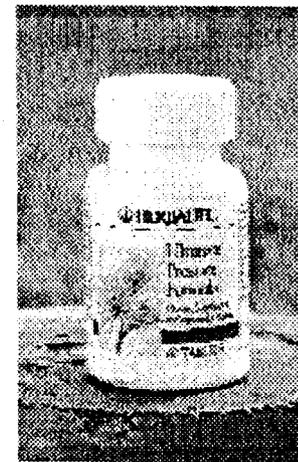
Ocular Defense Formula
This scientifically advanced supplement contains potent antioxidants that are believed to help protect the eyes from the effects of harmful free radicals. **\$15.95**

Mega Ginseng Blend
Dietary supplement for good health and well-being. Contains an unique mixture of the world's most widely used Ginsengs. **\$14.95**



Ultimate Prostate Formula
Contains a superior blend of vitamins, minerals and herbs that help support good urinary function. **\$17.95**

Male Factor 1000*
Helps increase vitality, stamina and endurance in men. **\$41.00**



#5