DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date JAN 6 1997

From Acting Director, Division of Programs and Enforcement Policy, Office of Special Nutritionals, HFS-455

Subject 75-Day Premarket Notification for New Dietary Ingredients

To Dockets Management Branch, HFS-305

New Dietary Ingredient:	Cordia boissieri Gnaphalium berlandieri
Firm:	Malabar Productos Naturales
Date Received by FDA:	October 31, 1996
90-Day Date:	January 29, 1997

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after January 29, 1997.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Attachment

95S-0316

RPT 8

MALABAR
productos naturales s.a.de c.v.

October 25, 1996.

Victor Fratelli, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street HFS-455
Washington, DC 20204

Dear Dr. Fratelli,

Notice is hereby given pursuant to the requirements to Section 413(a)(2) (21 U.S.C. 350b) of the Federal Food, Drug and Cosmetic Act of two new dietary ingredients wich will be introduced in the dietary supplement Gripté. These new dietary ingredients have a long history of safe use in Mexico, and published articles support the conclusion that these ingredients are safe in expected use.

The new dietary ingredients, and citations to published articles supporting their safety, are:

Anacahuite (scientific name *Cordia Boissieri D.C.*, Mexican name Anacahuite)
-Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana* (**1952**), Anacahuite, pp.62
-Selecciones del Reader's Digest, *Plantas Medicinales* (**1987**), Anacahiute, pp.307
-M. Martinez, *Las Plantas Medicinales de México* (**1959**), Anacahuite, pp.37 -38

Gordolobo (scientific name *Gnaphalium berlandieri D.C.*, Mexican name Gordolobo)
-Selecciones del Reader's Digest, *Plantas Medicinales* (**1987**), Gordolobo, pp.200
-Selecciones del Reader's Digest, *Plantas Medicinales* (**1987**), Gordolobo Europeo,pp.201
-M.Martinez, *Las Plantas Medicinales de México* (**1959**), Gordolobo, pp.424
-Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana* (**1952**), Gordolobo, pp.228
-I.Gabriel, *Herb Identifier and Handbook* (**1979**), Great Mullein, pp. 156

Copies of the eight articles are enclosed, along with English translations (made by an expert translator) of the seven articles originally in Spanish. These new dietary ingredient will not be marketed in the US for 75 days after your expected receipt of this notice.

Very truly yours,

Malabar Productos Naturales S.A. De C.V.

Natalia Garza
Export Manager

49527

MALABAR PRODUCTOS NATURALES, S.A. DE C.V. EMPACADORES DE TE ALIMENTICIO Y MEDICINAL
Barbadillo 416 Norte, Apdo. Postal 212, Cd. Guadalupe, N.L. CP 67100 México. , Tel./Fx (918) 367-6976. 367-3508. 367-3895.

NEW DIETARY INGREDIENTS:

*Cordia Boissieri D.C.

*Gnaphalium Berlandieri D.C.

ANACAHUITE

Synonyms: Amaquahuitl, in Nahuatl; anacuahuitl and anacahuitl, in Mexica; siricote, rascaviejo, anacahuite and trompillo, in Spanish.-

Scientific Name: Cordia Boissieri, A. DC., Boraginaceae family.

Location: Brushwood near Tampico, Monterrey and Zimapán.

Parts Used: Sticks.

Description: Variable size sticks, in lengthy slices, with one or two flat faces, as obtained from one or two cuts of the branches. Gray, rough and cracked bark with a very developed "Liberian" layer, saturated with calcium oxalate. Yellowish wood, more or less dark, according to age with a number of very visible concentric circles and medullar lines.
Wood splints and bark chips that upon splitting release a whitish cloud of dust, very particular of this drug. Null odor or taste.

Therapeutic Use.- Pectoral.

Dose.- Free

Siricote

Anacahuite, cueramo, macahuite, nacagua, nacahuite, rascaviejo, trompillo.
Cordia Bosieri, D.C.
Boraginaceae

About 30 species of the Cordia genus grow in Mexico, among which there are large size trees, particular of the tropical forests, the wood of which is very used in woodwork due to its beautiful streaks. Although this is not the case with respect to Siricote, which is used for yokes and tool handles, this little tree has a many other virtues. It is frequently cultivated in public squares and gardens due to its cool shade and beautiful aspect. Those who do not know it and watch it without flowers, will admire that it is more or less decorative with is neatly round crown; but it is during the flowering time that it is understood why Siricote is cultivated as an ornamental species, since it is fully covered of beautiful and scented funnel-shaped white flowers. Fruit appears afterwards, partially covered by a thin and fibrous calyx; when maturing, they take a reddish-brown color, very dark, and become fleshy and sweet. Pets like them and marmalades and preserves may be made of it.

In traditional Mexican medicine, Siricote is reputed for cough, chronic colds and bronchitis relief. From its wood, an extract is obtained to manufacture pills for pectoral disease; flowers cooking is recommended to soothe cough, and from fruits a syrup is prepared for the same purpose.

Habitat: Thorny woods and xerophylous bush.

Geographic distribution: Natural of North America, it stretches from southern New Mexico and western Texas to North of Mexico. In our country, it may be found in Coahuila, Nuevo Leon, Tamaulipas and San Luis Potosí.

Identification: Bush or small tree, reaching a maximum of 8 meters high. 20 cm diameter trunk, with light bark of reddish-gray color, detached in layers. Alternate, petiolate, full, oval or elliptic leaves, about 8 to 12 cm. long, with rounded tip and smooth or slightly jagged borders. Terminal, cymose flowers, of dichotomic branching, with flowers of 3 to 5 cm. long, sessile, with a short peduncle; tubular calyx, with five teeth, white funnel-shaped corolla with five terminal lobules and yellow throat; 5 stamens, 1 pistil with bifid stigma. Fruit is a dark brown drupe, semi-covered by the calyx, this is persistent. It flowers from April to June.

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.

ANACAHUITE

Other common names: Anacuáhuitl, rasca viejo, siricote, trompillo, macahuite (in Tuxpan, Ver.).

Botanical Name: Cordia Boisieri, A.D.C.- Boraginaceae family.

Places to be found; Humid, warm climates, particularly in Nuevo Leon, Tamaulipas, Veracruz, Hidalgo and San Luis Potosí.

Features: Tree or bush about 5 to 6 meters high. Its trunk is woody, covered by a gray bark that may be easily detached in layers. Alternate, petiolate, oval or elliptic leaves, slightly jagged, 8 to 10 cm long by 5 to 6 cm wide. Flowers in terminal corymbs, fuzzy and tawny; fuzzy calyx with five divisions; funnel-shaped corolla in five divisions, 5 stamens, superous ovary and bifid stigma. Fruit is approximately 2 cm long; it is a drupe with blackish and sweet mesocarp.

Parts used: Wood, flowers and fruit.

Chemical composition: Wood contains tannic and gallic acids, gum, resin and calcium oxalate.

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.

About 30 species of Cordia can be found in Mexico

Source: Farmacopea Mexicana. Maximino Martínez.- Plantas ütiles de la Flora Mexicana.- 1959.

GORDOLOBO

(great mullein, common mullein, high taper)
Gnaphalium Conoideum H.B.K. Compositae

Several species of the Gnaphalium genus are known in Mexico with the name of Gordolobo, so that if you look for this remedy in a medicinal herbs stand, they can give you G. Conoideum, or G. Stramineum, G. Canescens, G. Oxyphyllum or any other species supposedly with the same medicinal virtues but of wider geographic distribution.

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.

The illustration here is not remarkable for its shape or color; it is an insignificant woolly, grayish-green color grass, with whitish flowers. The fuzzy hair that covers it has the name *tzom* (from Nahuatl, *tzontli*, "hair") included in some common names. The name of the genus derives from Greek *gnaphalion*, wooly plant also used to fill pillows.

Habitat: prairies, stony grounds, cultivated fields, and in general, altered land.

Geographic Distribution: Original from Mexico, it can be found in Durango, San Luis Potosí, Hidalgo, Tlaxcala and the Valley of Mexico.

Identification: Annual, 6 to 60 cm. high grass. Erect or leaning woolly stems. Alternate, sessile, full, oblong or lanceolate, slim, feathery grayish green leaves. Flowers in bell-shaped groups to form terminal panicles or corymbs, with involucres of 3 to 5 series of imbricate bracts of yellowish-white color, the external ones are woolly; plain receptacle; peripheral flowers are feminine, filiform and the central are hermaphrodite, tubular; one and the other are white or yellow and bear no ligula. Fruits are oblong achene, with a vilane of whitish hairs. Flowering from July to October.

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.

GORDOLOBO EUROPEO
(European great mullein)

Verbascum Taphsus L.
Scrophulariaceae

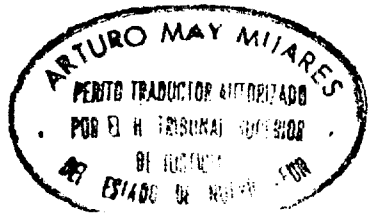
This plant has a long history in folklore and medicine. In the religious processions of Antique Rome, for instance, torches made up of stripped off flowers and leaves of European great mullein stems, covered with grease were used. According to traditions spread in further times, those torches were instruments for witches, but at the same time drove them away. Some used to say that by carrying this plant, women pregnancy was assured, but others said that by putting them inside a shoe pregnancy was avoided.
European and American plant only look similar only with respect to color of flowers and to woolly texture of leaves. They do not belong to the same genus and not even the same family of plants, and the fact that in Mexico the native plant was given the same name than that of the foreign plant derives solely from the similarity in the medicinal applications. Dioscorides prescribed the plant to alleviate breathing disease; Plinus acknowledged its usefulness in case of injuries or lung irritation and modern herbalists consider it as bechical and balsamic plant. Smoking leaves of this plant is an old remedy against cough and asthma; a lotion to smooth skin is also made of this plant and from flowers a yellow tint is extracted.

Habitat: pastures, roadsides, abandoned cultivated land.

Geographical Distribution: European plant introduced to America; in Mexico it is cultivated in some tempered areas, sometimes it becomes wild.

Identification: Biennial plant, 0.8 to 2 meters high. The first year, the plant produces a crown of basal leaves from which a single thick, straight and velvety stem emerges on the second year, encircled by leaves with a spike at the tip. Large felty , petiolate leaves; limb is narrow at the base and extends along the stem and then it widens. Thick spike of pale yellow, hairy calyx, persistent, five-sepal flowers, of caduceus funnel-shaped corolla, with 5 petals, 5 stamens, three out of them shorter and fuzzy. Fruit is an oval capsule. Flowers from June to September.

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.



GORDOLOBO
(Great Mullein)
Gnaphalium conoideum H.B.K.

Found in the Valley of Mexico, San Luis Potosí, Hidalgo, etc.

It is a herbaceous, 30-80 cm. woolly plant, with alternate, long, narrow leaves, terminal inflorescence grouped in yellow, bright heads, multi-orderly involucre, scarious and glossy bracts; heterogamous; flowers at the margin are feminine; those of the center are hermaphrodite; flat, naked receptacle, cylindrical, oblong achenes, single-orderly hairy pappus; odorless.

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. There are other species, such as G. Berlandieri, D.C., G. Canescens, D.C., G. Oxyphyllum, D.C., G. Sphacellatum H.B.K., very probably with similar features.

A few flowers are boiled in a cup of water to drink it hot, preferably at night.

Source: Farmpacopea Mexicana.

ARTURO MAY MIJARES
PERITO TRADUCTOR AUTORIZADO
POR EL H. TRIBUNAL SUPERIOR
DE JUSTICIA
DEL ESTADO DE NUEVO LEON

MEXICAN GORDOLOBO
(Great Mullein)

Synonyms; Papaconi, Tzompotonic, Tlacochichic.
Gnaphalium conoides, H.B.K., G. Berlandieri, D.C., etc.- Composite.

Location: Valle de México

Part Used: Inflorescence.

Physical features: Multi-orderly involucre, scarious and glossy bracts; heterobamous, flowers at the margin are feminine; those of the center are hermaphrodite; flat, naked receptacle; cylindrical, oblong achenes; single-orderly hairy pappus; odorless.

Those are the general features presented by several species of Gnaphalium, used under the same number of great mulein.

Usage: Its features seem to be the same as European great mullein Verbascum Tahpsus, L., that is, emollient and pectoral substance, so it is used as a substitution.

BAJO PROTESTA DE DECIR VERDAD, EL SUSCRITO ARTURO MAY MIJARES, PERITO TRADUCTOR AUTORIZADO POR EL TRIBUNAL SUPERIOR DE JUSTICIA DEL ESTADO DE NUEVO LEON MEDIANTE OFICIO No. 413/80 DE FECHA 26 DE MAYO DE 1980. CERTIFICA Y DA FE QUE LA ANTERIOR TRADUCCION DEL INGLES AL ESPAÑOL QUE CONSTA DE 1 FOJAS, ES FIEL Y CORRECTA, SIN OMISIONES NI AGREGADOS, LA CUAL CORRESPONDE AL DOCUMENTO TAMBIEN ANEXO REDACTADO EN IDIOMA INGLES INTEGRADO POR 8 FOJAS EXPEDIDA EN MONTERREY, N. L., A 22 DE Octubre DE 1980 CONSTE.

EL C. ARTURO MAY MIJARES
PERITO TRADUCTOR
R. F. C. MAMA-441224.

A. May