DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 6 1997

Ms. Natalia Garza
Export Manager
Malabar Productos Naturales S.A. De C.V.
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Guadalupe, N.L. CP 67100 México

Dear Ms Garza:

This is in response to your submission dated October 25, 1996, concerning the marketing of new dietary ingredients (i.e., Anacahuite and Gordolobo). This submission was received by the Food and Drug Administration (FDA) on October 31, 1996 and was given pursuant to the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

Section 413 of the act requires a manufacturer or distributor of a dietary supplement which contains a new dietary ingredient to submit certain information to the agency. Specifically, the act requires that at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient provide the FDA with information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. Because you submitted to FDA information which is the basis on which you concluded that the dietary supplement will reasonably be expected to be safe, the agency will consider your submission to be the required 75-day premarket notification of your intent to sell Anacahuite and Gordolobo as dietary supplements. As required by section 413(a)(2) of the act, we will keep your submission confidential for 90 days from the date of receipt, and thus after January 29, 1997, it will be placed on public display at Dockets Management Branch. Commercial and confidential information in the notification will not be made available to the public.

It is unclear whether you intend to make claims for these dietary ingredients. Pursuant to section 403(r)(6) of the act, a statement of nutritional support for a dietary supplement may be made if the statement

> (1) claims a benefit related to a classical nutrient deficiency disease and disclosed the prevalence of such disease in the United States,
> (2) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,
> (3) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or

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(4) describes general well-being from consumption of a nutrient or dietary ingredient

Section 403(r)(6) permits these statements, however, only under certain conditions. For example, the statement may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. In addition, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. Furthermore, the nutritional support statement must prominently contain the following disclaimer:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Finally, pursuant to section 403(r)(6) of the act, a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. If you intend to make a nutritional support statement on the label or in the labeling of your dietary supplement product, you must submit to FDA a notification following the requirements listed in section 403(r)(6) of the act. The notification must include the nutritional support statement that will appear on the label or in the labeling of the dietary supplement.

We would like to comment on the nature of the information you submitted with regard to the use of these dietary ingredients in humans. Therapeutic use claimed for these substances are stated below:

Cordia boissieri (Anacahuite):

Therapeutic Use - Pectoral (relieving disorders of the respiratory tract).

Usage: Siricote is used mainly as bronchial disease remedy. Probably it is effective due to the antiseptic action of the essence oil and to the astringent effect of gallic and tannic acids it contains.

Usage: An extract is prepared to manufacture pills recommended for pectoral disease from its wood. Flowers, when cooked, are used for cough. A preserve is made with fruits which supposedly has pectoral virtues. For chronic, constipated colds and bronchitis, B. Cuevas, MD recommends a syrup prepared with approximately 40 fruits and pieces of bark cooked in one and a half liter of water; strain and concentrate the liquid and take 3 to 4 teaspoons a day.

Gnaphalium berlandieri (Gordolobo)

This plant has appeared in the Mexican domestic recipes since pre-Hispanic times, except that in other times it was used to "purge phlegmatic humors" (as per the wording of Spanish doctor and naturalist of the XVI century Francisco

Hernández) and today its flowers are used to treat cough, throat inflammation and bronchial disease. In this case, it is recommended to drink a hot cup of flowers tea at night. It is said also that this drink favors venous circulation thus alleviating hemorrhoids and varicose veins.

Usage: Flowers are used in infusion to treat respiratory disease, since they calm down cough and help expectoration and diminish inflammation of mucous membranes. The mucilage they contain probably supports the emollient and pectoral features attributed to the plant. No other effectiveness has been proved in other cases.

Usage: High contents of mucilage of this plant makes it useful smooth skin and mucous membrane and to work as expectorant; it is effective in treatment of cough, throat irritation, bronchitis and asthma. Laboratory tests prove it has an anti-inflammatory action. It is said that the essential oils of its flowers alleviate ear pain.

It is commonly used as an emollient and pectoral substance, drinking it as a tea before breakfast. It is recommended against cough and throat pain, it soothes chest pain caused by bronchitis.

Some of the traditional folk uses of these substance cited in your submission suggest that the products may be intended for use as drugs. If you intend to label or market these products for the uses stated above, you must comply with the drug provisions of the act.

Be advised that there is no requirement that dietary supplements be approved by the FDA prior to marketing. It is the responsibility of the person who introduces a dietary supplement into interstate commerce to ensure that the dietary supplement is safe for its intended use and is properly labeled.

Please contact us if we may be of further assistance.

Sincerely yours

James Tanner, Ph.D.
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