



OCT 17 2002

Ms. Jennifer Wollers
Director of Product Development
Natural 2 U
3133 Orchard Vista Drive, SE
Grand Rapids, Michigan 49546

Dear Ms. Wollers:

This is in response to your letters of September 27, 2002 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 submission states that Natural 2 U is making the following claims, among others, for the following products:

iVillage Headache Rescue - Feverfew Complex

Cayur Headache Relief - Headache Relief

"...relieve headache discomfort"

iVillage Smooth Movin' - Joint Support

Cayur Herbal InflaRelief - Herbal InflaRelief

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

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..."

Cayur Smoke Shield - Detox Smoke and Pollution

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

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Cayur Probiotic Complex - Probiotic Complex

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

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 prevent diseases (i.e., headaches, inflammatory joint disorders, hypertension, smoking-related diseases, and infectious diseases caused by pathogenic microorganisms). 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 claim “Too little Calcium and Magnesium can also result in...elevated blood pressure...” being made for **Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit**, **Cayur Calcium Magnesium Powered Drink Mix Unflavored**, and **Cayur Calcium Magnesium Powered Drink Mix Hot Apple Cider** may be intended by you as a claim about the usefulness of these products in treating or preventing calcium and/or magnesium deficiencies. 21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that “claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States.”

If the statements identified above are intended to be claims within the scope of 21 U.S.C. 343(r)(6)(A), then the statements that you are making for **Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit**, **Cayur Calcium Magnesium Powered Drink Mix Unflavored**, and **Cayur Calcium Magnesium Powered Drink Mix Hot Apple** misbrand these products under 21 U.S.C. 343(r)(6)(A) because they describe a benefit related to a classical nutrient deficiency disease but do not disclose the prevalence of the subject deficiency disease in the United States.

21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. The statements being made for the products **Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit**, **Cayur Calcium Magnesium Powered Drink Mix Unflavored**, and **Cayur Calcium Magnesium Powered Drink Mix Hot Apple** are not made in accordance with 21 U.S.C. 343(r)(6), however, and these statements suggest that the

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products are intended to treat, prevent, mitigate, or cure diseases or are articles (other than food) intended to affect the structure or any function of the body of man. Therefore, these claims suggest that the products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), and that they are subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is written in a cursive style and is positioned above the typed name.

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

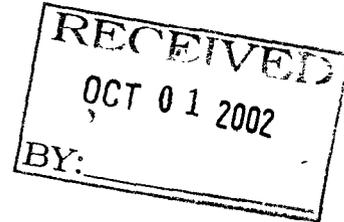
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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

NATURAL2U

Bringing to market value-added, natural, organic and environmentally conscious brands of unsurpassed integrity.

September 27, 2002



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, MD 20740

Re: Notification of § 403(r)(6) Statements

Gentlemen:

In accordance with 21 C.F.R. § 101.93, Natural2U, LLC of 3133 Orchard Vista Drive, S.E., Grand Rapids, Michigan 49546, hereby provides notification to the Office of Nutritional Products, Labeling and Dietary Supplements that Natural2U, LLC, as distributor of the respective products listed below, has included the following statements on the labels or in the labeling of the respective products, all of which were first marketed less than thirty (30) days ago.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Aloe Vera	Aloe Vera	You may know Aloe Vera for its benefits to promote the healing of damaged skin.
Cayur Smoke Shield	Detox Smoke and Pollution	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.

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Office of Nutritional Products

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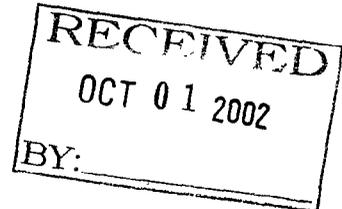
BRAND NAME	NAME OF DIETARY SUPPLEMENT	CONTENT OF THE STATEMENT(S)
Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> 1. Calcium and Magnesium levels in the body affect the health of your bones and teeth, but they also influence 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. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.
Cayur Calcium Magnesium Powered Drink Mix Unflavored	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> 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. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.
Cayur Calcium Magnesium Powered Drink Mix Hot Apple Cider	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> 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. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.
Cayur Headache Relief	Headache Relief	<ol style="list-style-type: none"> 1. Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to relieve headache discomfort..
Cayur Herbal InflaRelief	Herbal InflaRelief	<ol style="list-style-type: none"> 1. Herbal InflaRelief promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation. 2. And, besides promoting normal cell growth, these herbs

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
		help to neutralize free radicals.
Cayur Probiotic Complex	Probiotic Complex	<ol style="list-style-type: none"> 1. A first line of protection against potentially harmful microorganisms 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.
Cayur Restful Sleep	Restful Sleep	<ol style="list-style-type: none"> 1. Your periods of deep sleep will be longer and more replenishing. 2. You will awake more rested and refreshed. Restful Sleep... an herbal lullaby
Cayur Ultimate Ginger	Ginger	The world's most potent, certified organic ginger extract, with 250 times the concentration for fresh ginger.
Cayur Ultimate Saw Palmetto Complex	Saw Palmetto	<ol style="list-style-type: none"> 1. Ultimate Saw Palmetto Complex which includes saw palmetto, green tea, pumpkin seed oil, ginger, and other herbs, may prove to be the best way to support prostate health. 2. And by inhibiting the enzyme that promotes prostate swelling, urinary and sexual health are enhanced.

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PRODUCT NAME	TYPE OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENTS
iVillage PMS Peacemaker	Evening Primrose & Borage Blend	Adding a blend of GLA (gamma-linolenic acids) from oils of Evening Primrose and Borage to your diet may provide gentle relief from cramps, breast tenderness, irritability and water retention.
iVillage Headache Rescue	Feverfew Complex	Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to relieve headache discomfort.
iVillage Stand Tall	Calcium Multimineral	1. Your bones need calcium. Magnesium helps your body take it in. 2. So we paired the two, plus added other minerals to bring the benefits of two, 8-ounce glasses of milk a day in just three tablets.

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BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Mommy Must-Have	Iron+Folic Acid	Additionally these nutrients are important in maintaining healthy blood cells.
iVillage See Clearly	Bilberry	<ol style="list-style-type: none"> 1. Bilberry strengthens blood vessels, especially important in the area of the retina called the macula. 2. Bilberry also helps maintain normal nighttime vision.
iVillage Smooth Movin'	Joint Support	<ol style="list-style-type: none"> 1. Smooth Movin promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation. 2. Our formula actually supports stomach and liver health. 3. And, besides promoting normal cell growth, these herbs help to neutralize free radicals.
iVillage Restful Sleep	Herbal Relief	<ol style="list-style-type: none"> 1. Your periods of deep sleep will be longer and more replenishing. 2. You will awake more rested and refreshed.
iVillage Tummy Tranquility	Ginger Complex	<ol style="list-style-type: none"> 1. If you're among the millions who believe in ginger's ability to support stomach, liver and intestinal health, you'll love Tummy Tranquility. 2. And, we've added rosemary extract, historically used for its antioxidant properties.
iVillage Pollution Patrol	Turmeric Complex	Turmeric, green tea, rosemary, clove and other herbs have been shown to act as herbal free radical scavengers, supporting the neutralizing process.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Bone Brew	Plain Calcium Drink	<ol style="list-style-type: none"> 1. Calcium and Magnesium are important in promoting the health of bones and teeth. 2. These minerals are essential for the 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. 4. iVillage Calcium Magnesium Drink Mix dissolves completely, ensuring proper absorption and utilization by the body.
iVillage Bone Brew	Pineapple Guava Calcium Drink	<ol style="list-style-type: none"> 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. 4. iVillage Calcium Magnesium Drink Mix dissolves completely, ensuring proper absorption and utilization by the body.
iVillage Take It to Heart	Vitamin E with Selenium	Vitamin E and Selenium work together to support cardiovascular health.

The undersigned, on behalf of Natural2U, LLC, hereby certifies that the information contained in this notice is complete and accurate and that Natural2U, LLC has appropriate substantiation that the statements are truthful and not misleading.