



HERBALIFE INTERNATIONAL OF AMERICA, INC.  
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JOHN P. VENARDOS  
Vice President, Regulatory Affairs  
International Product Management

August 4, 1998

RECEIVED  
8/10/98

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

Ref.: **Ocular Defense Formula Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Ocular Defense Formula dietary supplement in the United States. This letter is intended to replace our June 15, 1998 notification letter to the FDA advising the agency of statements being made for the Ocular Defense Formula product. It contains a revision of certain statements made in our June 15 notification letter, and reflects the Company's response to the FDA's comments on the statements made in our June 15 letter, as set forth by the agency in its June 25, 1998 courtesy letter to us.

Ocular Defense Formula is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

**LABEL**

Suggested Serving: One tablet per day.

Ocular Defense Formula is a nutritional supplement combining potent antioxidants that have been shown to help protect the eyes from the effects of harmful free radicals. This exclusive formula includes the antioxidant rich herb, Bilberry, which is highly beneficial for the eyes.

**PRODUCT LITERATURE**

In today's health-conscious environment, staying physically fit is important. But how many people focus on the health of their eyes? Now you can support the health of your eyes with daily use of Ocular Defense Formula.

- Contains potent antioxidants that are believed to help protect the eyes from the harmful effects of free radicals.
- Includes the antioxidant-rich herb, Bilberry, which is highly beneficial for eyes.

Product labeling 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."

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Office of Special Nutritionals (HFS-450)  
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 August 4, 1998  
 Page 2

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: Ocular Defense Formula Dietary Supplement

<p>Suggested Serving: One tablet per day</p> <p>Ocular Defense Formula is a nutritional supplement combining potent antioxidants that have been shown to help protect the eyes from the effects of harmful free radicals. This exclusive formula includes the antioxidant rich herb, Bilberry, which is highly beneficial for the eyes.</p> <p><small>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.</small></p> <p>Herbalife products are available only through Herbalife Independent Distributors.</p> <p>30-day money back guarantee.</p> <p>3007-US-00 © 1998 HERBALIFE INTERNATIONAL, INC. U.S.A.</p>	  <p>Ocular        Defense        Formula        Dietary Supplement        for Healthy Eyes</p> <p>30 TABLETS</p>	<p>EACH TABLET PROVIDES</p> <table border="0"> <tr> <td>VITAMIN A</td> <td>500 I.U.</td> <td>CURCUMINOIDS</td> <td>10 MG</td> </tr> <tr> <td>VITAMIN C</td> <td>150 MG</td> <td>LUTEIN</td> <td>4 MG</td> </tr> <tr> <td>CITRUS</td> <td></td> <td>ZINC</td> <td>2.5 MG</td> </tr> <tr> <td>BIOFLAVONOID</td> <td>75 MG</td> <td>N-ACETYLCYSTEINE</td> <td>2 MG</td> </tr> <tr> <td>BILBERRY</td> <td></td> <td>ALPHA-LIPOIC ACID</td> <td>2 MG</td> </tr> <tr> <td>EXTRACT (4:1)</td> <td>50 MG</td> <td>MANGANESE</td> <td>1 MG</td> </tr> <tr> <td>MAGNESIUM</td> <td></td> <td>COPPER</td> <td>0.5 MG</td> </tr> <tr> <td>TAURATE</td> <td>25 MG</td> <td>SELENIUM</td> <td>0.025 MG</td> </tr> <tr> <td>QUERCETIN</td> <td>10 MG</td> <td></td> <td></td> </tr> </table> <p>FORMULATED EXCLUSIVELY FOR        HERBALIFE INTERNATIONAL OF AMERICA, INC.        LOS ANGELES, CA 90030-0210, U.S.A.        MADE IN U.S.A.</p>	VITAMIN A	500 I.U.	CURCUMINOIDS	10 MG	VITAMIN C	150 MG	LUTEIN	4 MG	CITRUS		ZINC	2.5 MG	BIOFLAVONOID	75 MG	N-ACETYLCYSTEINE	2 MG	BILBERRY		ALPHA-LIPOIC ACID	2 MG	EXTRACT (4:1)	50 MG	MANGANESE	1 MG	MAGNESIUM		COPPER	0.5 MG	TAURATE	25 MG	SELENIUM	0.025 MG	QUERCETIN	10 MG		
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## Nutritional Support From Mother Nature



### Ocular Defense Formula

Dietary supplement for healthy eyes.

In today's health-conscious environment, staying physically fit is important. But how many people focus on the health of their eyes? Now you can support the health of your eyes with daily use of Ocular Defense Formula.

- Contains potent antioxidants that are believed to help protect the eyes from the harmful effects of free radicals.
- Includes the antioxidant-rich herb, Bilberry, which is highly beneficial for eyes.

#3007 (case of 12)

#0164 (HAP or unit) \$15.95

### Mega Ginseng Blend

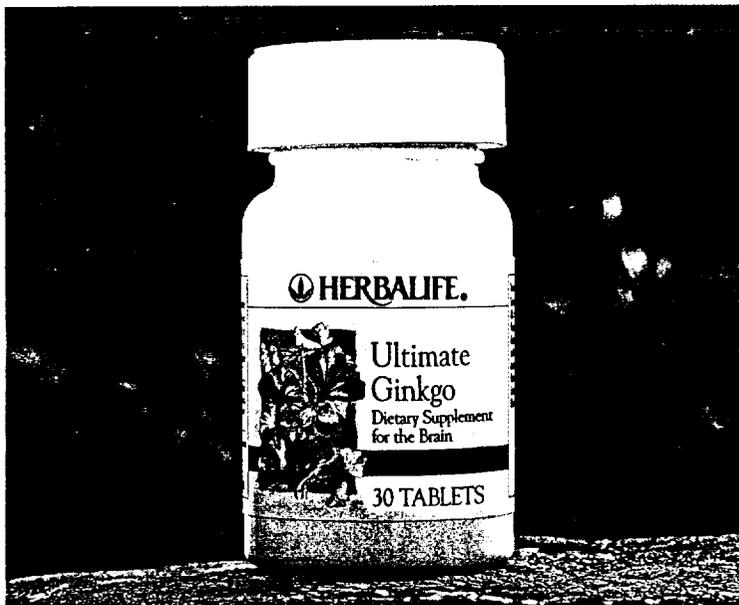
Dietary supplement for good health and well-being.

Eastern cultures have benefited from Ginsengs' remarkable health properties for centuries. Ginsengs are adaptogens which have long been used in traditional Chinese herbalism. Now you can experience the powerful effects of a variety of these ancient Chinese herbs with daily use of our Mega Ginseng Blend.

- Contains a unique mixture of the world's most widely used Ginsengs.

#3011 (case of 12)

#0163 (HAP or unit) \$14.95



### Ultimate Ginkgo

Dietary supplement for the brain.

A healthy, balanced diet and regular exercise can help you stay physically fit...but you need to stay mentally fit as well. Mother Nature offers a solution that's been around for millions of years in the form of the Ginkgo Biloba tree. Studies have shown that Ginkgo Biloba may help improve blood flow to the brain, stimulate neural activity and help maintain blood vessel tone. Herbalife has captured the botanical treasures of this ancient tree and formulated its goodness into Ultimate Ginkgo.

- Provides flavonoid glycosides and terpene lactones which can support healthy brain function.
- Contains DHA, an essential fatty acid present in the brain.
- Includes phosphatidylserine, an important component of neurons.

#3008 (case of 12)

#0160 (HAP or unit) \$16.95