



OCT 24 1997

0805 '97 DEC 16 P1:42

Dr. Philip A. Duterme  
Chief Executive Officer  
Ayurvedic Concepts  
6950 Portwest Drive  
Suite 170  
Houston, Texas 77024

Dear Dr. Duterme:

This is in response to your letters of October 9, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submissions state that Ayurvedic Concepts, Ltd. is making a number of claims for various dietary supplements.

**Glucosim**

“...gentle and safe glycemic management (sugar level in the blood stream)”  
“...control serum triglycerides and cholesterol”

**Rumalaya**

“...attenuate the discomfort caused by impaired movement”  
“...demonstrated very good results in morning stiffness and sport-related sprains”

**Menstricare**

“...helps women cope with their monthly cycle's stress and discomfort”

Section 403(r)(6) of the act 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 diseases, namely hyperglycemia (i.e., diabetes), hypercholesterolemia, hypertriglyceridemia, joint illnesses and injuries, and premenstrual syndrome. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and

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Page 2 - Dr. Philip A. Duterme

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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
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, Dallas District Office, Office of Compliance, HFR-SW140

October 09, 1997

0806 '97 DEC 16 P1:42

OCT 14 1997

Dr. Elizabeth A. Yetley  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration - HFS-455  
200 C Street SW  
Washington, DC 20204

Dear Dr. Yetley,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement "MenstriCare™". MenstriCare™ was first marketed with these statements of nutritional support on September 19, 1997. The statements of nutritional support are as follows :

"Nature's Balanced Monthly Comfort Formula. MenstriCare™ is an all natural herbal supplement that helps women cope with their monthly cycle's stress and discomfort. It offers a broad range of health benefits for increased well being."

Very truly yours,



Ayurvedic Concepts Ltd.,  
Dr. Philip A. Duterme, Chief Executive Officer

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October 09, 1997

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OCT 14 1997

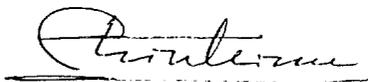
Dr. Elizabeth A. Yetley  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration - HFS-455  
200 C Street SW  
Washington, DC 20204

Dear Dr. Yetley,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement "Rumalaya®". Rumalaya® is a product of the Himalaya ProSelect™ line and was first marketed with these statements of nutritional support on September 19, 1997. The statements of nutritional support are as follows :

"Natural Joint Support. Rumalaya® helps support the connective tissue structure of the articulation and attenuate the discomfort caused by impaired movement. It promotes circulation and has demonstrated very good results in morning stiffness and sport-related sprains."

Very truly yours,

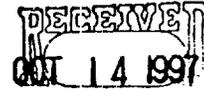


Ayurvedic Concepts Ltd.,  
Dr. Philip A. Duterme, Chief Executive Officer

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October 09, 1997

0808 '97 DEC 16 P1:42



Dr. Elizabeth A. Yetley  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration - HFS-455  
200 C Street SW  
Washington, DC 20204

Dear Dr. Yetley,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement "Glucosim™". Glucosim™ is a product of the Himalaya ProSelect™ line and was first marketed with these statements of nutritional support on September 19, 1997. The statements of nutritional support are as follows :

"Natural Glucose Regulator. Glucosim™ is a natural formula that contains Gymnema, the herb of choice for gentle and safe glycemc management (sugar level in the blood stream). It also helps support the pancreas function and control serum triglycerides and cholesterol."

Very truly yours,

Ayurvedic Concepts Ltd.,  
Dr. Philip A. Duterme, Chief Executive Officer

55160