



NF Formulas



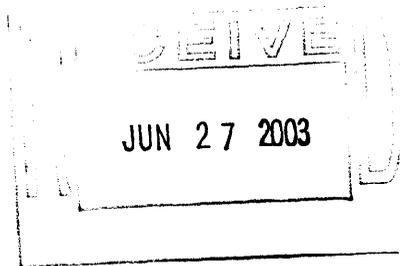
PhytoPharmica



Tyler Encapsulations



Vitaline Formulas



June 19, 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 NF Formulas (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. NF Formulas 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
Blue Heron	"[Borage seed is a source of two essential omega-6 fatty acids: gamma linolenic acid (GLA) and linoleic acid. Gamma linolenic acid is a precursor to prostaglandin E-1 (PGE-1)]. Both PGE-1 and GLA have been shown to protect the gastric mucosa against gastrointestinal irritants.**"	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)

97S 0162

LET 12194

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



Mario Roxas, N.D.
Director of Technical Services

6/19/03

Date



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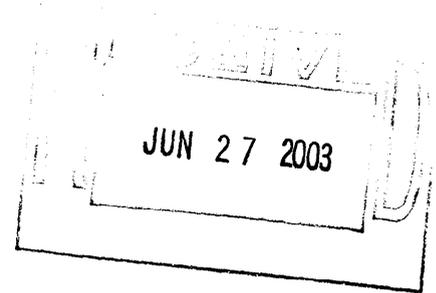
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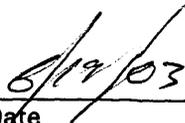
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Product Name	Statement	Ingredient(s) to which claim refers
Blue Heron	"The oils and mucilaginous properties of Flax and Borage provide an intestinal lubrication to aid in proper elimination of waste products.**"	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)

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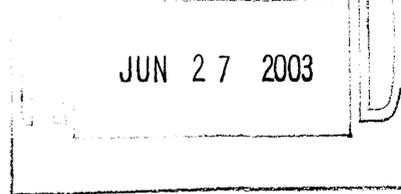
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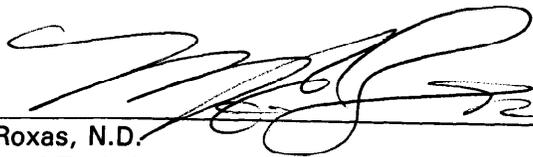
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Product Name	Statement	Ingredient(s) to which claim refers
Blue Heron	"[The formulation also includes a blend of eight strains of beneficial microflora: <i>Lactobacillus acidophilus</i> , <i>L. bulgaricus</i> , <i>L. casei</i> , <i>L. salivarius</i> , <i>Bifidobacterium bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , and <i>Streptococcus thermophilus</i> .] These are all friendly strains of bacteria that promote a proper intestinal environment."	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)

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6/09/03

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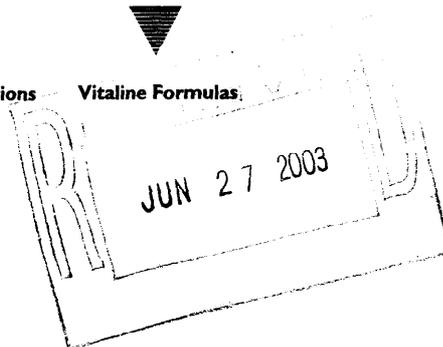
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Product Name	Statement	Ingredient(s) to which claim refers
Blue Heron	"Triphala is used because of its effectiveness in providing nutritional support to the lower gastrointestinal tract, as well as aiding detoxification and smooth elimination.**"	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)



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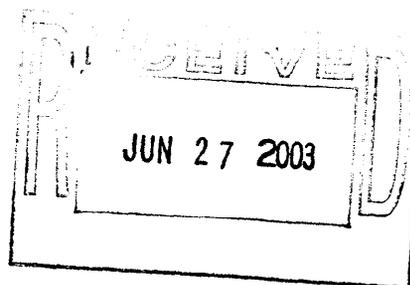
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Product Name	Statement	Ingredient(s) to which claim refers
Blue Heron	"Triphala is believed to be a 'good manager of the house,' coordinating digestion, absorption and metabolism.**"	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)

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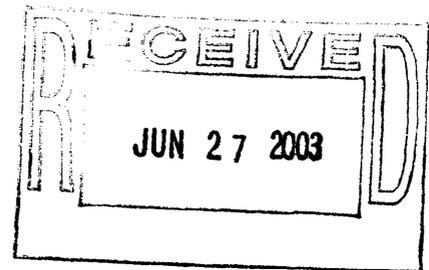
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Product Name	Statement	Ingredient(s) to which claim refers
Blue Heron	"Blue Heron is a balanced blend of dietary fiber, nutritional herbs and intestinal microflora synergistically formulated to provide convenient, effective and gentle intestinal support.**"	Borage seed (<i>Borago officinalis</i>) Flax seed (<i>Linum usitatissimum</i>) Oat bran (<i>Avena sativa</i>) Psyllium seed and husk (<i>Plantago arenaria</i>) Bentonite Clay Prune fruit (<i>Prunus domestica</i>) Fenugreek seed (<i>Trigonella foenum-graecum</i>) Marshmallow root (<i>Althaea officinalis</i>) Slippery Elm bark (<i>Ulmus rubra</i>) Triphala (a blend of Indian Gooseberry fruit, Belleric myrobalan fruit and Tropical Almond fruit) Spectra Probiotic bacterial blend <i>Lactobacillus acidophilus</i> , <i>Bifidobacterium bifidum</i> , <i>infantis</i> , <i>longum</i> ; <i>Lactobacillus bulgaricus</i> , <i>casei</i> , <i>salivarius</i> ; and <i>Streptococcus thermophilus</i> . Papain (Papaya enzyme)

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Mario Roxas, N.D. Date 4/19/03
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