

PHARMATON
NATURAL HEALTH PRODUCTS

Thomas W. Peterson
VICE PRESIDENT, GENERAL MANAGER

June 10, 1998

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VIA HAND DELIVERY

RECEIVED
7/2/98

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Re: MOVANA™ Dietary Supplement for Mood Support

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

The dietary supplement for which the statements are made is MOVANA™ tablets, which consist of St. John's Wort Extract WS-5572. The statements of nutritional support for this product read as follows:

Dietary supplement for mood support

Safely and naturally balances emotions and promotes a feeling of well-being

Safely and naturally maintains healthy motivation and self-esteem

... beneficial effects in maintaining emotional balance

MOVANA™ safely promotes normal levels of neuro-transmitters responsible for maintaining positive emotions

97S - 0162

900 Ridgebury Road, P.O. Box 368, Ridgefield CT 06877, Tel (203) 798-4243 • Fax (203) 798-5771

A DIVISION OF BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

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Linda S. Kahl, Ph.D.

June 10, 1998

Page 2

Use MOVANA™ regularly ... to maintain normal emotional balance, a healthy good mood and sense of well being, even during times of stress and low light seasons.

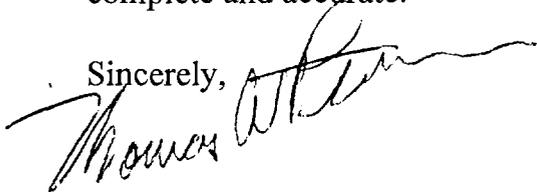
MOVANA™ helps maintain a healthy motivation and positive outlook on life.

A copy of the package and container label of the product (for both product sizes – 36 and 72* tablets) is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The information is printed in bold in a box.)

The Company certifies that it possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA, and that the information contained in this notice is complete and accurate.

Sincerely,



Thomas W. Peterson

Enclosure

Original plus two copies enclosed

*Please note there is also a 90 tablet size.

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048088

Advanced St. John's Wort
Movana[™]
DIETARY SUPPLEMENT FOR MOOD SUPPORT

Advanced St. John's Wort
Movana[™]

DIETARY SUPPLEMENT FOR MOOD SUPPORT

NEW FROM GINKOBA |

HYPERFORIN-RICH FORMULA

Advanced St. John's Wort
Movana[™]

DIETARY SUPPLEMENT FOR MOOD SUPPORT

Safely & Naturally:

- ▲ Balances emotions and promotes a feeling of well-being
- ▲ Maintains healthy motivation and self-esteem

U.S. Patent Pending

36
TABLETS
300 mg Each

MOVANA: The extract from the St. John's Wort plant has been growing in popularity for years, due to its beneficial effects in maintaining emotional balance. However, a recent discovery has made possible the Advanced St. John's Wort Extract (WS-5572) found in MOVANA[™]. Researchers have identified a component of St. John's Wort - called "hyperforin" - that is a key ingredient responsible for its effectiveness. Normally this component degrades readily, but in MOVANA[™] the hyperforin content is stabilized to insure the presence of a specified minimum amount. This technique is such a breakthrough that the extract in MOVANA[™] has patents pending around the world. MOVANA[™] safely promotes normal levels of neuro-transmitters responsible for maintaining positive emotions.

Suggested Use: Use MOVANA[™] regularly, as directed below, to maintain normal emotional balance, a healthy good mood and a sense of well-being even during times of stress, and low-light seasons. MOVANA[™] helps maintain a healthy motivation and positive outlook on life.

Recommended Adult Intake: Adults (12 years and older) should take one tablet 3 times per day. Like most herbal supplements, MOVANA[™] takes time to work; optimal effectiveness has been shown in as little as 2 weeks with continued use. Doses above 900 mg per day have not shown any greater effectiveness.

Precautions: As with vitamins and other supplements, please keep this product out of the reach of children. No serious side effects have been reported to date. However, if you are taking a prescription medicine, are pregnant or lactating, consult your physician. If you have fair and sensitive skin avoid prolonged direct sunlight, as photosensitivity may occur. There have been rare reports (<1%) of gastrointestinal disturbances, allergic reactions, unrest, or fatigue. In case of accidental overdose, seek the advice of a healthcare professional immediately.

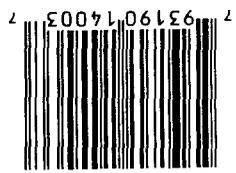
SUPPLEMENT FACTS:	
Serving Size: 1 Tablet	
Amount Per Tablet	
St. John's Wort Extract WS-5572 (flower & leaves)	
(Stabilized minimum Hyperforin content 3%,	
Standardized Hypericin content 0.3%)	300mg*
* Daily Value not established.	

Other Ingredients: Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, PEG-4000, Magnesium Stearate, Silicon Dioxide, Ascorbic Acid, Synthetic Iron Oxide, Titanium Dioxide, Talc, Vanillin.

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

Contains no artificial stimulants, caffeine, or sugar.

Store in a cool dry place. Avoid excessive moisture and heat (above 86° C).



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Product of Germany
NATURAL HEALTH PRODUCTS
Ridgefield, CT 06877

PHARMATON

Distributed by:

Division of Boehringer Ingelheim Pharmaceuticals, Inc.
MOVANA is a Trademark of Pharmaton Natural Health Products.

Advanced St. John's Wort

HYPERFORIN-RICH FORMULA

Advanced St. John's Wort

Movana

DIETARY SUPPLEMENT FOR MOOD SUPPORT

060888

NEW FROM GINKOBA

HYPERFORIN-RICH FORMULA

Advanced St. John's Wort

Movana

DIETARY SUPPLEMENT FOR MOOD SUPPORT

Advanced St. John's Wort
MovanaTM
DIETARY SUPPLEMENT FOR MOOD SUPPORT

Advanced St. John's Wort
MovanaTM
DIETARY SUPPLEMENT FOR MOOD SUPPORT

Safely & Naturally:

- ▲ Balances emotions and promotes a feeling of well-being
- ▲ Maintains healthy motivation and self-esteem

72
TABLETS
300 mg Each

U.S. Patent Pending

MOVANA: The extract from the St. John's Wort plant has been growing in popularity for years, due to its beneficial effects in maintaining emotional balance. However, a recent discovery has made possible the Advanced St. John's Wort Extract (WS-5572) found in MOVANATM. Researchers have identified a component of St. John's Wort - called "hyperforin" - that is a key ingredient responsible for its effectiveness. Normally this component degrades readily, but in MOVANATM the hyperforin content is stabilized to insure the presence of a specified minimum amount. This technique is such a breakthrough that the extract in MOVANATM has patents pending around the world. MOVANATM safely promotes normal levels of neuro-transmitters responsible for maintaining positive emotions.

Suggested Use: Use MOVANATM regularly, as directed below, to maintain normal emotional balance, a healthy good mood and a sense of well-being even during times of stress, and low-light seasons. MOVANATM helps maintain a healthy motivation and positive outlook on life.

Recommended Adult Intake: Adults (12 years and older) should take one tablet 3 times per day. Like most herbal supplements, MOVANATM takes time to work; optimal effectiveness has been shown in as little as 2 weeks with continued use. Doses above 900 mg per day have not shown any greater effectiveness.

Precautions: As with vitamins and other supplements, please keep this product out of the reach of children. No serious side effects have been reported to date. However, if you are taking a prescription medicine, are pregnant or lactating, consult your physician. If you have fair and sensitive skin avoid prolonged direct sunlight, as photosensitivity may occur. There have been rare reports (<1%) of gastrointestinal disturbances, allergic reactions, unrest, or fatigue. In case of accidental overdose, seek the advice of a healthcare professional immediately.

SUPPLEMENT FACTS:

Serving Size: 1 Tablet

Amount Per Tablet

St. John's Wort Extract WS-5572 (flower & leaves)	
(Stabilized minimum Hyperforin content 3%;	
Standardized Hypericin content 0.3%)	300mg*

* Daily Value not established.

Other Ingredients: Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, PEG-4000, Magnesium Stearate, Silicon Dioxide, Ascorbic Acid, Synthetic Iron Oxide, Titanium Dioxide, Talc, Vanillin.

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MOVANA is a Trademark of Pharmaton Natural Health Products.



NEW FROM GINKOBA

HYPERFORIN-RICH FORMULA

Advanced St. John's Wort

Movana™

DIETARY SUPPLEMENT FOR MOOD SUPPORT

\$2.00
Rebate
Inside

HYPERFORIN-RICH FORMULA

Advanced St. John's Wort

Movana™

DIETARY SUPPLEMENT FOR MOOD SUPPORT

Safely & Naturally:

- ▲ Balances emotions and promotes a feeling of well-being
- ▲ Maintains healthy motivation and self-esteem

ECONOMY SIZE
90
TABLETS
300 mg Each

NEW FROM GINKOBA

U.S. Patent Pending

DIETARY SUPPLEMENT FOR MOOD SUPPORT

Advanced St. John's Wort
Movana™

8B1060

Ref 7

Advanced St. John's Wort
Movana™

DIETARY SUPPLEMENT FOR MOOD SUPPORT

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Amount Per Tablet

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(Stabilized minimum Hyperforin content 3%)	
Standardized Hypericin content (0.3%)	300mg*

* Daily Value not established.

Other Ingredients: Microcrystalline Cellulose, Corn Starch, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, PEG-4000, Magnesium Stearate, Silicon Dioxide, Ascorbic Acid, Synthetic Iron Oxide, Titanium Dioxide, Talc, Vanillin.

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