



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

RECEIVED  
2/15/98  
AUG 5 PM 4:42

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.

97S-0162

see docket 97S-0163 also

60157

LET 1921

HF30120 06/03/98

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	Psyllium seed husk.
2	Fructooligosaccharides.
3	Psyllium Seed Husk.
4	Psyllium Seed Husk.
5	Fructooligosaccharides (FOS) Acidophilus.
6	Psyllium Seed Husk.
7	Psyllium Seed Husk, Slippery Elm Bark, Marshmallow Root, Acidophilus, FOS.
8	Slippery Elm Bark, Marshmallow Root.
9	Psyllium Seed Husk, Slippery Elm Bark, Marshmallow Root, Acidophilus, Fructooligosaccharides (FOS).
10	Fructooligosaccharides (FOS) Acidophilus.
11	Psyllium Seed Husk.
12	Psyllium Seed Husk.
13	Slippery Elm Bark.
14	Marshmallow Root.
15	Fructooligosaccharides (FOS).

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® Fiber Formula	Both
2	Harmony Formulas® Fiber Formula	Label
3	Harmony Formulas® Fiber Formula	Labeling
4	Harmony Formulas® Fiber Formula	Labeling
5	Harmony Formulas® Fiber Formula	Labeling
6	Harmony Formulas® Fiber Formula	Labeling
7	Harmony Formulas® Fiber Formula	Labeling
8	Harmony Formulas® Fiber Formula	Labeling
9	Harmony Formulas® Fiber Formula	Labeling
10	Harmony Formulas® Fiber Formula	Labeling
11	Harmony Formulas® Fiber Formula	Labeling
12	Harmony Formulas® Fiber Formula	Labeling
13	Harmony Formulas® Fiber Formula	Labeling
14	Harmony Formulas® Fiber Formula	Labeling
15	Harmony Formulas® Fiber 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.