



MAR 13 1998

Rec'd 3/26/98 jt

Ms. Kathy Larson
Director of Quality Assurance
Frontier Natural Products Co-op
3021 78th Street
P.O. Box 299
Norway, Iowa 52318

Dear Ms. Larson:

This is in response to your letter of February 25, 1998, and letters from Steve Phillips dated September 9, 1996 and January 31, 1997, 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 submissions state that Frontier Natural Products Co-op is making the following statements, among others, for the products:

Elder flowers

“support during cold and flu season”

Echinacea-Goldenseal

“Natural resistance during cold and flu season”

Usnea

“Support during cold and flu season”

Yarrow Flowers

“Support during cold and flu season”

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, or mitigate a disease, namely the common cold and influenza. 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 137

Page 2 - Ms. Kathy Larson

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

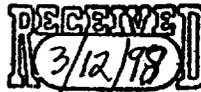
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Kansas District Office, Compliance Branch, HFR-SW340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (file)
HFS-450 (r/f, file, OSN#56458)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/12/98
Init:GCFf-1:LNickerson:3/12/98
f/t:rjm:HFS-456:3/13/98:57703.adv:disc26

FRONTIER

NATURAL PRODUCTS



February 25, 1998

Office of Special Nutrients
Center for Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20202

Dear Madam or Sir:

Frontier Natural Products is notifying you of our use of the enclosed list of dietary supplement label statements for "Frontier" brand products.

To the best of our knowledge at this time, the following information is true and correct: the name and address of the company is correctly stated, the text of the statement is identical to the statement on the label, the name of the dietary ingredient that is the subject of our statement and the brand of the product are both stated in this submission as they are on the product.

Because the FDA has refused to define the term "substantiation", we do not know the type and amount of information necessary to satisfy the agency's substantiation requirement. Therefore it is impossible to "substantiate" that the statement in this submission is truthful. It is equally impossible to say that any statement could never be misleading to someone at sometime. However, we do believe that we have a reasonable basis for believing at the time of this submission and based on the information reasonably available to us and despite the lack of definition of "substantiation" by the FDA that the statements we are submitting are truthful and are not misleading.

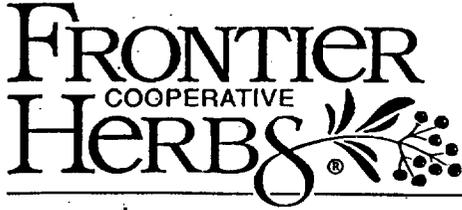
Sincerely,

Kathy Larson
Director of Quality Assurance

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Astragalus root	benefits for enhancing natural resistance
Bee Pollen	research findings indicate it may assist in maintaining liver health, it is particularly high in phytic acid which may enhance the body's natural detoxifying functions
Echinacea purpurea herb	enhancing natural resistance through gentle stimulation of the body's own defense mechanisms
Echinacea purpurea root	enhancing natural resistance through gentle stimulation of the body's own defense mechanisms
Eleuthero ginseng root Eyebright herb	herbal adaptogen, may enhance physical and mental performance support of eye health
Feverfew leaf & flowers	in scientific studies, feverfew has been shown to inhibit the formation of prostaglandins
Gingko leaf	improve peripheral circulation, thus increasing blood supply to the brain, head, hands, legs and feet, ability to enhance oxygen flow to the brain
Hawthorn berries	supporting healthy cardiovascular functions when combined with regular exercise and good dietary habits
Horsetail herb	natural support of the urinary tract
Kelp	an abundant source of iodine content, making it a desirable nutritional element for proper thyroid functioning
Psyllium seed husk	helps support healthy bowel function, fibers ability to absorb and hold water contributes to maintaining normal transit time of waste material through the body
Psyllium seed	
Red Clover herb	a powerful anti-oxidant compound called flavone in red clover
Senna leaf	supports healthy bowel function, support healthy elimination
Valerian root	promotes relaxation at night, natural enhancement of nighttime rest and relaxation
Echinacea angustifolia root	helps support natural resistance

Echinacea angustifolia herb	helps support natural resistance
Chamomile flowers	calms evening restlessness and nutritionally supports the digestive system
Devils Claw root tuber	enhance joint and muscle health
Fenugreek seed	support healthy blood sugar levels
Korean Ginseng root	offer support for people seeking to optimize physical and mental performance
Cascara Sagrada bark	supports healthy bowel function, naturally enhance the body's elimination process
Butcher's Broom root	research suggests it may have benefits for the circulatory system, helping to tone vessels and support circulation
Guggul resin	promotes healthy cholesterol levels, research suggests that guggul, along with good dietary choices may help the body maintain healthy cholesterol and triglyceride levels to support circulatory function
Saw Palmetto berry	help maintain healthy urinary function in mature men
Kava Kava root	Scientific studies show that kava kava may be of benefit whenever relaxation is needed
Uva Ursi leaf	supports healthy urinary tract, support healthy urinary function
Cranberry fruit	support for urinary and bladder health
Valerian root	natural enhancement of nighttime rest and relaxation
<i>see docket 975-0163</i> [Elder flowers	support during cold and flu season
St. John's Wort herb	useful in maintaining a healthy and stable mood



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OFFICE OF SPECIAL
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3021 78th St., P.O. Box 299, Norway, IA 52318
Business Office (319) 227-7968 FAX (319) 227-7966

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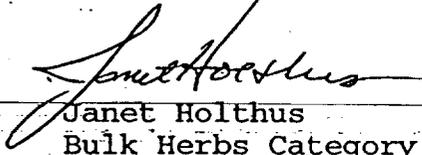
September 9, 1996

Dr. Elizabeth A. Yetley, Ph.D. (HFS-450)
Director, Office of Special Nutritionals
The Center for Food Safety and Applied Nutritionals
200 C Street, S.W., Room 1832A
Washington, D.C. 20204

Dear Dr. Yetley,

Frontier Herbs is now making Structure/Function claims for
the products contained on the attached list.

Sincerely,


Janet Holthus
Bulk Herbs Category


Steve Phillips
Packaged Herbs Category

Enclosure

Frontier's structure function claims for herbs

Psyllium Seed Husk	8/19/96
Botanical fiber source, promotes healthy cholesterol levels*	
Psyllium Seed	8/19/96
Botanical fiber source, promotes healthy cholesterol levels*	
Red Clover Herb	8/19/96
Spring purification herb*	
Red Raspberry Leaf	8/19/96
Traditional female balancing herb*	
Sage Leaf	8/19/96
Natural antioxidant*	
Saw Palmetto Berries	8/19/96
Promotes prostate health*	
Schisandra Berries	8/19/96
Natural antioxidant and support for healthy liver function*	
Scullycap Herb	8/19/96
Naturally promotes relaxation*	
Slippery Elm Bark	8/19/96
Nature's gentle demulcent*	
Spirulina	8/19/96
Green superfood for optimal health and well being*	
Squawvine Herb	8/19/96
Natural female balance*	
St. John's Wort Herb	8/19/96
Botanical mood food*	
Usnea	8/19/96
Support during cold and flu season*	
Valerian Root	8/19/96
Promotes relaxation at night*	
White Oak Bark	8/19/96
Soothing and astringent purification herb*	

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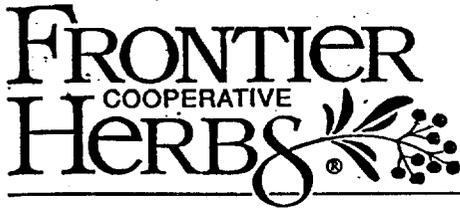
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Frontier's structure function claims for herbs

White Willow Bark	8/19/96
Support for head well-being*	
Wild Yam Root	8/19/96
Traditional women's herb*	
Yarrow Flowers	8/19/96
Support during cold and flu season*	
Yellowdock Root	8/19/96
Traditional purifying tonic*	
Yerba Santa Leaf	8/19/96
Support for healthy respiratory function*	
Yucca Root	8/19/96
Support for healthy joint function*	

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Toll Free Customer Support 1-800-669-3275

January 31, 1997

Dr. Elizabeth A. Yetley, Ph.D. (HFS-450)
Director, Office of Special Nutritionals
The Center for Food Safety and Applied Nutritionals
200 C. Street, S.W., Room 1832A
Washington, D.C. 20204

Dear Dr. Yetley,

As of January, 1997 Frontier Herbs is making
Structure/Function claims for the products contained on the
attached list.

Sincerely,

A handwritten signature in cursive script that reads "Steve Phillips".

Steve Phillips
Packaged Herbs Category

Enclosure

Frontier Herbal Products

We began using structure function claims on the following herbal combinations on January 15, 1997.

Cramp Bark - Valerian
Herbal support for women

Dandelion - Burdock
Supports normal liver function

Dandelion - Marshmallow
Supports urinary tract good health

Echinacea - Astragalus
Enhances natural resistance

Echinacea - Goldenseal
Natural resistance during cold and flu season

Elecampane - Pleurisy Root
Natural bronchial formulation

Eleuthero - Chamomile
Herbal reinforcement for environmental stress

Eyebright - Horseradish
Traditional sinus formulation

Fennel - Chamomile
Strengthens digestive function

Feverfew - Scullcap
Promotes head well-being

Ginkgo - Gotu Kola
Support for healthy memory function

Ginseng - Ginkgo
Promotes energy and mental clarity

Hawthorn - Motherwort
Support for good heart health

5/10/97