



NF Formulas



PhytoPharmica

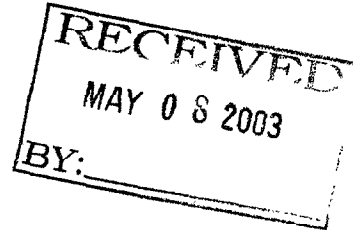


Tyler Encapsulations



Vitaline Formulas

2739 '03 MAY 27 P3:15



May 2, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

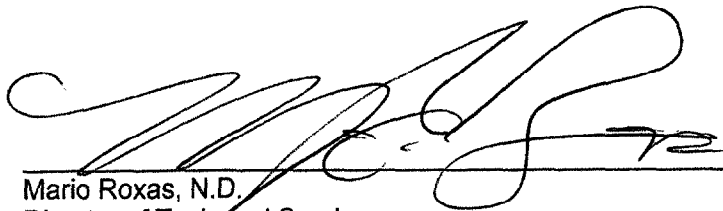
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"Indoplex® is a dietary supplement with research that associates changes in estrogen metabolites with indices of health*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 5/2/03

97S 0162 LET 11980

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NF Formulas



PhytoPharmica



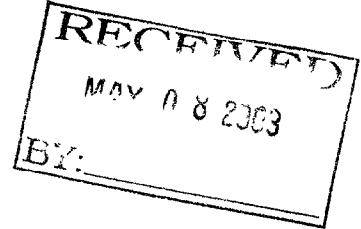
Tyler Encapsulations



Vitaline Formulas

April 30, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740




Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"In clinical testing, supplementation of volunteers with pure, unprocessed DIM did not alter the metabolite ratio*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.



Mario Roxas, N.D.
Director of Technical Services

Date 4/30/03



NF Formulas



PhytoPharmica

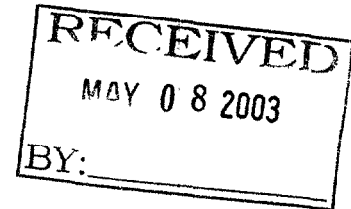


Tyler Encapsulations



Vitaline Formulas

April 28, 2003



Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

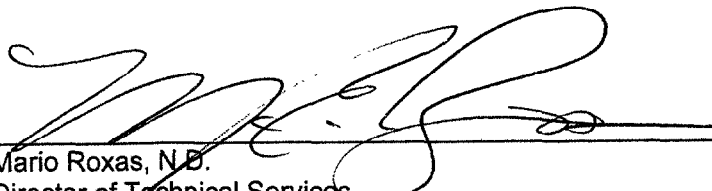
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"DIM enhances the activity of the CYP1A enzymes*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.



 Mario Roxas, N.D.
 Director of Technical Services

Date 4/28/03



NF Formulas



PhytoPharmica



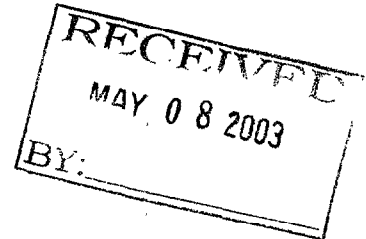
Tyler Encapsulations



Vitaline Formulas

April 25, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"I3C and Indoplex® modify cytochrome p450 (CYP) enzyme activity and support detoxification*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 4/25/03



NF Formulas



PhytoPharmica



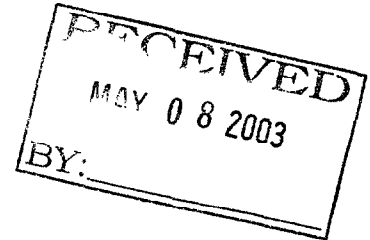
Tyler Encapsulations



Vitaline Formulas

April 23, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"The role of DIM in breast health has been investigated since the mid 1990's*." "Animal and <i>in vitro</i> studies continue to consistently report positive findings*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.

Mario Roxas, N.D.
Director of Technical Services

Date

4/28/03



NF Formulas



PhytoPharmica



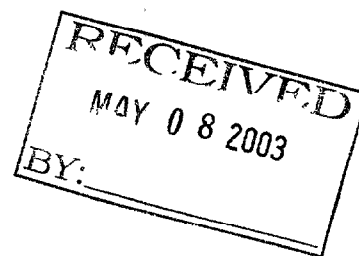
Tyler Encapsulations



Vitaline Formulas

April 18, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



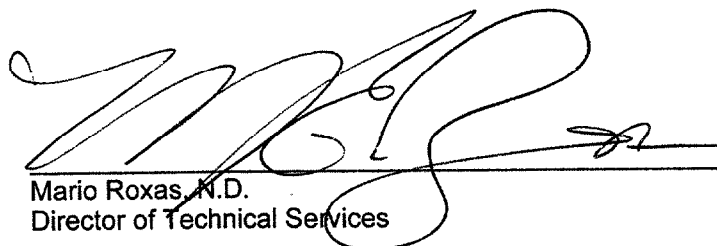
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"DIM induces 2-hydroxyestrone (2OH1) and 2-hydroxyestradiol (2-OH2) in diverse tissues, leading to net inhibition of excessive estrogen stimulation*." "Once present in the circulation, 2-OH1 and 2-OH2 are metabolized by catechol-O-methyl transferase (COMT), resulting in 2-methoxyestrone and 2-methoxyestradiol*." "These critical metabolites have been shown to promote healthy cell development in animals and humans*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 4/18/03



NF Formulas



PhytoPharmica



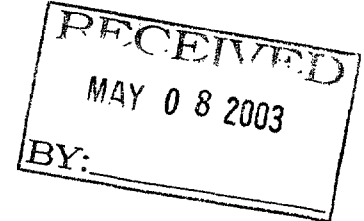
Tyler Encapsulations



Vitaline Formulas

April 15, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"Indoplex® is a dietary supplement to support healthy estrogen metabolism*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


 Mario Roxas, N.D.
 Director of Technical Services

Date 4/15/03



NF Formulas



PhytoPharmica

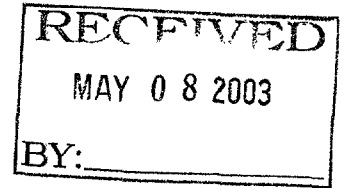


Tyler Encapsulations



Vitaline Formulas

May 1, 2003



Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

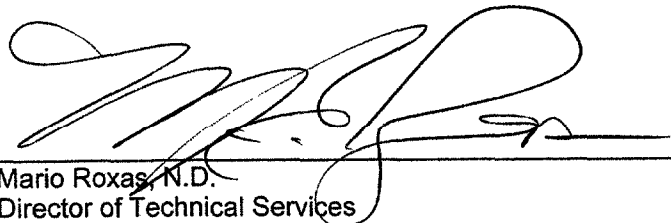
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	[In clinical testing, supplementation of volunteers with pure, unprocessed DIM did not alter the metabolite ratio] "However, repeat testing of the same volunteers at much lower doses using Indoplex® did beneficially alter the metabolite ratio, favoring an increase of 2-hydroxy over 16-hydroxy estrogen metabolites, promoting metabolism to the desirable 2-methoxy estrogen metabolites*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 5/1/03



NF Formulas



PhytoPharmica

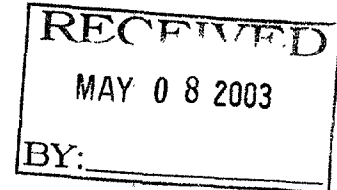


Tyler Encapsulations



Vitaline Formulas

April 17, 2003



Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	[Both I3C and DIM have been shown to increase the production of 2-hydroxyestrogen metabolism] "DIM is the most potent inducer of 2-hydroxylase, the enzyme responsible for this beneficial shift in estrogen metabolites*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.

Mario Roxas, N.D.
Director of Technical Services

Date 4/17/03



NF Formulas



PhytoPharmica

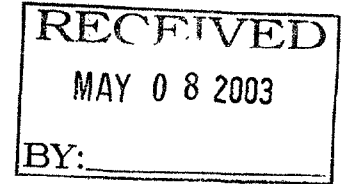


Tyler Encapsulations



Vitaline Formulas

April 29, 2003



Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

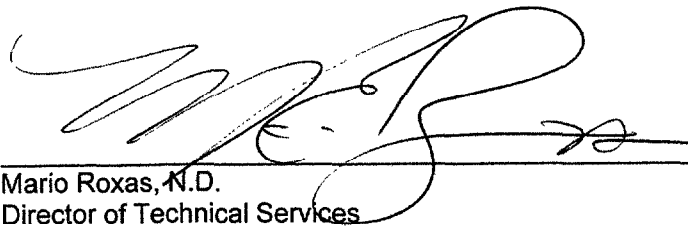
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	[DIM enhances the activity of the CYP1A enzymes]"These are the enzymes that are important in healthy estrogen metabolism*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 4/29/03



NF Formulas



PhytoPharmica

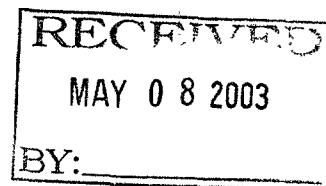


Tyler Encapsulations



Vitaline Formulas

April 11, 2003



Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"DIM is less reactive and less of an enzyme inducer than I3C*." Doubling the typical dose of I3C from 400 to 800mg/day can cause unwanted side effects in humans*." "No side effects of any sort are seen with DIM even when the typical dose of 150 mg/day is tripled to 450 mg/day*."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 4/11/03



NF Formulas



PhytoPharmica



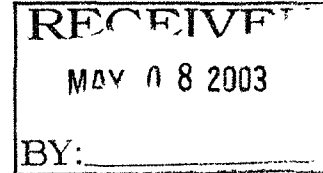
Tyler Encapsulations



Vitaline Formulas

April 16, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"Both I3C and DIM have been shown to increase the production of 2-hydroxyestrogen metabolism".	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.

Mario Roxas, N.D.
Director of Technical Services

Date

4/16/03



NF Formulas



PhytoPharmica



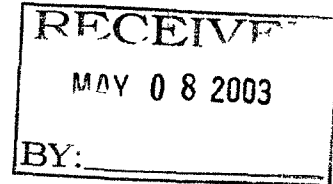
Tyler Encapsulations



Vitaline Formulas

April 14 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



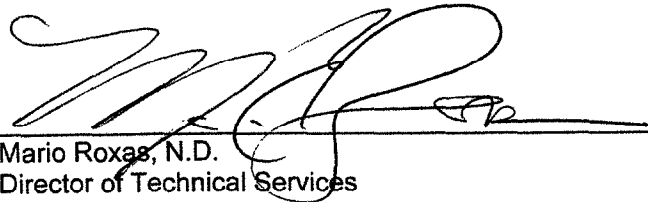
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Product Name	Statement	Ingredient(s) to which claim refers
Indoplex®	"DIM [(3,3'-diindolylmethane)] has multiple biochemical activities in the human body, important for both men and women."	Indoplex® Complex (containing modified food grade starch, 25% diindolylmethane, tocophersolan, phosphatidylcholine, silica)

I certify that the information contained in this notice is complete and accurate, and that Tyler has substantiation that the statement is truthful and not misleading.


Mario Roxas, N.D.
Director of Technical Services

Date 4/14/03