



Boehringer
Ingelheim

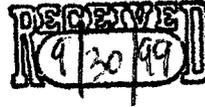
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Robert P. Carraher
Vice President, General Manager

Boehringer Ingelheim
Pharmaceuticals Inc.

Pharmaton Natural Health
Products

September 30, 1999



VIA HAND DELIVERY

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

Dear Sir/Madam:

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.

Telephone 203-798-4628
Telefax 203-798-5771
E-Mail rcarrahe@rdg.boehringer-
ingelheim.com

900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368
Telephone (203) 798-9988

The dietary supplement for which the statements are made is PRELIEVE PMS™ Dietary Supplement for Women Tablets, which consist principally of standardized vitex agnus castus extract (2.1) (fruit) 20 mg. The statements of nutritional support for this product read as follows:

Dietary Supplement for Women

- Helps Control Irritability
- Evens Out Emotional Ups and Downs
- Helps Maintain Hormonal Balance.

(The bullet points refer to the required DSHEA disclaimer.)

97S-0162

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Office of Special Nutritionals
September 30, 1999
Page 2

Prelieve PMS™ - is a unique standardized extract of the fruit of the Chaste tree Vitex Agnus Castus. Women who experience PMS can have a higher than normal level of the hormone Prolactin. This imbalance, combined with other hormonal changes your body goes through just before your period, can cause the irritability, moodiness and emotional sensitivity you associate with PMS. For some it also causes breast tenderness.*
Prelieve PMS is natural and safe to use. It works by slowing down the daily production of the hormone Prolactin. When taken as directed Prelieve PMS gradually and gently over time returns Prolactin to healthy levels -- to help maintain your normal hormonal balance which can help control the irritability, moodiness and emotional sensitivity, even reduce breast tenderness, you may experience.*

(The asterisks refer to the required DSHEA disclaimer.)

A copy of the package for each size of the product -- 28 and 56 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 on the principal display panel and back panel of the package and are referenced by bullet points or asterisks to the statements of nutritional support.)

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,



Robert P. Carraher
Vice President and General Manager

Enclosure

Original plus two copies enclosed

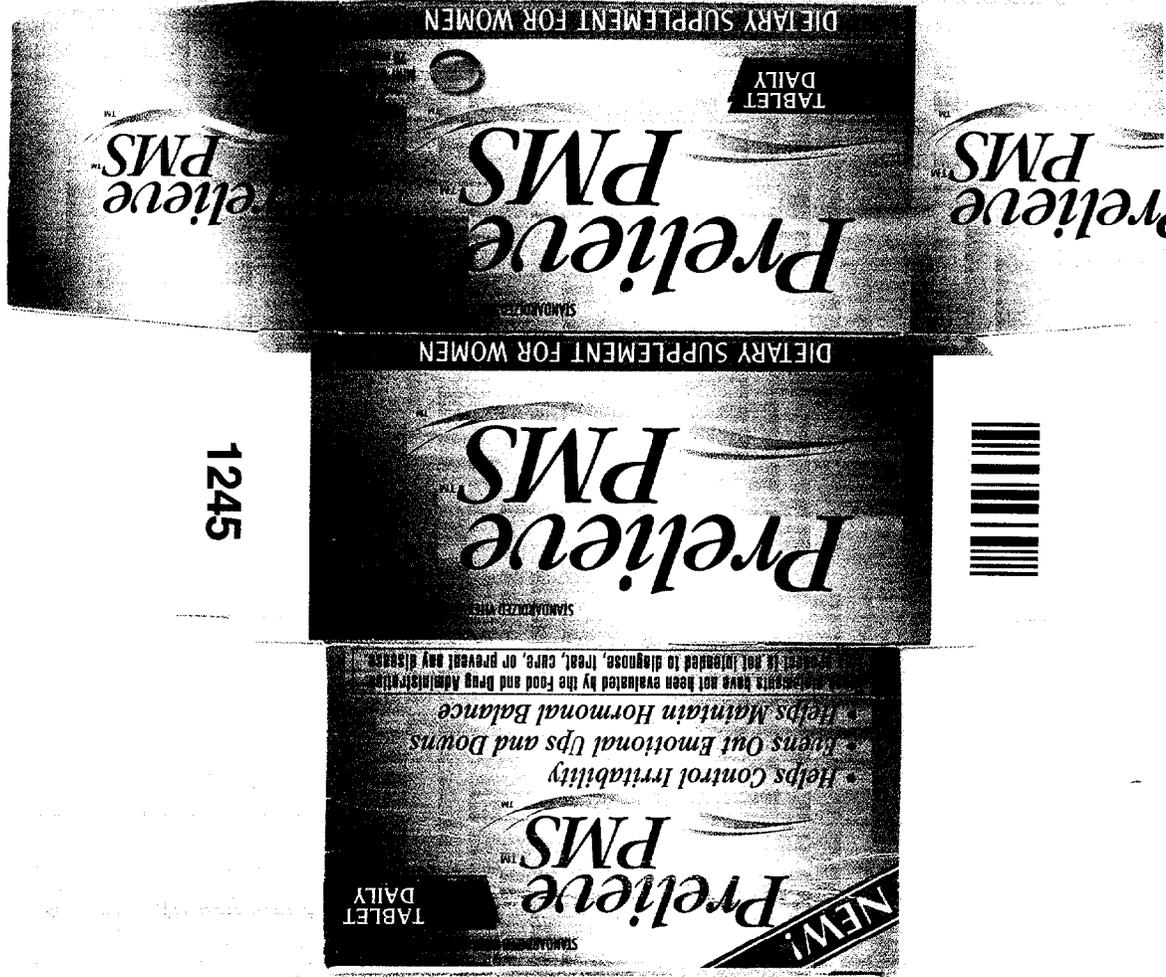
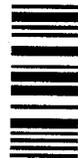
Boehringer Ingelheim Pharmaceuticals Inc.
Pharmaton Natural Health Products

PRELIEVE PMS

Dietary Supplement for Women

56 Tablet Package and Label

1245



8856100
Store at room temperature and avoid excessive heat above 40°C (104°F).
Other ingredients: lactose, magnesium stearate, polydione, talc, PEG-100, polydimethylsiloxane, FD&C blue #2, titanium dioxide, synthetic iron oxide.
Daily value not established.
Amount Per Tablet: Standardized Vitex Agnus Castus Extract (2:1) 20 mg (fruit)
Serving Size: 1 mini-tablet
SUPPLEMENT FACTS:



Recommended Adult Intake: Prelieve PMS™ should be taken as part of a daily regimen. Women (over 12 years old) should take one mini-tablet with water. Optimal effectiveness has been shown after only 2-3 menstrual cycles with continuous daily use.
Precautions: As with other vitamins and supplements, please keep this product out of the reach of children. No serious or significant adverse reactions or drug interactions have been reported to date. However, as with any supplement, contact your doctor if you are taking a prescription medicine, pregnant or lactating. The efficacy of dopamine receptor antagonists such as, haloperidol, may be altered by the administration of the Agnus Castus extract. There have been rare reports of itching and allergic rashes with the use of the extract in this product.
Questions? Call 1-800-451-6688

Prelieve PMS™ - is a unique standardized extract of the fruit of the Chaste tree Vitex Agnus Castus. Women who experience PMS can have a higher than normal level of the hormone Prolactin. This imbalance, combined with other hormonal changes your body goes through just before your period, can cause the irritability, moodiness and emotional sensitivity you associate with PMS. For some it also causes breast tenderness.* Prelieve PMS is natural and safe to use. It works by slowing down the daily production of the hormone Prolactin. When taken as directed Prelieve PMS gradually and gently over time returns Prolactin to healthy levels - to help maintain your normal hormonal balance which can help control the irritability, moodiness and emotional sensitivity, even reduce breast tenderness, you may experience.*

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Pharmaton Quality Guarantee:

Questions about Prelieve PMS™? Call toll-free 1-800-451-6688

This extract has been proven safe and effective in well-controlled clinical studies and is manufactured according to our highest quality standards.

Safety sealed for your protection. Do not use if safety seal under cap is torn or missing.

Satisfaction or your money back.

* 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.

SUPPLEMENT FACTS:
Serving Size: 1 mini-tablet
Amount Per Tablet:
Standardized Vitex Agnus Castus Extract (2:1) (fruit) 20 mg†
†Daily value not established

Other Ingredients: lactose, magnesium stearate, polydione, talc, PEG-100, polymethacrylic acid derivatives, FD&C blue #2, titanium dioxide, synthetic iron oxide.

Contains no artificial stimulants, hormones or sedatives.

Store at room temperature and avoid excessive heat above 104°F (40°C).

Imported and distributed by:
PHARMATON
NATURAL HEALTH PRODUCTS Ridgfield, CT 06877
Product of Germany

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Boehringer Ingelheim Pharmaceuticals Inc.
Pharmaton Natural Health Products

PRELIEVE PMS
Dietary Supplement for Women

28 Tablet Package

Prelieve PMS™ is a unique standardized extract of the fruit of the Chaste tree Vitex Agnus Castus. Women who experience PMS can have a higher than normal level of the hormone Prolactin. This imbalance, combined with other hormonal changes your body goes through just before your period, can cause the irritability, moodiness and emotional sensitivity you associate with PMS. For some it also causes breast tenderness.* Prelieve PMS is natural and safe to use. It works by slowing down the daily production of the hormone Prolactin. When taken as directed Prelieve PMS gradually and gently over time returns Prolactin to healthy levels - to help maintain your normal hormonal balance which can help control the irritability, moodiness and emotional sensitivity, even reduce breast tenderness, you may experience.*

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Serving Size: 1 mini-tablet
Amount Per Tablet:
Standardized Vitex Agnus Castus
Extract (2:1) (fruit) 20 mg†

† Daily value not established

Other Ingredients: lactose, magnesium stearate, polyvidone, talc, PEG-100, polymethacrylic acid derivatives, FD&C blue #2, titanium dioxide, synthetic iron oxide.

Contains no artificial stimulants, hormones or sedatives.

Imported and distributed by: Pharmaton Natural Health Products, Ridgefield, CT 06877
Product of Germany

Safety sealed for your protection. Do not use if individual blister seals are broken.

* 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.



Pharmaton Quality Guarantee:
This extract has been proven safe and effective in well-controlled clinical studies and is manufactured according to our highest quality standards.

Questions about Prelieve?
Call toll-free 1-800-451-6688
Satisfaction or your money back.



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Prelieve PMS™

244

Prelieve PMS™

TABLET DAILY

NEW!

Prelieve PMS™

- Helps Control Irritability
- Evens Out Emotional Ups and Downs
- Helps Maintain Hormonal Balance

TABLET DAILY

28
MINI TABLETS
20 mg Each

DIETARY SUPPLEMENT FOR WOMEN

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© 1999 Boehringer Ingelheim Pharmaceuticals, Inc. All rights reserved. U.S. Patent Pending.
Store in a cool, dry place and avoid excessive heat above 104°F (40°C).

EXP APR 2002

Prelieve PMS™