



MAR 18 1999 1263 '99 MAR 23 P2:13

Mr. Brian Ross  
President  
Te Nation, Inc.  
1125 SE Madison  
Suite 100 "B"  
Portland, Oregon 97214

Dear Mr. Ross:

This is in response to your letters of February 12, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Te Nation, Inc. is making the following statements, among others, for the products:

**Echinacea Te**

"Colds, flu and other yuckiness have ruined our days ..."  
"...world of colds, flus and achiness, enjoy a cup of sanctuary"

**Ginger Te**

"Stomach aches, fevers and migraines have plagued us..."  
"...a natural remedy for practically anything that makes you wish you had an airsick bag..."

**Throat Te**

"Sore throats have been a pain in the neck..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to prevent, treat, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 260

Page 2 - Mr. Brian Ross

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Office of Compliance, HFR-PA340

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (File)  
HFS-450 (file, r/f, OSN#63752)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605 (Bowers)  
HFV-228 (Benz)  
HFV-232 (Brown)  
GCF-1 (Nickerson, Dorsey)  
r/d:HFS-456:RMoore:2/19/99  
reviewed:GCF-1:DDorsey:3/16/99  
f/t:HFS-456:rjm:3/17/99:docname:63752.adv:disc35

1125 SE Madison Suite 100B Portland Oregon 97214 503.233.7630 888.345.7630 Fax 503.233.7709 www.tenation.com

63752

NOTIFICATION LETTER

No boundaries.

Tē Nation, Inc.  
1125 SE Madison  
Suite 100 "B"  
Portland, OR 97214

phone (503) 233-7630

February 12 1999

To the Office of Special Nutritionals.

The purpose of this letter is to provide notification of a statement of nutritional support for Echinacea Tē by Tē Nation. Echinacea Tē is a ready to drink herbal tea in an aseptic package

The herbal supplement that is the subject of the statement is Echinacea root. The text of the statement is the following:

"Wellness Booster."

"To get the most out of Echinacea Tē drink it hot. Start drinking it as soon as you begin to feel like you need a boost. Drink about 5 cups a day. But don't over do it. The benefits of echinacea may max out after a couple of weeks. Wait a week or so before you begin to sip again."

The product's herbal supplemental are

- Echinacea root (*angustifolia & purpurea*)
- Barberry bark (*berberis vulgaris*)
- Oregon Grape root (*mahonia repens*)
- St. Johnswort (*hypericum perforatum*)

Recommended dosage: 5 cups (servings) per day.

Warning; Recommended for adults only. Take only when needed. Echinacea should not be used by anyone with tuberculosis, leukoses, coloagenosis, multiple sclerosis, AIDS, HIV infections, or other auto immune diseases. Do not use if you have allergies to the daisy family (Asteraceae) or are pregnant or nursing.

Tē Nation has substantiation that the statement made under 403 (6) (r) is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Sincerely,

Brian Ross  
President, Tē Nation, Inc.



BY 353

Cold, flu and other yuckness have rained our days since humans were packing woolly mammoths with long pointy sticks. Meanwhile, back at the cave, some smart witch-doctor had a nice hot cup of Echinacea waiting for them. (The only difference is: Today, witch-doctors don't make house calls. Usually.)

So you have to do it. And face it, brewing medicinal tea yourself takes too long. To extract the maximum benefits from loose herbs and roots they need to be steeped for a long time. Literally 15-30 minutes. Besides, most medicinal herbs taste like sting carpet. Green slung carpet.

So we thought it was about time for an uprising. Te Nation has taken the revolutionary step of taking the essential herbs and roots for you. And because the essential oils of Te Nation blend Te with natural flavor extracts and juices without using any preservatives, you're going to love the process of feeling better.

Manufactured for Te Nation, Valhalla, New York 10595 800.242.9895 www.TeNation.com



The substance prepared on this package from Echinacea, is a natural herb. It is not intended to diagnose, treat, cure or prevent any disease.

32 fluid ounces  
946 milliliters

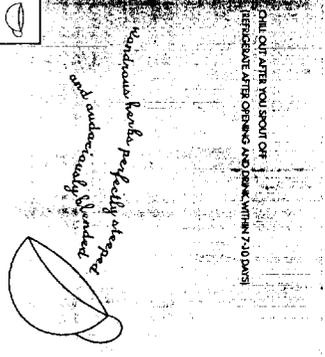
Shake it up baby.



JUST POUR & DRINK - HOT OR COLD HERBAL SUPPLEMENT

# Echinacea Te

WELLNESS BOOSTER



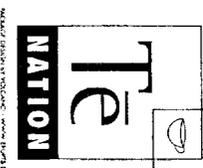
### Nutrition Facts

SEVING SIZE: 8 fluid ounces (237ml)	
SERVINGS PER CONTAINER: 4	
AMOUNT PER SERVING	
CALORIES 40	CAL FROM FAT 0
TOTAL FAT 0g	% Daily Value*
SODIUM 10mg	0%
TOTAL CARBOHYDRATES 15g	5%
SUGARS 15g	
PROTEIN 0g	0%

### Supplement Facts

SEVING SIZE: 8 fluid ounces (237ml)	Amount per serving	% Daily Value
ECHINACEA ROOT†	470mg	100%
BARBERRY BARK	200mg	100%
ORGANIC GRAPE ROOT	200mg	100%
ST. JOHNSWORT	200mg	100%

Other ingredients - FILTERED WATER, REAL SAGE, ROSEMARY, CAYENNE, APPLE JUICE FROM CONCENTRATE, RAW SUGAR, PEPPERMINT, SERRANO PEPPER, CINNAMON BARK, HIBISCUS, AND LEMON OILS.



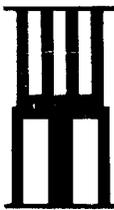
DON'T MICROWAVE THE PACKAGE. FEEL FREE TO POUR TE INTO A CUP AND ZAP IT ALL YOU WANT, BUT MICROWAVING THE PACKAGE COULD RESULT IN THE SMALL APPLIANCE EQUIVALENT OF INVITING JOHNNY DEPP OVER FOR THE WEEKEND.

*buy, choose, flip, flipper, cold, cooler*

4 1 3 3 5  
6 1 0 6 0



Tetra Brk  
MEDIC  
Printed in USA



1125 SE Madison Suite 100B Portland Oregon 97214 503 233 7630 888 345 7630 FAX 503 233 7700 WWW.TE-NATION.COM

NOTIFICATION LETTER

No boundaries.

Te Nation, Inc.  
1125 SE Madison  
Suite 100 "B"  
Portland, OR 97214

phone (503) 233-7630

February 12, 1999

To the Office of Special Nutritionals

The purpose of this letter is to provide notification of a statement of nutritional support for Ginger Te by Te Nation. Ginger Te is a ready to drink herbal tea in an aseptic package.

The herbal supplement that is the subject of the statement is Ginger root. The text of the statement is the following:

Stomach settler.

Fart control is perhaps the most obscure and underutilized benefit of ginger root.

The product's herbal supplemental are:

- Fresh Ginger root (*Zingiber officinale*)
- Blackberry leaf (*Rubus villosus*)

Warning: Pregnant or nursing women, or anyone who is suffering from gall stones should consult a health professional prior to using this product.

Te Nation has substantiation that the statement made under 403 (b) (1) is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Sincerely,

Brian Ross  
President, Te Nation





Stomach aches, fevers and migraines have plagued us since Noah spent all day getting away from personal with a couple of slugs. Lucky for him, there was a cup of hot ginger tea waiting for him up the gang plank. (Today, the slugs would file a harassment suit, his wife would write an exposé and he'd have to brew the tea himself.)

And face it, brewing medicinal tea takes too long. To extract the maximum benefits from loose herbs and roots they need to be steeped for a long time. Ideally 15-30 minutes. Besides, most medicinal herbs taste like slug carpet. Green slug carpet.

So we thought it was about time for an uprising. Te Nation has taken the revolutionary step of taking the necessary time to steep these unadorned herbs and roots for you. And because the constituents of Te Nation blend in with natural flavors, spices and juices without using extracts, you're going to love the process of feeling better.

Manufactured for Te Nation, Valhalla, New York 10595 800.242.9895 www.TeNation.com



37 fluid ounces  
946 milliliters

Shake it up baby!



JUST POUR & DRINK - HOT OR COLD  
HERBAL SUPPLEMENT

# Ginger Tea

STOMACH SETTLER\*

*Handmade herbs perfectly steeped and professionally blended.*



CALL OUT AFTER YOU SHOUT OFF  
[REPEAT AFTER ORDERING AND DRINK WITHIN 7-10 DAYS]



### Nutrition Facts

SERVING SIZE: 8 fluid ounces (237 mL)	
AMOUNT PER SERVING	% Daily Value*
CAIOMES 50	100%
TOTAL FAT 0g	0%
SODIUM 10mg	0%
TOTAL CARBOHYDRATES 13g	4%
SUGARS 12g	
PROTEIN 0g	

\*Percent Daily Values are based on a diet of 2,000 calories. Daily intake of significant amounts of calories from fat, cholesterol, sodium, and dietary fiber is not recommended.

### Supplement Facts

SERVING SIZE: 8 fluid ounces (237 mL)	Amount per serving	% Daily Value
FRESH GINGER ROOT	630mg	1
BLACKBERRY LEAF	170mg	1
Other Ingredients		
*Percent Daily Values are not established.		
OTHER INGREDIENTS - FILTERED WATER, PRENATAL VITAMIN COMPLEX, CONCENTRATED SUGAR, SODIUM ACETATE, ASCORBIC ACID		

**WARNING:** Refrigerate or store in refrigerator. Do not consume if you notice mold or other signs of spoilage. This product is not intended for diagnostic, retail, use or parent use. Always follow the directions on the label. For more information, please visit our website at [www.TeNation.com](http://www.TeNation.com).

BEN FRANKLIN SAID IT BEST: "HAT PRODUCE." BUT HE SAID IT BEFORE THERE WERE BEANSPOCKETS, SMALL CANS AND LONG PLANE RIDES. FART CONTROL IS PERHAPS THE MOST OBSCURE AND UNDERUTILIZED BENEFIT OF GINGER ROOT (SEND A CARE TO YOUR BAWMKS.)

DON'T MICROWAVE THE PACKAGE. FEEL FREE TO POUR TE INTO A CUP AND ZAP IT ALL YOU WANT, BUT MICROWAVING THE PACKAGE COULD RESULT IN THE SMALL APPLIANCE EQUIVALENT OF INVITING JOHNNY DEPP OVER FOR THE WEEKEND.

*stomach suits, mind mender, fever flopper*



MADE IN THE USA. VALHALLA, NY 10595. WWW.TE.NATION.COM

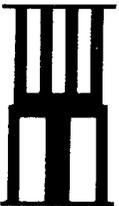


01061

MA



Printed in USA  
TetraBrik™  
Aseptic  
Packaging



No boundaries.

NOTIFICATION LETTER

Tea Nation, Inc.  
1125 SE Madison  
Suite 100 B  
Portland, OR 97214  
phone (503) 233-7630

February 12, 1999

To the Office of Special Nutritional

The purpose of this letter is to provide notification of a statement of nutritional support for Threat  
Tea by Tea Nation. Threat Tea is a ready to drink herbal tea in an aseptic package.

The herbal supplements that are the subject of the statement are Slippery Elm Bark and  
Marshmallow root. The text of the statement is the following:

Do not drink more than 8 cups in a 24 hour period.

The products' herbal supplementals are:

- Slippery Elm Bark (*Ulmus glaberrimus* & *purpureus*)
- Marshmallow root (*Althaea officinalis*)
- Echium root (*Echium vulgare*)
- Oregon Grape root (*Mahonia aquifolium*)
- Manjistha root (*Albizia julibrissin*)

Recommended dosage: 1-6 cups servings per day

Warning: Children, pregnant or nursing women, or those with chronic conditions should consult a  
health professional prior to using this product.

Tea Nation has substantiation that the statement made under 408 (b) (1) is truthful and not misleading  
and scientifically valid and that the product does not present a significant or unreasonable risk of  
illness or injury under the conditions of use recommended or suggested in the labeling.

Sincerely,

Brian Fross  
President, Tea Nation, Inc.





Sore throats have been a pain in the neck since the first Neanderthal realized he didn't have one. (A neck, that is.) And short of chewing on some slippery elm bark, where could he turn for relief? (Besides, he had the attention span of a flea. So there was no way he could brew tea.)

And face it, brewing medicinal tea takes a long time. To extract the maximum benefits from loose herbs and roots they need to be steeped a lot. Literally 15-30 minutes. Besides, most medicinal herbs taste like shag carpet. Green shag carpet.

So we thought it was about time for an uprising. Te Nation has taken the revolutionary step of taking the necessary time to steep these enchanted herbs and roots for you. And because the anarchists at Te Nation blend Te with natural flavors, spikes and juices without using extracts, you're going to love the process of feeling better.

Manufactured for Te Nation, Valhalla, New York 10595 800.242.9895 www.TeNation.com

\*The statements presented on this package have not been evaluated by the food and drug administration. This product is not intended to diagnose, treat, cure or prevent any disease.



32 fluid ounces  
946 milliliters

Shake it up baby!

CHILL OUT AFTER YOU SPOUT OFF  
(REFRIGERATE AFTER OPENING AND DRINK WITHIN 7-10 DAYS)

*Hand-picked herbs perfectly steeped and out-crazily blended*



JUST POUR HEAT AND DRINK

HERBAL SUPPLEMENT

SOOTHING HERBAL TEA  
**Throat Tē**

Nutrition Facts	
SERVING SIZE: 8 fluid ounces (237ml)	
SERVINGS PER CONTAINER: 4	
AMOUNT PER SERVING	
CALORIES 60	CAL FROM FAT 0
% daily value*	
TOTAL FAT 0g	0%
SODIUM 10mg	0%
TOTAL CARBOHYDRATES 14g	5%
SUGARS 14g	
PROTEIN 0g	

\*Percent Daily Values based on 2,000 calories diet. This is a significant source of calories from fat, saturated fat, cholesterol and dietary fiber.

Supplement Facts	
SERVING SIZE: 8 fluid ounces (237ml)	
Amount per serving	
% daily value	
SLEEPY ELM BARK (Sideroxylon) 1485mg †	
MARSHMALLOW ROOT (Althaea officinalis) 1485mg †	
LICORICE ROOT (Glycyrrhiza glabra) 380mg †	
OREGON GRAPE ROOT 190mg †	
ECHINACEA ROOT** (Spurred) 40mg †	

\*Percent Daily Values not established.  
\*\*Organically grown in accordance with the California Organic Foods Act of 1990

OTHER INGREDIENTS - FILTERED WATER, PEAR JUICE FROM CONCENTRATE, RAW SUGAR, PAPAIA PUREE, WHITE GRAPE JUICE FROM CONCENTRATE, APPLE JUICE FROM CONCENTRATE, CINNAMON BARK, NUTMEG, ANISE, CLOVES, WILD CHERRY BARK, VANILLA, CITRIC ACID

WARNING: Children, pregnant or nursing women, or those with chronic conditions should consult a health professional prior to using this product.

PLEASE BE CAREFUL. THIS STUFF IS SO SOOTHING THAT IT MUST BE KEPT OUT OF REACH OF TV, EVANGELISTS, LOUNGE ACTS AND ELVIS IMITATORS. REMEMBER: IF THESE PEOPLE GET THEIR HANDS ON THROAT Tē, THEY MAY NEVER SHUT UP.

Do not drink more than 8 cups in a 24 hour period.

DON'T MICROWAVE THE PACKAGE. FEEL FREE TO POUR TE INTO A CUP AND ZAP IT ALL YOU WANT BUT MICROWAVING THE PACKAGE COULD RESULT IN THE SMALL APPLIANCE EQUIVALENT OF INVITING JOHNNY DEPP OVER FOR THE WEEKEND.

*resp. weathe. frag. tykes. occas. itches*



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Tetra Brik  
Aseptic  
Tetra Pak



B 2345