



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 23 2007

Mr. Avraham Harris
Regulatory Operations Consultant
Sara's Tea, Inc.
1615 East 31st Street
Brooklyn, New York 11234

Dear Mr. Harris:

This is in response to your letter of December 11, 2006 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)) on behalf of Sarah's Tea, Inc. Your submission stated that Sarah's Tea, Inc. is making the following claims, among others, for the product **Breathe Again** herbal tea and dietary supplement:

"As a child, he suffered from severe asthma, high fevers and recurring throat and ear infections...Sarah developed a tea...to strengthen the immune system and promote natural resistance."

"This special formula ...providing symptomatic relief."

"Her son's symptoms diminished and disappeared completely."

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 this product suggests that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

97S 0153 LET 924

Page 2 - Mr. Avraham Harris

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

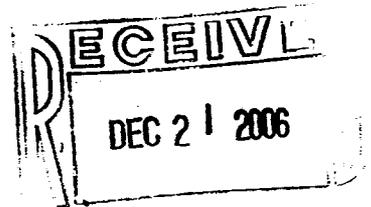
FDA, New York District Office, Office of Compliance, HFR-NE140

Sarah's Tea, Inc.

1615 East 31st Street Brooklyn, NY 11234 718.376.9395 fax:718.627.2531 sales@sarahstea.com

Monday, December 11, 2006

Dr. Bill Frankos, Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740
USA
202-205-5229



Dear Sir or Madam,

Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR § 101.93

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and Rule 21 CFR § 101.93, Sarah's Tea Inc., located at 1615 E 31st street Brooklyn, NY, 11234 wishes to notify the FDA that the Company plans to begin marketing **Breathe Again, Healthy Heart, A lighter You and A lighter You - Ultra** -herbal tea and dietary supplements with labels which bear the structure/function claims as listed in the table below:

Dietary Supplement

A Lighter You herbal tea and dietary supplement

Structure/Function Claims

Back panel:

"Eighteen years ago, Sarah Maayan was a young herbalist who was severely overweight. Desperate to shed the extra pounds, she tried a multitude of diet programs, but never succeeded in reaching her ideal weight.

With this in mind, she developed a tea brewed from a unique combination of herbs known for their ability to detoxify, balance and cleanse the body. This in turn results in supporting metabolic health, reducing fat naturally.

The results were outstanding - Sarah lost 70 pounds in a few months and happily maintains her new weight until this very day.

Sarah has since shared her secret with thousands of satisfied customers who have slimmed down and improved their overall health."

2006-9312

Sarah's Tea, Inc.

1615 East 31st Street Brooklyn, NY 11234 718.376.9395 fax:718.627.2531 sales@sarahstea.com

Top Panel: "3 cups a day for a healthy cardiac system"
"Helps strengthen the cardiovascular system"
"Promotes overall cardiac well-being"

Dietary ingredients subject of the statements

- Madagascar periwinkle leaves [Catharanthus roseus (L.) G. Don (Apocynaceae), syn. Vinca rosea L.]
- Stinging nettle leaves [Urtica dioica L. ssp. dioica (Urticaceae)]
- Alfalfa leaves [Medicago sativa L. (Fabaceae)]
- Dandelion leaves [Taraxacum officinale Weber ex F.H. Wigg. (Asteraceae)]
- Rosemary leaves [Rosmarinus officinalis L. (Lamiaceae)]
- Olive leaves [Olea europaea L. (Oleaceae)]

These statements will be followed by the required disclaimer indicating that these statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

None of the plants used are New Dietary Ingredients.

As authorized to do so by Sarah's Tea Inc., I certify by signature below that Sarah's Tea, Inc. possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under DSHEA, and that the information contained in this notice is complete and accurate.

Sincerely,



Avraham Harris
Regulatory Operations Consultant
FOR SARAH'S TEA INC.

11 Dec 06.

Date Signed