



DEC 13 2002 8 05 9 '02 DEC 16 P3:32

Mr. Steven R. Heacock
Chief Legal/Finance Officer
Natural 2 U
3133 Orchard Vista Drive, SE
Grand Rapids, Michigan 49546

Dear Mr. Heacock:

This is in response to your letter of November 26, 2002 to the Food and Drug Administration (FDA) responding to our October 17, 2002 letter concerning claims being made for several of your products pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your current letter, you included revised claims for the product claims that we stated appeared to be disease claims that caused your products to be subject to regulation as drugs under the Act.

**iVillage Headache Rescue - Feverfew Complex
Cayur Headache Relief - Headache Relief**

In our previous letter, we stated that the claim "...relieve headache discomfort" was a disease claim. You submitted a revised claim that states "Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to help minimize the stress and tension of the day." The use of the word "headache" in the product name is still a disease claim. In fact, FDA stated in the preamble to the January 6, 2000 final rule on structure function claims (65 FR 1000 at 1031) stated that nervous tension headache was a disease claim because tension headache meets the definition of disease.

"...promotes healthy joint function by inhibiting the COX-2 enzyme,
associated with joint inflammation"

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 statement that you are making for these products, including the use of the word "headache" in the product name, suggests

975-0163

LET 661

that they are intended to prevent diseases (i.e., headaches). 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 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, 7520 Standish Place, Rockville, Maryland 20855.

The revised claims you proposed for the products **iVillage Smooth Movin' - Joint Support, Cayur Herbal InflaRelief - Herbal InflaRelief, Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit, Cayur Calcium Magnesium Powered Drink Mix Unflavored, Cayur Calcium Magnesium Powered Drink Mix Hot Apple Cider, Cayur Smoke Shield - Detox Smoke and Pollution, and Cayur Probiotic Complex - Probiotic Complex** appear to resolve the issues we raised in our October 17, 2002 letter.

Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret

Director

Division of Compliance and Enforcement

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-300

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

FDA, Detroit District Office, Office of Compliance, HFR-MW240

DEC 4 2002

JBF

Steve Heacock
Chief Legal / Finance Officer



November 26, 2002

Mr. John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Department of Health & Human Services
Food and Drug Administration
College Park, Maryland 20740

Re: Natural2U – Labels for iVillage and Cayur products

Dear Mr. Foret:

This is in response to your letter to Ms. Jennifer Wolbers of Natural2U dated October 17, 2002 (a copy of which is attached). I am counsel to Natural2U. Your letter raised several concerns regarding claims made on labels for certain iVillage and Cayur products. We have amended the labels to resolve the concerns you raised. While you did not ask for a response to your letter, I am writing to provide you with the changes Natural2U has made to labels as a result of your assessment. To ease your review, I will restate for each of your concerns, the product, and the language you identified as possible problematic, the language included on the original label and the language from the revised labels.

iVillage Headache Rescue – Feverfew Complex

Cayur Headache Relief – Headache Relief

“...relieve headache discomfort.”

Old language -- Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to relieve headache discomfort.

3133 Orchard Vista Drive, SE
Grand Rapids, Michigan 49546
ph 616.464 5030
fax 616 575 0556

82782

New language -- Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to help minimize the stress and tension of the day.

iVillage Smoothie Movin' - Joint Support

Cayur Herbal InflaRelief – Herbal InflaRelief

“..promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation.”

Old Language – Herbal InflaRelief promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation.

New Language – Herbal InflaRelief promotes healthy joint function by inhibiting the COX-2 enzyme, associated with impacting healthy joint movement.

Cayur - Calcium Magnesium Powered Drink Mix Tropical Fruit

Cayur - Calcium Magnesium Powered Drink Mix Unflavored

Cayur - Calcium Magnesium Powered Drink Mix Hot Apple Cider

“Too little Calcium and Magnesium can also result in ...elevated blood pressure...”

Old Language - 1. Calcium and Magnesium levels in the body affect the health of your bones and teeth, but they also influence nerve and muscle health and help maintain cardiovascular function and a healthy circulatory system. 2. Too little Calcium and Magnesium can also result in restless sleep, increased PMS symptoms, elevated blood pressure, and muscle tension.

New Language - 1. Calcium and Magnesium are important in promoting the health of bones and teeth. 2. These minerals are essential for contraction and relaxation of muscles, and can ease the feeling of tension that can lead to a host of discomforts. 3. Calcium and Magnesium also play a critical role in maintaining an already healthy blood pressure.

Cayur Smoke Shield - Detox Smoke and Pollution

“...if you...smoke...you are subjected to airborne toxins that can wreak havoc with your body”

Old Language - 1. These days, if you drive, smoke or cook you are subjected to airborne toxins that can wreak havoc with your body. 2. Turmeric, green tea, rosemary, clove and other herbs have been shown to act as herbal free radical scavengers, increasing enzymes that promote detoxification, as we live and breathe.

New Language - Turmeric, green tea, rosemary, clove and other herbs have been shown to act as herbal free radical scavengers, supporting the neutralizing process.

Cayur Probiotic Complex - Probiotic Complex

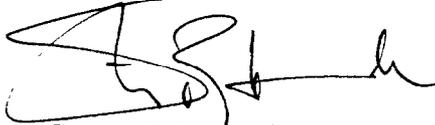
“A first line of protection against potentially harmful micro-organisms in your food and environment.”

Old Language – 1. A first line of protection against potentially harmful micro-organisms in your food and environment probiotics are the healthy bacteria that colonize in your digestive tract. 2. Probiotic Complex consists of the eight best researched, stable strains of friendly flora, including *Lactobacillus acidophilus*. 3. And we've taken the added step of including the bacterial by products, now known to be intrinsically beneficial to digestive health.

New Language - Probiotic Complex consists of the eight best researched, stable strains of friendly flora (healthy bacteria), including *Lactobacillus acidophilus* to support healthy digestion.

Please contact me if you have further comments or concerns.

Respectfully,

A handwritten signature in black ink, appearing to read 'S. Heacock', written over a horizontal line.

Steven R. Heacock
CLO/CFO