

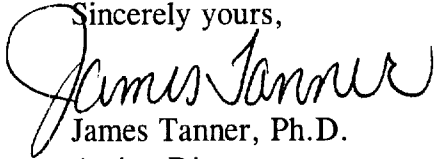


DEC 17 1996  
**Memorandum**

Date **DEC 26 1996**  
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: Leucophyllum texanum  
Solanum verbascifolium  
Conyza filaginoides  
Castilleja canescens  
Firm: Malabar Productos Naturales  
Date Received by FDA: October 16, 1996  
90-Day Date: January 13, 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 ingredients should be placed on public display in docket number 95S-0316 after January 13, 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

DEC 17 1996

95S-0316

RPT 7



RECEIVED BY THE  
OFFICE OF SPECIAL  
NUTRITIONALS, HFS-450

'96 OCT 16 P2:22

September 23, 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 four new dietary ingredients which will be introduced in the dietary supplement Higabol. 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:

**Cenizo** (scientific name *Leucophyllum texanum*)

- M.Martinez, *Las Plantas Medicinales de México* (1959), *Leucophyllum texanum*, pp. 393-394
- M.S. Nicholson and C.B. Arzeni. *The Market Medicinal Plants of Monterrey* (1993), *Economic Botany*, Vol.47, pp.190.

**Malabar** (scientific name *Solanum verbascifolium*)

- M.Martinez, *Las Plantas Medicinales de México* (1959), *Solanum Verbascifolium*, pp.487.
- J.F. Morton. *Atlas of Medicinal Plants of Middle América, Bahamas to Yucatán* (1981) *Solanaceae*, pp.803

**Simonillo** (scientific name *Conyza filaginoides*)

- M.S. Nicholson and C.B. Arzeni. *The Market Medicinal Plants of Monterrey* (1993), *Economic Botany*, Vol.47, pp.186.
- E.Estrada Lugo/Universidad Autónoma Chapingo, *Plantas medicinales de México* (1992), pp.130
- Sociedad Farmacéutica Mexicana. *La Nueva Farmacopea Mexicana* (1952), *Conyza filaginoides*, pp.383-385
- M.Martinez, *Las Plantas Medicinales de México* (1959), *Conyza filaginoides*, pp.291-293

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**Garañona** (scientific name *Castilleja canescens* )

-T. Cechini. *Enciclopedia de las Hierbas y las Plantas Medicinales* (1978), pp.483

-M.Martinez, *Las Plantas Medicinales de México* (1959), *Castilleja canescens*,pp.142-143

-Sociedad Farmacéutica Mexicana. *La Nueva Farmacopea Mexicana* (1952), *Castilleja canescens*. pp.146-147.

Copies of the ten articles are enclosed, along with English translations (made by an expert translator) of the eight articles originally in Spanish.

These new dietary ingredients 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 T.  
Export Manager

## **NEW DIETARY INGREDIENTS:**

- \*Leucophyllum texanum**
- \*Solanum verbascifolium**
- \*Conyza filaginoides**
- \*Castilleja canescens**

# ENGLISH TRANSLATIONS

\**Leucophyllum texanum*

\**Solanum verbascifolium*

\**Conyza filaginoides*

\**Castilleja canescens*

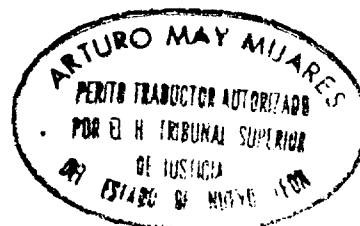
**CENIZO (*Leucophyllum texanum*)**

Located in Tamaulipas, Nuevo León, Coahuila. It's a dense tomentose bush, with almost obovated leaves measuring 2-2.5 cm and almost sessile, of a white color. In Nuevo León it's called "palo cenizo" and in Coahuila "hierba del cenizo". It's used commonly against fever, drinking an brew made with the leaves. Also useful against ichterycia and liver ailments. Similar properties are also attributed to the *leucophyllum ambiguum*, located in the states of Zacatecas to Hidalgo.

The name of "cenizo" is commonly applied to a species in the north of this country, (from Baja California to Coahuila, San Luis Potosí and Zacatecas), called *Atriplex canescens* (Pursh.) Nutt. It receives the name of "costillas de vaca" (cow's ribs) in Zacatecas, and "chamiso" in Baja California and Chihuahua. This plant is not mentioned as medicinal.

Of the *Atriplex lentiformis*, that exists in Northern Sonora, it is said that the natives use the powder of the root to cure wounds.

**SACA MANTECA (Sinaloa) *Solanum verbascifolium*. L.** It's very commonly found in most Mexico. In Tamaulipas it's called "salvadora"; "hierba de San Pedro" and "gordolobo" in the State of Nuevo León; "sosa" in Morelos, Veracruz and San Luis Potosí; "xtuhum", "tonpaap" and "xaxox" in Yucatán; "hoja de manteca" or "galatea" in Oaxaca; "friega plato" or "berengena" in Veracruz. Its leaves are finely vellous and are applied heated to the forehead to calm headaches, and in poultice against ulcers. In Nayarit the cooked roots are taken against fever.



For diseases of the excreting system:

Tzonpopato (*Conyza Filaginoides* Hieron?) Of dry and hot quality, when mixed with tlatlancueye, it cause urination; mixed with oatmeal, it was used to relieve the urine acidity.

#### SIMONILLO

*Conyza filaginoides*, Hieron.

Description: Simple and ordinary stem on the base, very straight; but occasionally with 2 or 3 branches, semi-bark, with a "gnaphalode" aspect, with some 0.30 to 0.40 mm in height, slightly rounded, the upper branches are very short and finished in a capitulum, of some 0.03 to 0.04 mm in length and almost fastigiate; it has alternate leaves of some 0.014 to 0.015 mm in length by 0.002 to 0.004 mm in width, measured linear, in the shape of a sharp dent, with its teeth pointed upwards, with a silky-arachnoid touch, as well as on the stem, specially in the upper part; lonely and terminal inflorescence and formed by 2-3 discoid heterogamous capitulums; bell shaped involucrem; biserial bracts, imbricate, green in the center, purple on the tip, transparent in the edges and hairy on the outside; slightly convexed receptacle, alveolate and barely striped; feminine flowers on the periphery, multi serial, tubular corollas, filiform, trimmed smooth, and 1/4 the length of the stylo; hermaphrodite flowers, regular, tubular with the limbo slightly broadened and 5-dented; stamen included; compressed achene, egg shaped, and hairy; biserial vilane, outside series much shorter than he inner one.

In phramacies it's sold in small bulk packages of approximately 30-40 grams.

Harvesting Period: July, August and September, when it flowers.

Substitutes: Frequently the same name is given to *C. parvifolia*, DC and *C. gnaphalodes*, H.B.K., which seems to be the same species modified by the environment. The people use these species with the same results. It should not be confused with *Calea zacatechichi*, normally called zacatechichi.

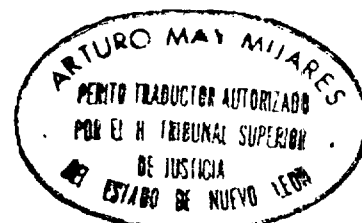
Chemical Composition: A body improperly called lenesene, which perhaps could be glucosate, of a greenish yellow color, water and alcohol soluble, very little soluble in sulphuric ether and insoluble in petroleum ether. The aqueous solution of this principle produces, when agitated, abundant foam. Besides from the glucosate it contains fatty material, resin, pectic substances, clorophile and mineral salts.

Therapeutic properties: Bitter tonic and cholagogic.

In strong doses it produces nausea and bilious vomiting. Toxic in higher amounts; it then alters the blood cells and the biliar functions of the liver and turns the urine dark and albuminous.

It is used to fight gastric colds accompanied by dyspepsia, and to cure the colds of the biliary conducts.

Dose: Brews of 5.00 grams in 200 c.c. of water, before breakfast, for several consecutive days; extract, 0.10 grams before each meal.



## SIMONILLO

Other common names: zacachichi (bitter herb).

Botanical name: *Conyza filaginoides* D.C. Family of the Composites.

Where it inhabits: Mexico Valley, Morelos, Michoacan, Hidalgo, Oaxaca, etc.

Characteristics: It is a herb that reaches 30-40 cm in height, of a simple stem, with branches only on the upper part; alternated leaves, dented, silky, the same as the stem; of some 3-4 cms long; solitary, terminal inflorescence, of 2-3 capitulum; involucre of biserial bracts, with its center green and the tips purple, feminine filiform flowers of shorter length than the stylo; its hermaphrodite flowers are tubular and regular with included stamen. It flowers in August and September.

Parts used: All the plant. (It has a very bitter taste).

Chemical composition: The analysis was made in the National Medical Institute, finding in the aqueous extract, salts, pectic substances and a bitter matter, that is an alkaloid called lenesene.

"The powder of the plant was saturated with gasoline and sulphuric ether, and partially only with absolute alcohol, it was saturated in distilled water. Absolute alcohol was added to the aqueous solution to precipitate the viscous principles and filtering and evaporating the liquid a bitter principle was therefore obtained".

From the experiences practiced in the same establishment, the conclusion is reached relative to the fact that simonillo has "a general energetic physiological action, operating, it seems, specially on the blood", if injected in certain doses, but taken gastrically it is harmless.

Uses: Since almost ever, the natives have used simonillo to fight some gastric diseases. Friar Francisco Ximenez, in his book "Los Cuatro Libros de la Naturaleza" (The Four Books of Nature), says it "excretes by vomiting all the principal fumes of cholera and phlegms", but also that "it should not be administered to the ill with fever".

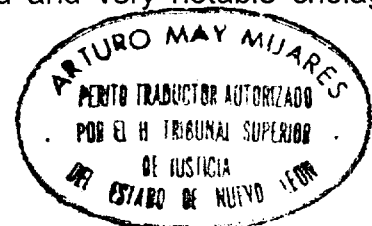
"It cures repression and ahito, opens the appetite and improves notably those with stomach pains due to the fact that the food lacks natural heat".

In the popular markets, there always is simonillo available, and it's recommended for "bile and tiredness".

Dr. Villaseñor, after observing several cases, concluded that simonillo increases the excretion of gastric fluids and bile, and excites the stomach's and intestinal peristaltic movements.

"Several doctors have prescribed it as a bitter tonic in gastric colds accompanied by dyspepsia and lack of appetite. But the main use is for curing the hepatic cramps by the brew of the plant, taken daily before breakfast during long periods" (Mat. Médica).

Dr. Eduardo Liceaga used this herb with very satisfactory results in numerous cases of colds in the biliar paths. "Pain was calmed, jaundice was reduced and very notable cholagogic





effects were observed. He used the cooking at the dose of 180 grams in the morning and another similar dose after lunch.

The doses should be reduced in case of vomit.

Against hepatic colics, the following formula has been recommended:

Powder of the whole plant (unsifted)	.....	5 grams
Boiling water	.....	200 grams

The brew is boiled for half an hour, drain and take unsweetened, in the morning, before breakfast, continuing the treatment for several days, reducing the dose if nausea occurs.

The extract can be used, preferably the hydro-alcoholic, in 5 centigram pills to be taken two daily before breakfast.

It has also been recommended in enema against meteorism (accumulation of gas in the intestine) and constipation. For this, use the cooking of simonillo, 10 grams for 500 of water, in an enema retained for some time.

#### References:

Dr. Fernando Altamirano. *Materia Médica Mexicana*. I, Pg. 285. Mexico, 1894

Francisco Ximenez, "Los Cuatro Libros de la Naturaleza". Pg. 161. Edition of Morelia, 1888.

Dr. Gonzalo Castañeda, *Catarros de las vías biliares*. Thesis, Mexico, 1893.

Prof. Miguel Sandoval. *The zacatechichi*. Thesis, Mexico 1882 (in this thesis, simonillo is mistakenly identified as *calea zacatechichi*).

Dr. Leopoldo Flores. *Manual terapeutico de las plantas mexicanas*. Archives of the Instituto Médico Nacional. VII. Pg. 356. Mexico, 1907.

Dr. I. Villaseñor, Archives of the Instituto Médico Nacional. Mexico, 1907.



## **GARAÑONA or MIRTO CIMARRON**

(*Castilleja canescens*)

Plant from the scrofulanate family, spontaneous in Mexico. It's a shrub of some .40 to 1.0 mts; the stem is pubescent and rough, the leaves of linear-lanceolate shape, and sessile. The flowers, with bilabiate calyx and corolla, elongated, are clustered in inflorescences forming a compact tusk, with floral bracts of bright red color.

### **PREPARATION**

The upper is the part of the plant used in home medicine and is taken before breakfast in a dose of 4 grams of plant in 150 grams of water. Acts as diuretic, it regularizes digestion and increases the biliar excretions.

### **GARAÑONA**

Other common names: Cola de borrego, mirto cimarrón, enchiladitas, bella Inés.

Botanical name: *Castilleja canescens* benth, and other species. From the scrofulanate family.

Where it grows: Mexico Valley, San Luis Potosí, Oaxaca, State of Mexico, etc.

Characteristics: Sub-shrub from 0.3 to 1.0 mts tall, canescent and rough stem; linear alternate leaves, lanceolate, semi-amplexicauline, its acute floral bracts, or red color. The flowers are produced in a dense tusk. Elongated and grooved calyx, with 2-3 tooth, elongated corolla.

Parts used: Leaves, stems and flowers.

Chemical composition: Clorofile, yellow pigment matter, red pigment matter, essential oil, resin, fatty materials, extractive matter, gum, starch, glucose and traces of tanine; carbonic, salisilicate, clorhydric, sulphuric and phosphoric acids; soda, potash, magnesia, limestone and iron.

Common Uses: Brewed for several stomach ailments; it causes salivation, increases urination and probably bile excretions; it normalizes digestion and has rendered valuable services in cases of blood poisoning due to the bile.

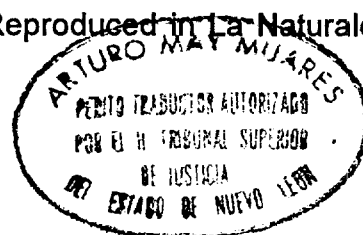
According to Dr. J. Galindo, as quoted by Drusina, it cures hepatic colics, and refers to a case "determined by the contraction of the bile channels; which, producing the accumulation of bile in the gall bladder, determining the acute pain that characterizes the detection of this fluid in it. Dyspepsia occurred consequently to this bile poisoning state and due perhaps to the lack of nervous action in the stomach, accompanied by vomiting. With the assistance of the plant's brew (4 grs per 120 grs of water) before breakfast, pain went away, and all other symptoms indicating the mixture of bile and blood, that is, the ichterycian color of the skin and the characteristic coloring of urine".

The author further adds his belief that the best pharmaceutical practice is the brew, the hydro-alcoholic extract and the dye, and concludes: "It would be desirable that doctors could perform serious research on this vegetable, since I have no doubt that, due to its special properties, it could be a brilliant acquisition for therapeutics".

Dose: Use the brew. Four grams per 120 grams of water, taken before breakfast. Also could be used in form of dye or hydro-alcoholic extract.

References: Fernando Luna Drusina. Thesis, Mexico, 1884. Reproduced in *La Naturaleza*, Book 7.

Farmacopea Mexicana, Mexico, 1896



## COLA DE BORREGO

Synoms - Castilleja, enchiladitas, bella Inés and mirto cimarrón.

Technical Name - *Castilleja canescens*, Benth., scrofulaneous.

Vegetation Area - Sierra Madre, San Luis Potosí and sundry points in the State of Mexico.

Parts used. All the plant.

Description - Straight stem, with alternate branches, sub-logs, hairy, rough and rouge. Cauline and tentering leaves, simple and alternate, semi-amplexicauline, linear lanceolate, extended, rough and hairy, greenish color on both sides, with three very distinctive nerves. The flowers are oval-lanceolate and colored red or orange on the tips. The inflorescence is a large clustered tusk, with flowers; lower flowers slightly pedicellate. Complete flowers, gamosepalous calyx, hypogene, tubular, persistent, tapered at the base, reddish, vellous, grooved in the rear with two lobes; gamopetalous corolla, tubular hypogene, vellous, with bilabiate limbo; the upper lip shaped as a tight hull, stretched, concavely curved; the lower lip is trilobate, very small and curved inward. Bidinamo stamen, ascending under the hull, inserted in the corolla and alternated with its lobes; cylindrical filaments; bilocular antennae, dehiscent locules along a different longitudinal channel, approximated, parallel, linear-oblong with bruhes in the base; semi-fixed exterior, hanging interior. Free ovarium, bi-loculate, with numerous ovules; the fruit is a capsule with septicide dehiscence.

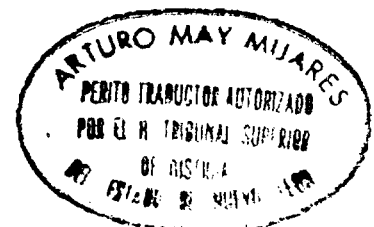
This drug has a herbish smell and bitter flavor.

Substitute - It's commonly substituted with "castilleja arvensis", Cham.. et. Schlt. which has the same common names and is easily known by its leaves which are longer than those of the species.

Chemical composition - Contains essential oils, fatty materials, bitter principle, yellow pigment matter and other non-important principles.

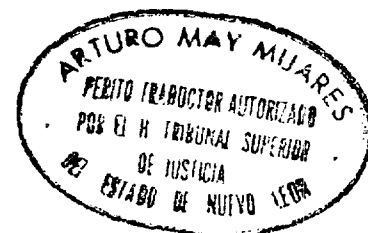
Therapeutic properties - Increases salivar and urination excretions.

Dose - Brew at 4%.



MOST COMMON ABBREVIATIONS  
IN THIS BOOK

a ant	before, prior to,	extra	extraction
a. vg.	vegetation area	Fals.	falsification (fraud)
adult.	adulteration	f.b.	gross formula
alt.	alteration	f.c.	constitution formula
andto	antidote	Form. farm.	pharmaceutical formulas
[a] <sup>p</sup>	rotary power	fr.	french
B.M.	water bath	gr.	gram
Benth.	Bentham	Gonz.	González Francisco
c.b.	as much as needed	Guib.	Guibort
c.b.p.	as much as needed to do	Hern.	Hernández
c.s.	sufficient amount	Herr.	Herrera
carac.	characters	H.B.K.	Humbolt, Bompland & Kunth
carac. f.	physical characters	higr.	hygroscopic
carac. f. q.	chemical & physical characters	Incomp.	incompatible
carac. h.	histological characters	inf.	infusion
carac. h. q.	histo-chemical characters	ing.	english
c.c.	cubic centimeters	Jaq.	Jacquin
c.c.	of each thing	Jim.	Jiménez
coc.	cooked	K.	Kerwins
Comp.	composition	lat.	latin
Comp. Q.	chemical composition	lev.	turning counter clockwise
conf.	confections	l.pr.	production site
cons.	conservation	L. Linn.	Linneo
contrav.	counterpoison	mac.	maceration
Cloq.	Cloquet	Mar.	Martius
cult.	cultured	Mex.	Mexican
Chev.	Chevrolat	Muhl.	Muhlenberg
d.	density	N.	Normal
ds.	dosage	N/2	half normal
Descr.	description	N/10	decinormal
dex.	turning clockwise	N/50	Fiftieth normal
D.C.	De Candolle	N/100	One hundredth normal
desf.	Desfontaines	2N.	double normal
Dur.	Durand	n.ind.	indian name
e. coln.	collection period	n.t.	technical name
ens.	assay	n.v.	common name
		of.	office
		Oliv.	Olivier
		P.	properties



P.F.———— physical properties  
 P.Q.———— chemical properties  
 P.a.———— atomic weight  
 P.m.———— molecular weight  
 pp.———— proportion  
 Prep.———— preparation  
 Pers.———— Person  
 Priest.———— Priestly  
 P. terp———— therapeutical properties  
 P.U.———— usual parts  
 pulv.———— make into powder  
 Purif.———— purify  
 Rio Loza———— Rio de la Loza, Leopoldo  
 Roxb———— Roxburgh  
 R.P.———— Ruiz y Pavón  
 S.———— synonymous  
 sp.n.———— new species  
 S.R.———— reactive solution  
 sust.———— substitution, substitute  
 S.V.———— volumetric solution  
 Schied———— Schiede  
 Schlecht———— Schlechtendal  
 Swar.———— Swart  
 t.———— temperature  
 t.e.———— boiling temperature  
 t.f.———— fusion temperature  
 U.———— uses  
 tint.———— tincture  
 U.ec.———— economic uses  
 U.ind.———— industrial uses  
 U. med.———— medicinal uses  
 U.m. y D.———— medicinal uses and dosages  
 U. terp.———— therapeutic uses  
 U. v.———— common uses  
 v.———— volume  
 varied.———— varieties  
 vea)———— see this or that  
 vg.———— vegetables  
 Willd.———— Willdenow



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