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DEC - 7 2005

Mr. Richard W. Enlow  
CEO  
New Health Systems, LLC  
dba Chicken Soup for the Soul Supplements  
722 Goddard  
Chesterfield, Missouri 63005-1100

Dear Mr. Enlow:

This is in response to your letters of October 25, 2005 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 New Health Systems, LLC is marketing the products GardenTrust™ Pure Fruit drink and TrimWorks™ premium meal replacement shake as dietary supplements.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. 21 U.S.C. 321(ff)(2)(B). The products identified above are represented for use as a conventional food (i.e., as a drink) or as a sole item of a meal (i.e., meal replacement shake). Therefore, in that they are either represented for use as conventional food or as a sole item of a meal, they are not dietary supplements within the meaning of 21 U.S.C. 321(ff) and claims made for them are not subject to 21 U.S.C. 343(r)(6).

Instead, these products appear to be conventional foods that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, they must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the products in their labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C.

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342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market these products as conventional foods and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', written in a cursive style.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Kansas City District Office, Office of Compliance, HFR-SW340



Office of Nutritional Products, Labeling, and  
Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740

- A

Re: Notification for Statements on Dietary Supplement Labels

Date: October 25, 2005

This notification is being submitted on behalf of New Health Systems, d.b.a. Chicken Soup for the Soul Supplements (hereafter "Chicken Soup"), Chesterfield, Missouri, a distributor of supplement products.

Pursuant to the requirements of Section 6 of Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 343(r) (6), and in accordance with the authorized provisions of 21 CFR 101.93(a), your Agency is hereby notified that Chicken Soup proposed to make [or "has made"] statements of "nutritional support", as described in 21 U.S.C. 343(r) (6) (A), for its dietary supplements as follows:

**GardenTrust™ Pure Fruit** drink is a premium daily fruit drink designed to optimize healthy lifestyles.\* This unique fruit powder is a powerful combination of berries, citrus, melon, apples, and grapes and other fruit designed to deliver outstanding nutritional impact and great taste.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

The undersigned certifies on behalf of Chicken Soup that the information presented and contained in this correspondence is complete and accurate

Sincerely yours,  
Chicken Soup for the Soul Supplements

  
Richard W. Enlow, CEO

05-7718

New Health Systems, LLC  
722 Goddard  
Chesterfield, MO 63005-1100

P. 636-736-2000  
F. 636-736-2008

www.chickensoupsupplements.com



Office of Nutritional Products, Labeling, and  
Dietary Supplements (HFS-810)  
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**TrimWorks™** premium meal replacement shake offers breakthrough taste while providing the perfect balance of protein, vitamins and minerals. This unique formula satisfies your hunger, provides lasting energy and an outstanding taste. With 21 vitamins, minerals, protein and fiber this shake is a great start to the day and an effective weight management tool.\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

The undersigned certifies on behalf of Chicken Soup that the information presented and contained in this correspondence is complete and accurate

Sincerely yours,  
Chicken Soup for the Soul Supplements

  
Richard W. Enlow, CEO

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