



7/5/98

NOTIFICATION PURSUANT TO 6916 '98 AUG -5 P1:42  
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 mucosphophilipid 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.

97S - 0162

see docket 97S-0163 also

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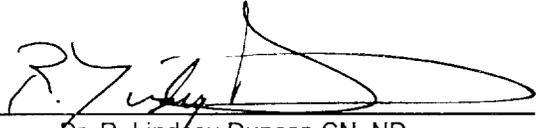
Gentian Root, Centaury Herb, Lecithin, L-Glutamine, Ginger Root, Orange Peel, Anise Seed, Cardamom Seed, Clovers, Fennel Seed, Licorice Root, Piper Longum Fruit.

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® Digestive Rebuilding Formula	Both
2	Harmony Formulas® Digestive Rebuilding Formula	Both
3	Harmony Formulas® Digestive Rebuilding Formula	Labeling
4	Harmony Formulas® Digestive Rebuilding Formula	Labeling
5	Harmony Formulas® Digestive Rebuilding Formula	Labeling
6	Harmony Formulas® Digestive Rebuilding Formula	Labeling
7	Harmony Formulas® Digestive Rebuilding Formula	Labeling
8	Harmony Formulas® Digestive Rebuilding Formula	Labeling
9	Harmony Formulas® Digestive Rebuilding Formula	Labeling
10	Harmony Formulas® Digestive Rebuilding 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.