



AUG - 6 1998

Rec'd 8/7/98 jk

Mr. James W. Taylor
Quality Assurance
4Health, Inc.
5485 Conestoga Court
Boulder, Colorado 80301

Dear Mr. Taylor:

This is in response to your letter of July 10, 1998 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 4Health, Inc. is making the following statements, among others, for the products:

**Vegetarian Enzyme
Enzyme Formula**

“People no longer have to live with digestive gas, bloating...and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.”

**Enzyme Rebuilder
Digestive Rebuilding Formula**

“Protect the mucosal barrier from bile salt injury”
“Help diminish gas”
“Carminative and antispasmodic”
“People no longer have to live with digestive gas, bloating...and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.”

**Ultimate Fiber
Fiber Formula**

“Fiber helps to stabilize blood sugar and keep insulin levels steady”

975-0163

LET 209

Candestroyer

Candestroyer Formula

- “Clinically formulated to facilitate the elimination of candida albicans”
- “Binds to the bad bacteria and fungus in your body rendering them ineffective”
- “Helps with digestive discomfort”

Probiotic Formula

Probiotic Rebuilder

- “Lactobacilli may inhibit pathogens...”
- “Prevents adherence of Candida albicans to the intestinal mucosa”
- “...align your body’s defenses against the proliferation of detrimental bacteria and fungus”

Super II

- “Eases indigestion, flatulence and colic”
- “...a strong antimicrobial ingredient”
- “Helps to counteract [sic] problems such as jaundice, gallstones, and hemorrhoids”
- “A soothing plant with mild, natural laxative properties. Its healing properties are well documented, both internally and externally”

ReDo Morning Multi

ReDo Evening Multi

- “Helps with seasonal reaction discomfort”
- “Aids in the discomfort of head pain”

Ultimate Energy

- “...enables your body to combat colds and infections”

4Health Heart

- “Proven to lower bad cholesterol and raise good cholesterol”
- “More effective than garlic at reducing cholesterol”

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 treat, prevent, mitigate, or cure diseases,

Page 3 - Mr. James W. Taylor

namely, various digestive disorders, impaired maintenance of blood glucose, seasonal affective disorder, colds and other infections caused by pathogenic microorganisms, jaundice, gall stones, hemorrhoids, and that they are intended as alternatives to approved over the counter drugs. 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.

Your submission also indicates that, for the products **Ultimate Fiber and Fiber Formula**, you are making the claim "Fiber lowers blood cholesterol levels..." Your submission also states that, for these two products, you are making the claim "The soluble fiber from psyllium seed husk in this product, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between soluble fiber from certain foods (such as psyllium) and risk of coronary heart disease and the ability of soluble fiber to reduce blood cholesterol (see 21 CFR 101.81). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between soluble fiber from psyllium and risk of coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.81 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease and/or hypercholesterolemia.

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

Page 4 - Mr. James W. Taylor

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, Denver District Office, Office of Compliance, HFR-SW340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

init:GCF-1:DDorsey:8/4/98

f/t:HFS-456:rjm:8/5/98:docname:60152.adv:disc31



RECEIVED
7/13/98

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of 4Health, Inc., doing business as 4Health, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **4Health Heart**. This product was only produced once and is not currently being sold, due to production costs.

The text of each structure-function statement for which notification is now being given is:

- Statement1. Proven to lower bad cholesterol and raise good cholesterol.
- Statement2. More effective than garlic at reducing cholesterol.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	PNT-56™
2	PNT-56™

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	4Health™ Heart.	Both
2	4Health™ Heart.	Both

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

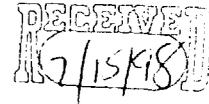
Date Signed: June 30 1998

By: [Signature]
Dr. R. Lindsey Duncan CN, ND
CEO and Formulator, 4Health, Inc.

see docket 975-0163 also

60152

HN30100 06/03/98



**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Ultimate Energy**.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Assists the body's natural ability to endure rigorous exercise.
- Statement 2. Aids the body to fight off general weakness and fatigue.
- Statement 3. Enhance mental stamina.
- Statement 4. Abate the effects of stress.
- Statement 5. Helps increase the body's ability to deal with fatigue and stress.
- Statement 6. Boosts energy.
- Statement 7. Sustains strength. Reinforces the body's natural defenses
- Statement 8. Supports the body's own ability to demonstrate improved vitality and increased endurance.
- Statement 9. Ginseng has been used to battle the effects of fatigue for thousands of years.
- Statement 10. The combination of these ginsengs reinforces your body's natural defenses and gives you vigor.
- Statement 11. Helps you perform at your physical best by enabling your body to use oxygen much more efficiently.
- Statement 12. By better utilizing oxygen your heart does not have to pump as hard and less lactic acid will be produced. Lowering lactates alleviates the stiff muscles from strenuous activities.
- Statement 13. Siberian Ginseng could be considered a nonspecific immunostimulant. Enhancement of the immune system enables your body to combat colds and infections.
- Statement 14. Supports the adrenal glands.
- Statement 15. Supports adrenal function.
- Statement 16. Beneficial for kidney health.
- Statement 17. Eucommia is believed to help strengthen tendons and bones.
- Statement 18. Important support ingredient for energy and balanced mood.
- Statement 19. Is beneficial to the liver.
- Statement 20. An agent to improve mental ability.
- Statement 21. Supports the body's ability to repair connective tissue, the skin, lymph, mucous membranes and blood vessels.
- Statement 22. Bioperine® - a purified alkaloid extract from black pepper specifically developed to address the problem of nutrient bioavailability

NS30051 06/02/98

see docket 975-0163 also

60152



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **ReDo Evening Multi** a part of the 2-part ReDo™ Program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. A balanced, comprehensive multi-mineral designed to support nighttime rest.
- Statement 2. Includes minerals & Herbs for nighttime relaxation.
- Statement 3. Designed to deliver nutrients to your body when your body needs them.
- Statement 4. Contains enzymes and a catalytic blend to support digestion and absorption of nutrients.
- Statement 5. Cleanses & Detoxifies the Body
- Statement 6. Improves Energy
- Statement 7. Enhances Mood
- Statement 8. Helps complexion and skin
- Statement 9. Aids in digestion
- Statement 10. Improves hair and finger nails
- Statement 11. Enhances the immune system
- Statement 12. Improves cardiovascular circulation
- Statement 13. Aids in weight loss.
- Statement 14. Helps with seasonal reaction discomfort.
- Statement 15. Aids in Joint Support.
- Statement 16. Enhances absorption of formula.
- Statement 17. Relaxing aid in sleep.
- Statement 18. Aids to relieve fatigue.
- Statement 19. Helps keep bones & teeth healthy.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

Statement Number	Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement
1	Magnesium, Passionflower extract, Kava Kava Extract, Scullcap Herb, Hops Flower, Shattered Cell Wall Chlorella, Taurine, Bromelain, Papain, Ginger Root, Licorice Root, Capsicum Fruit, Bioperine®.
2	Magnesium, Passionflower extract, Kava Kava Extract, Scullcap Herb, Hops Flower, Shattered Cell Wall Chlorella, Taurine, Bromelain, Papain, Ginger Root, Licorice Root, Capsicum Fruit, Bioperine®.
3	Evening Multi blend.
4	Taurine, Bromelain, Lecithin (Phosphatidyl-choline), Bioperine®.
5	Capsicum Fruit, Ginger Root, Scullcap herb, Shattered Cell Wall Chlorella, Vitamin C (Ascorbic Acid), Molybdenum, Taurine.

see docket 97S-0163 also

60152

HN30052 06/03/98



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **ReDo Morning Multi** a part of the 2-part ReDo™ Program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. A balanced, comprehensive multi-mineral designed to support daytime energy.
- Statement 2. Includes minerals & Herbs for daytime energy.
- Statement 3. Designed to deliver nutrients to your body when your body needs them.
- Statement 4. Contains enzymes and a catalytic blend to support digestion and absorption of nutrients.
- Statement 5. Cleanses & Detoxifies the Body
- Statement 6. Improves Energy
- Statement 7. Enhances Mood
- Statement 8. Helps complexion and skin
- Statement 9. Aids in digestion
- Statement 10. Enhances the immune system
- Statement 11. Improves cardiovascular circulation
- Statement 12. Aids in weight loss.
- Statement 13. Helps with seasonal reaction discomfort.
- Statement 14. Aids in Joint Support.
- Statement 15. Enhances absorption of formula.
- Statement 16. Relaxing aid in sleep.
- Statement 17. Aids in the discomfort of head pain.
- Statement 18. Aids to relieve fatigue.
- Statement 19. Helps keep bones & teeth healthy.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

Statement Number	Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement
1	Siberian Ginseng Root Extract, Citrus Bioflavonoids, Shattered Cell Wall Chlorella, Astragalus Root, Cayenne Fruit, L-Aspartic Acid, Bromelain, Papain, Lecithin, Ginger Root, Red Raspberry Leaf, Peppermint Leaf, Bioperine®.
2	Siberian Ginseng Root Extract, Citrus Bioflavonoids, Shattered Cell Wall Chlorella, Astragalus Root, Cayenne Fruit, L-Aspartic Acid, Bromelain, Papain, Lecithin, Ginger Root, Red Raspberry Leaf, Peppermint Leaf, Bioperine®.
3	Morning Multi blend.
4	Bromelain, L-Aspartic Acid, Lecithin.

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see docket 975-0163 a 150



RECEIVED
7/15/18

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas®, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Super II**.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. A natural bowel cleanser.
- Statement 2. The formula is comprised of various herbs that gently stimulate the bowel.
- Statement 3. Provides extra-support for the sluggish colon.
- Statement 4. Promotes three bowel movements a day.
- Statement 5. Enhances and supports your body's natural ability to function on its own.
- Statement 6. A soothing plant with mild, natural laxative properties. Its healing properties are well documented, both internally and externally.]
- Statement 7. Soothing to the digestive and eliminative tract.
- Statement 8. Eases indigestion, flatulence and colic. It is also used as an expectorant.
- Statement 9. Stimulates peristalsis and proper bowel function.
- Statement 10. Increases secretion of the liver and gall bladder.
- Statement 11. Stimulates digestion, absorption and assimilation of all nutrients.
- Statement 12. Supports the liver and digestive system.
- Statement 13. Works synergistically with the other herbs facilitating their absorption by the body.
- Statement 14. Soothes the digestive tract.
- Statement 15. The fiber in this herb helps to absorb toxins.
- Statement 16. Barberrry bark is a natural source of berberine, a strong antimicrobial ingredient.
- Statement 17. Increases the activity of the glands in the walls of the intestinal tract.
- Statement 18. Helps to counteract problems such as jaundice, gallstones and hemorrhoids.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Aloe Vera Leaf, Cascara Sagrada Bark, Barberrry, Butternut, Turkey Rhubarb root.
2	Aloe Vera Leaf, Cascara Sagrada Bark, Barberrry, Butternut, Turkey Rhubarb root.
3	Aloe Vera Leaf, Cascara Sagrada Bark, Barberrry, Butternut, Turkey Rhubarb root.
4	Aloe Vera Leaf, Cascara Sagrada Bark, Barberrry, Butternut, Turkey Rhubarb root.
5	Aloe Vera Leaf, Cascara Sagrada Bark, Barberrry, Butternut, Turkey Rhubarb root.

see docket 975-c163 also

60152



7/15/98

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Probiotic Rebuilder a part of the 2-part Candistroy program and sold individually.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Supplementation with the beneficial bacteria is vital to a healthy and well-balanced intestinal system.
- Statement 2. Contains a unique proprietary blend of F.O.S and NAG that have been proven to help enhance the proliferation of your beneficial bacteria in both the small and large intestines.
- Statement 3. Produce a variety of factors which positively affect microbial balance in the human intestinal tract.
- Statement 4. Lactobacilli may inhibit pathogens by lowering pH in the intestines.
- Statement 5. Increases the number of bifidobacteria in stool samples.
- Statement 6. Results in lower stool pH, indicating increased numbers of favorable bacteria.
- Statement 7. Prevents adherence of Candida albicans to the intestinal mucosa.
- Statement 8. Supplementation with the beneficial bacteria can align your body's defenses against the proliferation of detrimental bacteria and fungus.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Lactobacillus Acidophilus BT1386™, B. Bifidum
2	Fructooligosacchirides, N Acetyl D Glucosamine
3	Lactobacillus Acidophilus BT1386™, B. Bifidum
4	Lactobacillus Acidophilus BT1386™, B. Bifidum
5	Fructooligosaccharides
6	Fructooligosaccharides
7	N-Acetyl D Glucosamine
8	Lactobacillus Acidophilus BT1386™, B. Bifidum

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Nature's Secret Probiotic Rebuilder	Both
2	Nature's Secret Probiotic Rebuilder	Both
3	Nature's Secret Probiotic Rebuilder	Labeling
4	Nature's Secret Probiotic Rebuilder	Labeling

see docket 975-0162 also

60152



DECEMBER 27/15/98

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas®, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Probiotic Formula a part of the 2-part Candida program and sold individually.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Supplementation with the beneficial bacteria is vital to a healthy and well-balanced intestinal system.
Statement 2. Contains a unique proprietary blend of F.O.S and NAG that have been proven to help enhance the proliferation of your beneficial bacteria in both the small and large intestines.
Statement 3. Produce a variety of factors which positively affect microbial balance in the human intestinal tract.
Statement 4. Lactobacilli may inhibit pathogens by lowering pH in the intestines.
Statement 5. Increases the number of bifidobacteria in stool samples.
Statement 6. Results in lower stool pH, indicating increased numbers of favorable bacteria.
Statement 7. Prevents adherence of Candida albicans to the intestinal mucosa.
Statement 8. Supplementation with the beneficial bacteria can align your body's defenses against the proliferation of detrimental bacteria and fungus.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

Table with 2 columns: Statement Number, Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement. Rows 1-8 list ingredients like Lactobacillus Acidophilus BT1386™, B. Bifidum, Fructooligosacchirides, N Acetyl D Glucosamine.

The following identifies the brand name of each supplement for which a statement is made:

Table with 3 columns: Statement Number, Brand Name, Label or Labeling?. Rows 1-5 show Harmony Formulas® Probiotic Formula with Both or Labeling.

see docket 975-0163 also

60152



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Candistroyer Formula**, part of the 2-part Candida program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Clinically formulated to facilitate the elimination of *Candida albicans*.
- Statement 2. Binds to the bad bacteria and fungus in your body rendering them ineffective.
- Statement 3. Contains herbs that stoke the body's natural digestive fires.
- Statement 4. Supports immune function by increasing the blood supply to the spleen.
- Statement 5. Helps with digestive discomfort

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Zinc Tannates, barberry Root Extract, Golden Seal Root, Oregon Grape Root, Cinnamon Bark, Cloves, Pau D' Arco, Ginger Root & Thyme Leaf.
2	Zinc Tannates
3	Cinnamon Bark
4	Oregon Grape Root
5	Peppermint Oil, Orange Peel, Cloves

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Harmony Formulas® Candistroyer Formula	Labeling
2	Harmony Formulas® Candistroyer Formula	Both
3	Harmony Formulas® Candistroyer Formula	Both
4	Harmony Formulas® Candistroyer Formula	Labeling
5	Harmony Formulas® Candistroyer Formula	Labeling

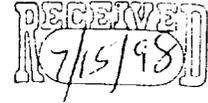
I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: 
Dr. R. Lindsey Duncan CN, ND
CEO and Formulator, 4Health, Inc.

60152

see docket 975-0163 also



**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Candestroyer**, part of the 2-part Candistroy program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Clinically formulated to facilitate the elimination of candida albicans.
- Statement 2. Binds to the bad bacteria and fungus in your body rendering them ineffective.
- Statement 3. Contains herbs that stoke the body's natural digestive fires.
- Statement 4. Supports immune function by increasing the blood supply to the spleen.
- Statement 5. Helps with digestive discomfort

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Zinc Tannates, barberry Root Extract, Golden Seal Root, Oregon Grape Root, Cinnamon Bark, Cloves, Pau D' Arco, Ginger Root & Thyme Leaf.
2	Zinc Tannates
3	Cinnamon Bark
4	Oregon Grape Root
5	Peppermint Oil, Orange Peel, Cloves

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Nature's Secret Candestroyer	Labeling
2	Nature's Secret Candestroyer	Both
3	Nature's Secret Candestroyer	Both
4	Nature's Secret Candestroyer	Labeling
5	Nature's Secret Candestroyer	Labeling

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: 
Dr. R. Lindsey Duncan, CN, ND
CEO and Formulator, 4Health, Inc.

See docket 975-0163 also

60152



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Ultimate Fiber®**.

The text of each structure-function statement for which notification is now being given is:

- Statement1. The soluble fiber from psyllium seed husk in this product, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.
- Statement2. Ultimate Fiber contains F.O.S. for the proliferation of the beneficial bacteria in your intestinal system.
- Statement3. Fiber lowers blood cholesterol levels, speeds bowel transit time, acts as a bulking agent - absorbing toxins and promoting easier elimination, helps to steady blood sugar levels, increases the growth of "good" bacteria in the intestines, etc.
- Statement4. Researchers believe that fiber deficiency is directly linked with the rise of chronic health problems in America.
- Statement5. Encourages the proliferation of "good" bacteria in your intestinal tract.
- Statement6. Provides the fibrous bulk needed to improve digestive, eliminative, and metabolic processes while gently sweeping and cleansing the entire gastrointestinal tract.
- Statement7. You will notice improved elimination and all around better bowel function.
- Statement8. Fiber helps to stabilize blood sugar and keep insulin levels steady. When taken on a daily basis, it helps to absorb and remove toxins from the intestinal system.
- Statement9. Ultimate Fiber soothes the digestive tract and helps to keep the digestive and eliminative system working properly.
- Statement10. Encourages the growth of "good" bacteria in the intestinal system.
- Statement11. As a soluble fiber, psyllium can help to lower blood lipid levels, but due to its bulking ability, it is much more effective at increasing bowel transit time.
- Statement12. Psyllium husk sweep, clean and lubricate the intestinal tract.
- Statement13. Slippery Elm Bark - A mucilage, soothes the intestinal tract. Slippery elm also assists in the absorption of toxins from the bowel.
- Statement14. Marshmallow Root - a demulcent, used traditionally as a healing agent and to remove mucous. Marshmallow root also soothes the intestinal tract.
- Statement15. Fructooligosaccharides are naturally occurring carbohydrates which specifically supply nutrients needed for the proliferation of "friendly" bacteria in the intestines. FOS works with acidophilus to help maintain the proper balance of intestinal flora.

See docket 975-0163 also

60152

NS30089 06/03/98



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas® Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Fiber Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement1. The soluble fiber from psyllium seed husk in this product, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.

Statement2. Fiber Formula contains F.O.S. for the proliferation of the beneficial bacteria in your intestinal system.

Statement3. Fiber lowers blood cholesterol levels, speeds bowel transit time, acts as a bulking agent - absorbing toxins and promoting easier elimination, helps to steady blood sugar levels, increases the growth of "good" bacteria in the intestines, etc.

Statement4. Researchers believe that fiber deficiency is directly linked with the rise of chronic health problems in America.

Statement5. Encourages the proliferation of "good" bacteria in your intestinal tract.

Statement6. Provides the fibrous bulk needed to improve digestive, eliminative, and metabolic processes while gently sweeping and cleansing the entire gastrointestinal tract.

Statement7. You will notice improved elimination and all around better bowel function.

Statement8. Fiber helps to stabilize blood sugar and keep insulin levels steady. When taken on a daily basis, it helps to absorb and remove toxins from the intestinal system.

Statement9. Ultimate Fiber soothes the digestive tract and helps to keep the digestive and eliminative system working properly.

Statement10. Encourages the growth of "good" bacteria in the intestinal system.

Statement11. As a soluble fiber, psyllium can help to lower blood lipid levels, but due to its bulking ability, it is much more effective at increasing bowel transit time.

Statement12. Psyllium husk sweep, clean and lubricate the intestinal tract.

Statement13. Slippery Elm Bark - A mucilage, soothes the intestinal tract. Slippery elm also assists in the absorption of toxins from the bowel.

Statement14. Marshmallow Root - a demulcent, used traditionally as a healing agent and to remove mucous. Marshmallow root also soothes the intestinal tract.

Statement15. Fructooligosaccharides are naturally occurring carbohydrates which specifically supply nutrients needed for the proliferation of "friendly" bacteria in the intestines. FOS works with acidophilus to help maintain the proper balance of intestinal flora.

see docket 975-0163 also

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HF30120 06/03/98



RECEIVED
7/5/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas®, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Digestive Rebuilding Formula** a part of the 2-part Digestive Rebuilding Program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Contains ingredients which work to support and rebuild the organs of digestion.
- Statement 2. This product contains bitters which have been shown to stimulate gastric secretions.
- Statement 3. This formula helps to balance digestive heat, stimulate proper gastric secretions, and revitalize overall digestive health.
- Statement 4. Protect the mucosal barrier from bile salt injury.
- Statement 5. Protect the gastrointestinal mucosa from chemical injury by strengthening the mucosphospholipid layer.
- Statement 6. Protect against damage to the intestinal mucosa under many conditions.
- Statement 7. Increase trypsin activity in buffer solution.
- Statement 8. Help diminish gas.
- Statement 9. Carminative and antispasmodic.
- Statement 10. People no longer have to live with digestive gas, bloating, lethargy after meals, bad breath, and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Ginger Root, Atractylodes Macrocephala Root.
2	Gentian Root, Centaury Herb, Ginger Root,.
3	Gentian Root, Centaury Herb, Lecithin, L-Glutamine, Ginger Root, Orange Peel, Anise Seed, Cardamom Seed, Clovers, Fennel Seed, Licorice Root, Piper Longum Fruit.
4	Lecithin, L-Glutamine
5	Lecithin
6	L-Glutamine
7	Cardamom Seed , Cloves
8	Orange Peel, Anise Seed,
9	Gentian Root, Centaury Herb, Ginger Root, Asafoetida Seed.

see docket 975-0163 also

60152



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Enzyme Rebuilder** a part of the 2-part Rezyme program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Contains ingredients which work to support and rebuild the organs of digestion.
- Statement 2. This product contains bitters which have been shown to stimulate gastric secretions.
- Statement 3. This formula helps to balance digestive heat, stimulate proper gastric secretions, and revitalize overall digestive health.
- Statement 4. Protect the mucosal barrier from bile salt injury.
- Statement 5. Protect the gastrointestinal mucosa from chemical injury by strengthening the mucosphospholipid layer.
- Statement 6. Protect against damage to the intestinal mucosa under many conditions.
- Statement 7. Increase trypsin activity in buffer solution.
- Statement 8. Help diminish gas.
- Statement 9. Carminative and antispasmodic.
- Statement 10. People no longer have to live with digestive gas, bloating, lethargy after meals, bad breath, and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Ginger Root, Atractylodes Macrocephala Root.
2	Gentian Root, Centaury Herb, Ginger Root,.
3	Gentian Root, Centaury Herb, Lecithin, L-Glutamine, Ginger Root, Orange Peel, Anise Seed, Cardamom Seed, Clovers, Fennel Seed, Licorice Root, Piper Longum Fruit.
4	Lecithin, L-Glutamine
5	Lecithin
6	L-Glutamine
7	Cardamom Seed , Cloves
8	Orange Peel, Anise Seed,
9	Gentian Root, Centaury Herb, Ginger Root, Asafoetida Seed.

see docket 975-0163 also

60152



RECEIVED
7/15/98

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

This notification is being filed on behalf of 4Health, Inc., doing business as Harmony Formulas®, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Enzyme Formula** a part of the 2-part Digestive Rebuilding Program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Designed to support the digestion of all foods including carbohydrates, fats, protein, dairy and gas-producing foods.
- Statement 2. Vegetarian enzymes for digestion and is an all-natural way to aid digestion.
- Statement 3. People no longer have to live with digestive gas, bloating, lethargy after meals, bad breath, and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1
2	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1
3	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Harmony Formulas® Enzyme Formula	Both
2	Harmony Formulas® Enzyme Formula	Both
3	Harmony Formulas® Enzyme Formula	Labeling

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: [Signature]
Dr. R. Lindsey Duncan CN, ND
CEO and Formulator, 4Health, Inc.

see docket 97S-0163 also

60152



6-30-98

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 CFR §101.93



This notification is being filed on behalf of 4Health, Inc., doing business as Nature's Secret, which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5485 Conestoga Court, Boulder CO 80301. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **Vegetarian Enzyme** a part of the 2-part Rezyme program.

The text of each structure-function statement for which notification is now being given is:

- Statement 1. Designed to support the digestion of all foods including carbohydrates, fats, protein, dairy and gas-producing foods
- Statement 2. Vegetarian enzymes for digestion and is an all-natural way to aid digestion.
- Statement 3. People no longer have to live with digestive gas, bloating, lethargy after meals, bad breath, and all the other symptoms associated with digestive weakening that drives millions of Americans into drug stores for medication and over the counter remedies.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1
2	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1
3	Amylase, Glucomaylase, Cellulase, Lipase, Protease, Lactase, Alpha galactosidase, Bromelain, Papain, Betaine HC1

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Nature's Secret Vegetarian Enzyme	Both
2	Nature's Secret Vegetarian Enzyme	Both
3	Nature's Secret Vegetarian Enzyme	Labeling

I, R. Lindsey Duncan, am authorized to certify this Notification on behalf of 4Health, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that 4Health, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 30, 1998

By: Dr. R. Lindsey Duncan CN, ND
CEO and Formulator, 4Health, Inc.

see docket 975-0163 also