

RECEIVED
12/4/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 C.F.R. § 101.93

This notification is being filed on behalf of Natural Balance, Inc., 3199 N. Commerce Court, P. O. Box 8002, Castle Rock, CO 80104 - 8002, which is the manufacturer of the product which bears the statements identified in the Notification. This Notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling statements appears is HTP.Calm™.

The text of each structure-function statement for which notification is now being given is:

- Statement 1: *5-HTP and St. John's Wort Advanced Mood Formula*
- Statement 2: *This sophisticated blend brings you the exciting benefits of 5-HTP along with proven St. John's Wort plus the popular mood-enhancing herbs Kava Kava, Passion Flower and Gotu Kola.*
- Statement 3: *Since the Middle Ages, St. John's Wort has been used as a natural choice to enhance mood and well-being.*
- Statement 4: *5-HTP (5-hydroxytryptophan), derived from the natural plant griffonia simplicifolia, helps increase your levels of serotonin, the calming neurotransmitter.*
- Statement 5: *The HTP.Calm formula also includes Vitamin B-6, which is metabolically essential to the production of serotonin.*
- Statement 6: *The all natural HTP.Calm formula from Natural Balance offers you a select blend of 5-HTP (5-hydroxytryptophan), with a standardized extract of St. John's Wort and other natural ingredients known to help you feel more relaxed, sleep better and enjoy a more positive outlook.*
- Statement 7: *St. John's Wort. Studies show that this standardized herbal extract helps improve your mood and instill a sense of well-being.*
- Statement 8: *5-HTP (5-hydroxytryptophan). A natural compound known to help increase the production of serotonin, a chemical in the brain which plays a key role in keeping you calm, improving your mood, helping you sleep more soundly.*
- Statement 9: *Vitamin B-6. An essential nutrient which helps synthesize serotonin in the brain.*
- Statement 10: *Kava Kava, Passion Flower, Gotu Kola. Three of the most popular, natural mood-enhancing herbs.*
- Statement 11: *This all natural formula offers a select blend of ingredients known to help you feel more relaxed, sleep better and enjoy a more positive outlook.*
- Statement 12: *The Natural Way to Feel Calm, Improve Your Mood, Sleep Better*
- Statement 13: *Improve Your Sense of Well-Being*

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 HTP.Calm™

The following summary identifies the dietary ingredient(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort</i>
2.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort, Kava Kava, Passion Flower, Gotu Kola</i>
3.	<i>St. John's Wort</i>
4.	<i>5-HTP (5-hydroxytryptophan)</i>
5.	<i>Vitamin B-6</i>
6.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort, Vitamin B-6, Kava Kava, Passion Flower, Gotu Kola</i>
7.	<i>St. John's Wort</i>
8.	<i>5-HTP (5-hydroxytryptophan)</i>
9.	<i>Vitamin B-6</i>
10.	<i>Kava Kava, Passion Flower, Gotu Kola</i>
11.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort, Vitamin B-6, Kava Kava, Passion Flower, Gotu Kola</i>
12.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort, Vitamin B-6, Kava Kava, Passion Flower, Gotu Kola</i>
13.	<i>5-HTP (5-hydroxytryptophan), St. John's Wort, Vitamin B-6, Kava Kava, Passion Flower, Gotu Kola</i>

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	<i>HTP.Calm</i>	<i>Printed Box – 60 Capsules Label – 60 Capsules</i>
2.	<i>HTP.Calm</i>	<i>Printed Box – 60 Capsules</i>
3.	<i>HTP.Calm</i>	<i>Printed Box – 60 Capsules</i>
4.	<i>HTP.Calm</i>	<i>Printed Box – 60 Capsules</i>

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HTP.Calm™

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| 5. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 6. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 7. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 8. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 9. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 10. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 11. | <i>HTP.Calm</i> | <i>Label – 60 Capsules</i> |
| 12. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i> |
| 13. | <i>HTP.Calm</i> | <i>Printed Box – 60 Capsules</i>
<i>Label – 60 Capsules</i> |

I, Patricia L. Vazquez, am authorized to certify this Notification on behalf of Natural Balance, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Natural Balance, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 12.1.98

By:

Title:

Patricia L. Vazquez
Director, Regulatory Affairs