



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration,
College Park, MD 20740

AUG 31 2004

SEP 2 10 53 AM '04

Ms. Heather Van Vorous
President
Heather & Company for IBS, LLC
409 10th Avenue East #202
Seattle, Washington 98102
Palantine, Illinois 60074

Dear Ms. Van Vorous:

This is in response to your letter of July 14, 2004 to the Food and Drug Administration (FDA). Although you do not state the purpose of your letter, it appears that it may be intended as the submission required pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual who is certifying that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject your product to regulation under the drug provisions of the Act.

Even if your submission complied with the requirements of the Act, information in your submission suggests that your products may violate one or more provisions of the Act. Your submission contained labels for three products that you market. The labels bear the following statements:

975-0160

LET 773

Heather's Tummy Fibers "[R]elieve pain, diarrhea, constipation, and bloating from Irritable Bowel Syndrome."
"Acacia has no IBS triggers"
"Who's Heather and why did she develop Acacia Tummy Fiber specifically for Irritable Bowel Syndrome? Visit HelpForIBS.com for her story, and for help from the entire IBS community!"

Organic Peppermint "[P]ain-relieving properties."

Each label (including that of the Organic Fennel product) bears a referral to the web site "HelpForIBS.com and a statement that reads, in part, "[P]roducts for Irritable Bowel Syndrome."

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, or mitigate a disease, namely, Irritable Bowel Syndrome. 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 Act¹. 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 20855.

Finally, although the products "Organic Fennel Loose Tea" and "Organic Peppermint Loose Leaf Tea" were included in the notification, they are not labeled as dietary supplements (see 21 CFR 101.3(g)) nor do they bear the "Supplement Facts" labeling required for dietary supplements in 21 CFR 101.36. If the products are intended to be marketed as dietary supplements, then they must be labeled as such or they may be deemed to be misbranded under the Act.

¹ Under the Act, as amended by the Dietary Supplement Health and Education Act (DSHEA), dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain conditions are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. 101.93(g)).

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Please contact if you have any questions regarding this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to be "SJ 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

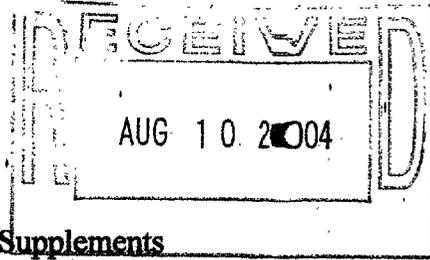
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

HEATHER & COMPANY FOR IBS LLC

July 14, 2004

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements
Division of Nutritional Programs and Labeling
200 C Street SW
Washington, DC 20204



Dear Sir or Madam:

Enclosed are labels with the FDA disclaimer. If you have any questions please feel free to contact me.

Sincerely,

A handwritten signature in cursive script, appearing to read "Heather Van Vorous".

Heather Van Vorous
President

89255

RECEIVED
AUG 10 2004

Heather's
Tummy Fibers

One of Africa...

Organic Acacia
Soluble fiber with a probiotic effect

*Soluble fiber can help relieve pain,
diarrhea, constipation, and bloating
from Irritable Bowel Syndrome.**

A DAILY DIETARY SUPPLEMENT - KOSHER CERTIFIED
SEE REVERSE FOR DOSAGE & CAUTIONS
*This statement has not been evaluated by the FDA.
*This product is not intended to diagnose, treat, cure, or prevent any disease

HelpForIBS.com
Education, support, & products for Irritable Bowel Syndrome

© 11.05.2004

NET WT: 16 OZ. (453 GRAMS)

See Reverse

AUG 10 2004

Heather's
Tummy Teas



*Organic Fennel
Loose Tea*

*Fennel is an ancient herb with a mild licorice flavor, traditionally used to aid digestion, and help relieve both gas and bloating.**

INGREDIENTS: PURE ORGANIC FENNEL SEEDS ~ CERTIFIED BY QAI
KOSHER CERTIFIED ~ CAFFEINE FREE

DIRECTIONS: BREW 1-2 TABLESPOONS PER 8 OUNCES BOILING WATER
USING A TEA STRAINER OR TEA BALL

HelpForIBS.com

Education, support, & products for Irritable Bowel Syndrome

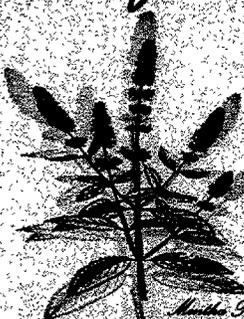
*This statement has not been evaluated by the FDA.
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NET WT: 16 OZ. (453 GRAMS)

See Reverse

AUG 10 2004

Heather's
Tummy Teas



Mentha Spicata

Organic Peppermint
Leaf Tea

*Peppermint is a cooling, calming herb with pain-relieving properties, traditionally used to soothe and relax the digestive tract.**

INGREDIENTS: PURE ORGANIC PEPPERMINT LEAF - CERTIFIED BY QAI
KOSHER CERTIFIED - CAFFEINE FREE

DIRECTIONS: BREW 1-2 TABLESPOONS PER 8 OUNCES BOILING WATER
USING A TEA STRAINER OR TEA BALL

HelpForIBS.com
Education, support, & products for Irritable Bowel Syndrome

*This statement has not been evaluated by the FDA.
*This product is not intended to diagnose, treat, cure, or prevent any disease.

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See Reverse