67701

Tom's OF MAINE

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

RECEIVED 10/18/99

October 12, 1999

This letter is intended to serve as official notification that Tom's of Maine, P.O. Box 710, Kennebunk, ME has begun to market the following dietary supplement products bearing statements of nutritional support as indicated:

Product name	Dietary supplement	Statement of nutritional support
Natural Echinacea tonic (elderberry flavor)	Extract of *Echinacea purpurea* (L.) Moench and *E. angustifolia* DC. roots	"Strengthens your natural defenses and gives your immune system a boost when you most need it"
Natural Echinacea tonic (ginger-orange flavor)	Extract of *Echinacea purpurea* (L.) Moench and *E. angustifolia* DC. roots	"Strengthens your natural defenses and gives your immune system a boost when you most need it"
Natural Echinacea tonic concentrate (elderberry)	Extract of *Echinacea purpurea* (L.) Moench and *E. angustifolia* DC. roots	"Strengthens your natural defenses and gives your immune system a boost when you most need it"
Natural Echinacea tonic concentrate (hibiscus)	Extract of *Echinacea purpurea* (L.) Moench and *E. angustifolia* DC. roots	"Strengthens your natural defenses and gives your immune system a boost when you most need it"
Natural Echinacea (liquid herbal extract)	Extract of *Echinacea purpurea* (L.) Moench and *E. angustifolia* DC. roots	"Strengthens your natural defenses and gives your immune system a boost when you most need it"
Natural Valerian w/ Lemon balm (liquid herbal extract)	Extract of *Valeriana officinalis* L., dried root	"promotes more restful sleep"
Natural American ginseng (liquid herbal extract)	Extract of *Panax quinquefolius* L. root	"supports physical performance in an active lifestyle"

97S-0162

Cindy K. Angelof
Group Team Leader, Product Research

10/12/99
Date

LET 4503

Lafayette Center P.O. Box 710 Kennebunk, Maine 04043-0710 USA Tel. (207) 985-2944 Fax (207) 985-2196

Printed on Recycled Paper.

NATURAL WELLNE

Tom's OF MAINE

NEW!

natural echinacea tonic

With Green Tea

Herbal Supplement

Use as Needed

NO ALCOHOL

Ginger–Orange Flavor

NET 2.4 Fl.Oz.(75ml)

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Other Ingredients: Vegetable glycerin (kosher), purified water, vitamin B6, xanthan gum, citric acid, natural orange flavor, natural benzoic acid.

100% Recycled Paperboard

65% Post-Consumer Content
35% Pre-Consumer Content

Supplement Facts

Serving Size 1 Tablespoon (15 ml)
Servings per Container 5

	Amount Per Tablespoon	% Daily Value*
Calories	15	
Total Carbohydrate	4 g	1%
Echinacea Extract *Echinacea purpurea* (L.) Moench**	450 mg fresh root	†
Echinacea Extract *Echinacea angustifolia* DC.**	315 mg dried root	†
Echinacea Neaneen Extract *Echinacea purpurea* (L.) Moench**	250 mg dried aerial parts	†
Ginger Extract *Zingiber officinale* Roscoe**	240 mg dried root	†
Hibiscus Extract *Hibiscus sabdariffa* L.**	150 mg dried flower	†
Green Tea Extract (decaffeinated) *Camellia sinensis* (L.) Kuntze	25 mg leaves	†

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
** ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

NATURAL WELLNE

Tom's OF MAINE

NEW!

natural echinacea tonic

With Green Tea

Herbal Supplement

Use as Needed

NO ALCOHOL

Elderberry Flavor

NET 2.4 Fl.Oz.(75ml)

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Other Ingredients: Vegetable glycerin (kosher), xanthan gum, citric acid, natural benzoic acid.

100% Recycled Paperboard

65% Post-Consumer Content
35% Pre-Consumer Content

Supplement Facts

Serving Size 1 Tablespoon (15 ml)
Servings per Container 5

	Amount Per Tablespoon	% Daily Value*
Calories	15	
Total Carbohydrate	4 g	1%
Echinacea Extract *Echinacea purpurea* (L.) Moench**	450 mg fresh root	†
Elderberry Extract *Sambucus canadensis* L. var. *vestita* (Lowes & Lorbeer)	450 mg fresh berries	†
Echinacea Extract *Echinacea angustifolia* DC.**	315 mg dried root	†
Echinacea Neaneen Extract *Echinacea purpurea* (L.) Moench**	250 mg dried aerial parts	†
Ginger Extract *Zingiber officinale* Roscoe	240 mg dried root	†
Green Tea Extract (decaffeinated) *Camellia sinensis* (L.) Kuntze	25 mg leaves	†

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
** ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

NATURAL WELLNE

Tom's OF MAINE

NEW!

natural echinacea tonic

CONCENTRATE

Herbal Supplement

Use as Needed

NO ALCOHOL

HIBISCUS

NET 1.7 Fl.Oz.(50ml)

*No Alcohol * No Caffeine*
*No Dyes * No Artificial*
Preservatives or Sweeteners
No Animal Ingredients

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM.

Our full spectrum tonics are monitored for quality, consistency, and potency at our own extraction facility.

Supplement Facts

Serving Size 1 Dropperful (1.25 ml)
Servings per Container 40

	Amount Per Dropperful	% Daily Value*
Organic Echinacea** *Echinacea purpurea* (L.) Moench	115 mg fresh root	†
Organic Echinacea** *Echinacea angustifolia* DC.	70 mg dried root	†
Organic Ginger** *Zingiber officinale* Roscoe	50 mg dried root	†
Organic Hibiscus** *Hibiscus sabdariffa* L.	40 mg dried flower	†

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
** ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

Other Ingredients: Vegetable glycerin (kosher), purified water.

Tom's of Maine, PO Box 710, Kennebunk, ME 04043 USA

Copyright ©1999 Tom's of Maine Inc.

www.tomsofmaine.com

No Alcohol ✻ No Caffeine
No Dyes ✻ No Artificial
Preservatives or Sweeteners
No Animal Ingredients

Dear Friends,
Tom's of Maine Natural Echinacea Tonic is a unique blend of herbal ingredients formulated to strengthen your natural defenses and give your immune system a boost when you most need it.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature, like echinacea, ginger, and green tea to create this safe and effective wellness tonic. In a non-alcoholic vegetable glycerin base, we have added hibiscus extract and natural orange oil for a refreshingly pleasant taste. Thanks for using our products, and please let us know what you think.

Kate and Tom
Kate & Tom Chappell

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM.

Our full spectrum tonics are monitored for quality, consistency, and potency at our own extraction facility.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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Kennebunk, ME 04043 USA
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www.tomsofmaine.com

#4400
0 77326 80025 6

natural echinacea tonic
With Green Tea

Directions: Adults take 1-2 tablespoonsful 2-4 times daily, when most needed. Children take 1-2 teaspoonsful 2-4 times daily, when most needed.

Precautions: Not intended for children under age 2. Take only when needed. Echinacea should not be used by anyone with autoimmune disease. People known to have allergies to plants in the daisy family (Asteraceae), or who are pregnant or nursing, should consult a health professional before using this product. If any adverse reaction occurs, discontinue use of this product.

Tom's of Maine products are tested for safety without the use of animals.

SHAKE WELL
Refrigerate After Opening

August 1999
PO# 23138
Toms#4400
B&F 074

No Alcohol ✻ No Caffeine
No Dyes ✻ No Artificial
Preservatives or Sweeteners
No Animal Ingredients

Dear Friends,
Tom's of Maine Natural Echinacea Tonic is a unique blend of herbal ingredients formulated to strengthen your natural defenses and give your immune system a boost when you most need it.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature, like echinacea, ginger, and green tea to create this safe and effective wellness tonic. In a non-alcoholic vegetable glycerin base, we have added elderberry extract for a bright and pleasant taste. Thanks for using our products, and please let us know what you think.

Kate and Tom
Kate & Tom Chappell

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM.

Our full spectrum tonics are monitored for quality, consistency, and potency at our own extraction facility.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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Kennebunk, ME 04043 USA
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www.tomsofmaine.com

#4401
0 77326 80125 3

natural echinacea tonic
With Green Tea

Directions: Adults take 1-2 tablespoonsful 2-4 times daily, when most needed. Children take 1-2 teaspoonsful 2-4 times daily, when most needed.

Precautions: Not intended for children under age 2. Take only when needed. Echinacea should not be used by anyone with autoimmune disease. People known to have allergies to plants in the daisy family (Asteraceae), or who are pregnant or nursing, should consult a health professional before using this product. If any adverse reaction occurs, discontinue use of this product.

Tom's of Maine products are tested for safety without the use of animals.

SHAKE WELL
Refrigerate After Opening

August 1999
PO# 23138
Toms#4401
B&F 075

natural echinacea tonic
CONCENTRATE

Dear Friends,
Tom's of Maine Natural Echinacea Tonic Concentrate is a unique blend of herbal ingredients formulated to strengthen your natural defenses and give your immune system a boost when you most need it.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature, like echinacea and ginger, to create this safe and effective wellness tonic. We have added hibiscus extract in a vegetable glycerin base to give our tonic a pleasant taste.

This is a concentrated formula containing the same healthful properties as our full size Echinacea Tonic. Thanks for using our products, and please let us know what you think.

Kate and Tom
Kate & Tom Chappell

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#4470
0 77326 83417 6

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Directions: Adults take 1-2 droppersful 2-4 times daily, when most needed. Children take ¼ dropperful 2-4 times daily, when most needed. **Not intended for children under age 2.** Take straight or add to juice or tea if desired.

Precautions: Take only when needed. Echinacea should not be used by anyone with autoimmune disease. People known to have allergies to plants in the daisy family (Asteraceae), or who are pregnant or nursing, should consult a health professional before using this product. If any adverse reaction occurs, discontinue use of this product.

SHAKE WELL
Store at Room Temperature

Tom's of Maine products are tested for safety without the use of animals.

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August 1999
PO# 23138
Toms#4470
B&F 079

NATURAL WELLNESS

Tom's OF MAINE

NEW!

natural american ginseng

Herbal Supplement

NO ALCOHOL

LIQUID GINSENG EXTRACT

NET 1.7 Fl.Oz.(50ml)

*No Alcohol * No Caffeine*
*No Dyes * No Artificial*
Preservatives or Sweeteners
No Animal Ingredients

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM

Our Natural American Ginseng is a full spectrum extract monitored for quality, consistency, and potency at our own extraction facility.

Supplement Facts

Serving Size 1 Dropperful (1.25 ml)
Servings per Container 40

	Amount Per Dropperful	% Daily Value*
American Ginseng *Panax quinquefolius* L.	625 mg dried whole root	†

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established

Other Ingredients: Vegetable glycerin (kosher), purified water.

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NATURAL WELLNESS

Tom's OF MAINE

NEW!

natural valerian

with Lemon Balm

Herbal Supplement

NO ALCOHOL

LIQUID VALERIAN EXTRACT

NET 1.7 Fl.Oz.(50ml)

*No Alcohol * No Caffeine*
*No Dyes * No Artificial*
Preservatives or Sweeteners
No Animal Ingredients

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM

Our Natural Valerian is a full spectrum extract monitored for quality, consistency, and potency at our own extraction facility.

Supplement Facts

Serving Size 1 Dropperful (1.25 ml)
Servings per Container 40

	Amount Per Dropperful	% Daily Value*
Valerian *Valeriana officinalis* L.**	250 mg dried root	†
Lemon Balm *Melissa officinalis* L.**	125 mg fresh herb	†

Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
**ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

Other Ingredients: Vegetable glycerin (kosher), purified water.

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10

NATURAL WELLNESS

Tom's OF MAINE

NEW!

natural echinacea tonic

CONCENTRATE

Herbal Supplement

Use As Needed

NO ALCOHOL

ELDERBERRY

NET 1.7 Fl.Oz.(50ml)

*No Alcohol * No Caffeine*
*No Dyes * No Artificial*
Preservatives or Sweeteners
No Animal Ingredients

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM.

Our full spectrum tonics are monitored for quality, consistency, and potency at our own extraction facility.

Supplement Facts

Serving Size 1 Dropperful (1.25 ml)
Servings per Container 40

	Amount Per Dropperful	% Daily Value*
Organic Echinacea** *Echinacea purpurea* (L.) Moench	115 mg fresh root	†
Elderberry *Sambucus canadensis* L. or *nigra* L.	75 mg wild harvested flowers & berries	†
Organic Echinacea** *Echinacea angustifolia* DC.	70 mg dried root	†
Organic Ginger** *Zingiber officinale* Roscoe	50 mg dried root	†

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
**ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

Other Ingredients: Vegetable glycerin (kosher), purified water.

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10

natural american ginseng

Dear Friends,

Tom's of Maine Natural American Ginseng is a full spectrum, single plant extract intended to support physical performance in an active lifestyle.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature to create this safe and effective liquid herbal extract.

In keeping with our philosophy of creating products without alcohol, we have formulated our american ginseng extract with vegetable glycerin to allow for a high-quality extraction and a pleasant taste. Thanks for using our products, and please let us know what you think.

Kate and Tom

Kate & Tom Chappell

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#4462

0 77326 83217 2

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Directions: Adults take 1-2 droppersful up to 3 times daily, when most needed. Take straight or add to juice or tea if desired.

Precautions: **Not intended for children.** If you experience adverse effects, irritation, or allergic reaction, discontinue use of this product. If pregnant or nursing, consult a health professional before using this product.

SHAKE WELL

Store at Room Temperature

Tom's of Maine products are tested for safety without the use of animals.

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August 1999
PO# 23138
Toms# 4462
B&F 076

natural valerian with Lemon Balm

Dear Friends,

Tom's of Maine Natural Valerian is a full spectrum extract intended to promote more restful sleep.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature to create this safe and effective liquid herbal extract.

In keeping with our philosophy of creating products without alcohol, we have formulated our valerian extract with vegetable glycerin to allow for a high-quality extraction. We have added lemon balm for a refreshing herbal complement and pleasant taste. Thanks for using our products, and please let us know what you think.

Kate and Tom

Kate & Tom Chappell

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#4461

0 77326 83117 5

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Directions: Adults take 1-2 droppersful up to 3 times daily, when most needed. Children take ½ dropperful up to 3 times daily, when most needed. **Not intended for children under age 2.** Take straight or add to juice or tea if desired.

Precautions: If you experience adverse effects, irritation, or allergic reaction, discontinue use of this product. If pregnant or nursing, consult a health professional before using this product.

SHAKE WELL

Store at Room Temperature

Tom's of Maine products are tested for safety without the use of animals.

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August 1999
PO# 23138
Toms# 4461
B&F 077

natural echinacea tonic CONCENTRATE

Dear Friends,

Tom's of Maine Natural Echinacea Tonic Concentrate is a unique blend of herbal ingredients formulated to strengthen your natural defenses and give your immune system a boost when you most need it.* Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature, like echinacea and ginger, to create this safe and effective wellness tonic. We have added hibiscus extract in a vegetable glycerin base to give our tonic a pleasant taste.

This is a concentrated formula containing the same healthful properties as our full size Echinacea Tonic. Thanks for using our products, and please let us know what you think.

Kate and Tom

Kate & Tom Chappell

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#4471

0 77326 83517 3

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Directions: Adults take 1-2 droppersful 2-4 times daily, when most needed. Children take ¼ dropperful 2-4 times daily, when most needed. **Not intended for children under age 2.** Take straight or add to juice or tea if desired.

Precautions: Take only when needed. Echinacea should not be used by anyone with autoimmune disease. People known to have allergies to plants in the daisy family (Asteraceae), or who are pregnant or nursing, should consult a health professional before using this product. If any adverse reaction occurs, discontinue use of this product.

SHAKE WELL

Store at Room Temperature

Tom's of Maine products are tested for safety without the use of animals.

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August 1999
PO# 23138
Toms#4471
B&F 080

natural echinacea

Dear Friends,

Tom's of Maine Natural Echinacea is a full spectrum, single plant extract intended to strengthen your natural defenses and give your immune system a boost when you most need it. Our team of herbalists and natural medicine scientists has drawn upon ingredients from nature to create this safe and effective liquid herbal extract.

In keeping with our philosophy of creating products without alcohol, we have formulated our echinacea extract with vegetable glycerin to allow for a high-quality extraction and a pleasant taste. Thanks for using our products, and please let us know what you think.

Kate and Tom

Kate & Tom Chappell

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

#4460

0 77326 63017 6

Do not use if neckband printed with "Natural Wellness" is damaged or missing.

Directions: Adults take 1-2 droppersful 2-4 times daily, when most needed. Children take 1/2 dropperful 2-4 times daily, when most needed. **Not intended for children under age 2.** Take straight or add to juice or tea if desired.

Precautions: Take only when needed. Echinacea should not be used by anyone with autoimmune disease. People known to have allergies to plants in the daisy family (Asteraceae), or who are pregnant or nursing, should consult a health professional before using this product. If any adverse reaction occurs, discontinue use of this product.

SHAKE WELL

Store at Room Temperature

Tom's of Maine products are tested for safety without the use of animals.

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August 1999
PO# 23138
Toms#4460
B&F 078

NATURAL WELLNESS

Tom's OF MAINE

NEW!

natural echinacea

Herbal Supplement

Use as Needed

NO ALCOHOL

LIQUID ECHINACEA EXTRACT

NET 1.7 Fl.Oz.(50ml)

No Alcohol ✻ No Caffeine
No Dyes ✻ No Artificial
Preservatives or Sweeteners
No Animal Ingredients

If you have questions about our natural wellness products, call 1-800-FOR-TOMS. For more information about herbal ingredients, call the University of Illinois at Chicago, toll free 1-877-ASK-PHARM.

Our Natural Echinacea is a full spectrum extract monitored for quality, consistency, and potency at our own extraction facility.

Supplement Facts

Serving Size 1 Dropperful (1.25 ml)
Servings per Container 40

	Amount Per Dropperful	% Daily Value*
Echinacea *Echinacea purpurea* (L.) Moench**	370 mg	† fresh root
Echinacea *Echinacea angustifolia* DC.**	90 mg	† dried root
Echinacea *Echinacea purpurea* DC.**	60 mg	† seed

*Percent Daily Values are based on a 2000 calorie diet
† Percent Value not established
**ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990

Other Ingredients: Vegetable glycerin (kosher), purified water.

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