

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 CFR \$1011934 A6:25

This notification is being filed on behalf of <u>New Chapter</u>, <u>Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> 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 the statements appear is <u>Tranquilnite™</u>.

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

(Statement 1): Gently and safely promotes the experience of deep and satisfying sleep.

(Statement 2): Recognized for at least two thousand years for its relaxing properties, valerian species are now officially acknowledged in numerous European and Asian pharmacopoeias for promoting a deep and restful sleep without side effects often associated with other preparations.

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

Statement Number	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement
1.	Valerian, Hops, Ginger, Lavender, Passion Flower, Chamomile,
	Peppermint
2.	Valerian

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

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Tranquilnite™	Label and Labeling
2.	Tranquilnite™	Label and Labeling

I, <u>Margaret Kilroy</u>, am authorized to certify this Notification on behalf of <u>New Chapter</u>, <u>Inc.</u> I certify that the information presented and contained in this Notification is complete and accurate, and that <u>New Chapter</u>, <u>Inc.</u> has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5/22, 2003 By: <u>Margaret E. Killing Onality</u> Assurance Technician [Name]
[Title]

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

(Statement 3): Now with the support of numerous clinical trials, more than 70 official European preparations combine hops with other herbs to promote satisfying sleep.

(Statement 4): An herb that has been known for centuries as a response to occasional stress, lavender helps promote a calm and peaceful mind.

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

Statement Number	Identity of Dietary Ingredient(s) or
Number	Supplement(s) that is the subject of the Statement
3.	Hops
4 .	Lavender

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

Statement <u>Number</u>	Brand Name	Label or Labeling?
3.	Tranquilnite ™	Label and Labeling
4.	Tranquilnite™	Label and Labeling

I, <u>Margaret Kilroy</u>, am authorized to certify this Notification on behalf of <u>New Chapter</u>, <u>Inc.</u>. I certify that the information presented and contained in this Notification is complete and accurate, and that <u>New Chapter</u>, <u>Inc.</u> has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5/27, 2003 By: Mangaelt & Wary Quality Assumme Technician [Name]

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

(Statement 5): Recommended in the earliest written records of the Aztecs to counter nervousness, passion flower is now recognized in the prestigious German Commission E as an important herb to help counter restlessness.

(Statement 6): Historically revered for its soothing effects both externally and internally on virtually every major system, modern research shows chamomile can deliver a satisfying sleep even during periods of occasional stress.

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

Statement Number	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement
5.	Passion Flower
6	Chamomile

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

Statement <u>Number</u>	Brand Name	Label or Labeling?
5.	Tranquilnite™	Label and Labeling
6.	Tranquilnite™	Label and Labeling

I, <u>Margaret Kilroy</u>, am authorized to certify this Notification on behalf of <u>New Chapter</u>, <u>Inc.</u>. I certify that the information presented and contained in this Notification is complete and accurate, and that <u>New Chapter</u>, <u>Inc.</u> has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5/22, 2003 By: Manuff. Kilm Quality Assurance Technician [Name]

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

(Statement 7): Peppermint is virtually synonymous with digestive relief, and through this mechanism it helps to promote deep sleep.

(Statement 8): Ginger counters digestive stress and enhances the efficacy of the other herbal components.

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

Statement <u>Number</u>	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement

7. Peppermint8. Ginger

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

Statement <u>Number</u>	Brand Name	Label or Labeling?
7.	Tranquilnite™	Label and Labeling
8.	Tranquilnite™	Label and Labeling

I, <u>Margaret Kilroy</u>, am authorized to certify this Notification on behalf of <u>New Chapter</u>, <u>Inc.</u>. I certify that the information presented and contained in this Notification is complete and accurate, and that <u>New Chapter</u>, <u>Inc.</u> has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5/22, 2003 By: Margaret & Win Quality Assume Technician [Name] (Title)