



OCT 10 1997

Mr. P. K. Dave  
Chief Operating Officer  
Nature Care Products Company  
6 Charles Park  
Guilderland, New York 12084

0786 '97 DEC 16 P1:40

Dear Mr. Dave:

This is in response to your letter of April 22, 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 submission states that Nature Care Products Company is making the following claims, among others, for the following products:

Gymnema

In Ayurveda, *Gymnema sylvestre* is believed to help remove "accumulated/excess sugars" in the body...

Guggul

In Ayurveda, Guggul is believed to help remove accumulated fat by-products such as cholesterol, a result of Kapha imbalance, and joint conditions/discomfort, a result of Vata imbalance.

Boswellia

In Ayurveda, *Boswellia serrata* is believed to help joint conditions/discomfort, a result of Vata and Kapha imbalance.

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, cure, mitigate, or prevent disease, namely hypercholesterolemia (i.e., remove accumulated fat by-products such as cholesterol), diabetes (i.e., remove accumulated/excess sugars), and diseases of the joints (i.e., help joint conditions/discomfort). 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 that it is subject to

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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 yours,

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, Buffalo District Office, Domestic Operations Branch, HFR-NE350



NATURE CARE™ PRODUCTS CO.

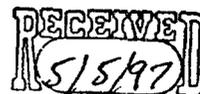
6 Charles Park, Guilderland, NY 12084

Telephone: (518) 464-6002 • (800) 923-9338 • Fax: (518) 464-6003

April 22, 1997

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street, S.W. (HFS-455)  
Washington, D.C. 20204

0787 '97 DEC 16 P1:40



Dear Sirs/Mesdames:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature Care Products Company wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support. The dietary supplement for which this statement is made is **Boswellia**. The statements of nutritional support read as follows:

- Joint Function.
- In Ayurveda, *Boswellia serrata* is believed to help joint conditions/discomfort, a result of Vata and Kapha imbalances.

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,

P.K. Davé  
Chief Operating Officer

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April 22, 1997

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Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 "C" Street, S.W. (HFS-455)  
Washington, D.C. 20204

0788 '97 DEC 16 P1:4 RECEIVED  
5/5/97

Dear Sirs/Mesdames:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature Care Products Company wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support. The dietary supplement for which this statement is made is **Guggul**. The statements of nutritional support read as follows:

- Fat Metabolism.
- In Ayurveda, Guggul is believed to help remove accumulated fat by-products such as cholesterol, a result of Kapha imbalance, and joint conditions/discomfort, a result of Vata imbalance.

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,

P.K. Davé  
Chief Operating Officer

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Dear Sirs/Mesdames:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature Care Products Company wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support. The dietary supplement for which this statement is made is **Gymnema**. The statements of nutritional support read as follows:

- Sugar Metabolism.
- In Ayurveda, *Gymnema sylvestre* is believed to help remove "accumulated / excess sugars" in the body, said to be the result of Pitta or Kapha imbalances.

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,

P.K. Davé  
Chief Operating Officer

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