DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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Ms. Natalia Garza
Export Manager
Malabar Productos Naturales S.A. De C.V.
Barbadillo 416 Apdo. Postal 212, Cd.
Guadalupe, N.L. CP 67100 Mexico

Dear Ms Natalia Garza:

This is in response to your submission dated September 23, 1996, concerning the marketing of new dietary ingredients (i.e., Leucophyllum texanum, Solanum verbascifolium, Conyza filaginoides, and Castilleja canescens). This submission was received by the Federal Food and Drug Administration (FDA) on October 16, 1996 and was submitted pursuant to the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

Section 413 of the Federal Food, Drug, and Cosmetic Act (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 Leucophyllum texanum, Solanum verbascifolium, Conyza filaginoides, Castilleja canescens 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 on January 13, 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

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> 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
> (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. 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 use against fever (Leucohyllum texanum and Solanum verbascifolium), to cure wounds (Leucohyllum texanum), to calm headaches (Solanum verbascifolium), against ulcers (Solanum verbascifolium), for diseases of the excreting system, "to fight gastric colds accompanied by dyspepsia" (Conyza filaginoides), "to cure the colds of the biliary conducts" (Conyza filaginoides), to excrete "by vomiting all the principal fumes of cholera and phlegms" (Conyza filaginoides), to cure "repression and ahito" (Conyza filaginoides), to improve "notably those with stomach pains due to the fact that the food lacks natural heat" (Conyza filaginoides), to treat "gastric colds accompanied by dyspepsia and lack of appetite" (Conyza filaginoides), to cure hepatic cramps (Conyza filaginoides), to use in "cases of colds in the biliar paths" (Conyza filaginoides), to calm pain (Conyza filaginoides), reduce jaundice (Conyza filaginoides), "against hepatic colics" (Conyza filaginoides), "for several stomach ailments" (Castilleja canescens), to render "valuable services in cases of blood poisoning due to the bile (Castilleja canescens), and to cure "hepatic colics" (Castilleja canescens), you must comply with the drug provisions of the act.

Further, the definition of a dietary supplement in section 201(ff)(2)(A)(i) of the act, states that the term "dietary supplement" means a product that is intended for ingestion in tablet, capsule, powder, softgel, or liquid form. The term "ingestion" has been addressed by the court (United States v Ten Cartons. Ener-B Nasal GEL, 888F. Supp. 393, (E.D.N.Y.) aff'd, 72F.3d 285 (2d Cir. 1995)) and found to mean to take into the stomach and gastrointestinal tract by means of enteral administration. Thus, any external use of Leucophyllum texanum to cure wounds, Solanum verbascifolium "applied heated to the forehead to calm headaches" and "in poultice against ulcers" or Conyza filaginoides as a enema, would not comply with the definition of a dietary supplement and would subject these products to regulation under 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.
Acting Director,
Division of Programs and
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and Applied Nutrition