



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

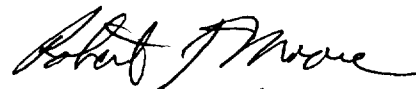
Memorandum

Date · APR 10 1998 3902 '98 APR 14 P2:29
From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy
(DPEP), Office of Special Nutritionals, HFS-456
Subject 75-day Premarket Notification for New Dietary Ingredient
To Dockets Management Branch, HFA-305

New Dietary Ingredients: Tronadora (*Tecoma mollis*, H.B.K.)
Zoapatle (*Montanoa tormentosa* Cerv.)
Pericon (*Tagetes lucida* Cav.)
Espinosa (*Loeselia mexicana* Lam.)
Chancarro (*Cecropia obtusifolia* Bert.)

Firm: Malabar Productos Naturales
Date Received by FDA: January 27, 1998
90-day Date: April 26, 1998

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 April 26, 1998.


Robert J. Moore, Ph.D.

95S-0316

RPT 20

APR 10 1998
3 0 3 98 APR 14 P 2:29

Natalia Garza
Export Manager
Malabar Productos Naturales
Barbadillo 416 Norte
Apdo. Postal 212
Cd. Guadalupe, N.L. CP 67100
MEXICO

Dear Ms. Garza:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 23, 1998, making a submission pursuant to 21 U.S.C. 350b (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) for a new dietary ingredient. Your letter notified FDA of your intent to market five new dietary ingredients.

21 U.S.C. 350b requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Your submission contained information that you purport to be evidence establishing that the new dietary ingredients Tronadora (*Tecoma mollis*, H.B.K.), Zoapatle (*Montanoa tormentosa* Cerv.), Pericon (*Tagetes lucida* Cav.), Espinosilla (*Loeselia mexicana*, Lam.), and Chancarro (*Cecropia obtusifolia* Bert.), when used under the conditions recommended or suggested in the labeling of the dietary supplements, will reasonably be expected to be safe. FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Tronadora, Zoapatle, Pericon, Espinosilla, or Chancarro will reasonably be expected to be safe.

The information in your submission does not provide an adequate basis to conclude that Tronadora (*Tecoma mollis*, H.B.K.), Pericon (*Tagetes lucida* Cav.), Espinosilla (*Loeselia mexicana*, Lam.), and Chancarro (*Cecropia obtusifolia* Bert.), when used

under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 343(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Based on the information in your submission, FDA disagrees with your conclusion that *Montanoa tormentosa*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Your submission contains information demonstrating that this botanical contains several terpene compounds that have adverse affects on fertility, including reduced sperm motility, inhibited implantation, stimulation or inhibition of uterine contraction, histologic endometrial changes, resorption of the early term fetus and abortion later in pregnancy. The submission also contains information that describes adverse affects associated with the consumption of this plant, including abortion, pain, exhaustion, burning thirst, respiratory fatigue, and death. Therefore, your product is adulterated under 21 U.S.C. 343(f)(1)(B) because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Please contact us if you have any questions concerning this matter.

Sincerely,

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

cc:

HFA-224 (w/incoming)
HFA-305 (Docket No. 95S-0316)
HFS-22 (CCO)
HFS-308 (Bolger, Wagstaff)
HFS-456 (r/f, File)
HFS-450 (r/f, File)
r/d:HFS-456:RMoore:3/20/98
revised per:GCF-1:Dorsey/Nickerson:4/8/98
f/t:rjm:HFS-456:4/8/98:docname:56802.osn.disc28



56802
390 RECEIVED
1/27/98

January 23, 1998

P2:29

Victor Fratelli, Ph.D.
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW.,
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 five new dietary ingredients which will be introduced in the following dietary supplements: **Jointaid, Pancrease, Gastritease, Menstrualaid, Laxatease**. These five 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.

Manufacturer of the dietary supplement that contains five new dietary ingredient:
Malabar Productos Naturales S.A. de C.V.

Address:
Barbadillo # 416 nte.
Guadalupe Centro
Guadalupe, N.L. 67100
México

The **new dietary ingredients**, and description of the dietary supplements that contain the new dietary ingredients are:

- Tronadora** (scientific name *Tecoma mollis*, H.B.K. or *T.stans* Juss., Mexican name Tronadora)
- Zoapatle** (scientific name *Montanoa tormentosa* Cerv., Mexican name Zoapatle)
- Pericón** (scientific name *Tagetes lucida* Cav. or *Tagetes florida* Sw., Mexican name Pericón)
- Espinosilla** (scientific name *Loeselia mexicana* (Lam.) Brand, Mexican name Espinosilla)
- Chancarro** (scientific name *Cecropia obtusifolia* Bert., Mexican name Guarumbo)

The two presentations of the dietary supplements are infusion tea bags (1gr) and capsules (350 mg.).

Level of the new dietary ingredient in the dietary supplement:

- 1) Pancrease
* **Tecoma mollis, H.B.K. (10%)**

Suggested use:
Infusion: *Take one cupful before breakfast and after each meal.*
Encapsulated: *Take two capsules after each meal.*

- 2) Gastritease
* **Tecoma mollis, H.B.K. (10%)**

Suggested use:
Infusion: *Take one cupful before breakfast, after each meal and before going to bed.*
Encapsulated: *Take two capsules after each meal and before going to bed.*

Level of the new dietary ingredient in the dietary supplement:

1) Menstrualaid This dietary supplement includes in the labeling the following NOTICE.

* **Montanoa tormentosa Cerv. (20%)**

Suggested use:

Infusion: *Take one cupful after each meal.*

Encapsulated: *Take two capsules after each meal.*

NOTICE: Not to be ingested in case of pregnancy and during breast-feeding

Level of the new dietary ingredient in the dietary supplement:

1) Jointaid

* **Tagetes lucida Cav. (5%)**

Suggested use:

Infusion: *Take one cupful before after each meal.*

Encapsulated: *Take two capsules after each meal.*

Level of the new dietary ingredient in the dietary supplement:

1) Laxatease This dietary supplement includes in the labeling the following NOTICE

* **Loeselia mexicana (Lam.) Brand. (5%)**

Suggested use:

Infusion: *Take one cupful before after each meal, with a full glass of water.*

Encapsulated: *Take two capsules after each meal, with a full glass of water.*

NOTICE: This product contains (Aloe vera; Senna, Cassia angustifolia; Cascara, Rhamnus purshiana). Read and follow directions carefully. Do not use if you have developed diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication or have a medical condition. , consult your physician before using this product.

Level of the new dietary ingredient in the dietary supplement:

1) Pancrease

* **Cecropia obtusifolia Bert. (10%)**

Suggested use:

Infusion: *Take one cupful before breakfast and after each meal.*

Encapsulated: *Take two capsules after each meal.*

The **new dietary ingredients**, and citations to published articles supporting their historical and safety use, are the following:

Tronadora (scientific *Tecoma mollis*, H.B.K. or *T.stans* Juss., Mexican name Tronadora)

-Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana (1952)*, Tronadora, pp.366-368

-M. Martinez, *Las Plantas Medicinales de México (1959)*, Tronadora, pp.330-333

-H. García Rivas, *Enciclopedia de Plantas Medicinales Mexicanas (1982)*, Tronadora, pp.469-470

- B. Juscafresca, *Guía de la Flora Medicinal (1995)*, Garocha, pp.245

- J.F. Morton, *Atlas of Medicinal Plants of Middle América, Bahamas to Yucatán (1981)*, Tecoma stans, pp.829-831

Zoapatle(scientific name *Montanoa tormentosa* Cerv., Mexican name Zoapatle)

- Instituto Mexicano del Seguro Social, *Plantas Medicinales del Herbario IMSS (1994)*, Zoapatle pp.93
- M. Martinez, *Las Plantas Medicinales de México (1959)*, Zoapatle, pp.356-364
- Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana (1952)*, Zoapatle, pp.428
- P. C. Standley, *Trees and shrubs of México (1961)*, Montanoa tormentosa, pp.1531- 1533

Pericón(scientific name *Tagetes lucida* Cav. or *Tagetes florida* Sw., Mexican name Pericón)

- Instituto Mexicano del Seguro Social, *Plantas Medicinales del Herbario IMSS (1994)*, Pericón, pp.104
- M. Martinez, *Las Plantas Medicinales de México (1959)*, Pericón, pp.248-249
- Linares Mazari, *Selección de Plantas Medicinales de México (1993)*, Pericón, pp.68
- S.del Amo, *Plantas Medicinales del Edo.de Veracruz (1979)*, Tagetes lucida, pp.212
- J.F. Morton, *Atlas of Medicinal Plants of Middle América, Bahamas to Yucatán (1981)*, Tagetes lucida, pp.971-972

Espinosilla (scientific name *Loeselia mexicana* (Lam.) Brand., Mexican name Espinosilla)

- M. Martinez, *Las Plantas Medicinales de México (1959)*, Espinosilla, pp.131-133
- Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana (1952)*, Espinosilla, pp.200
- Instituto Mexicano del Seguro Social, *Plantas Medicinales del Herbario IMSS (1994)*, Espinosilla, pp.44
- H. García Rivas, *Enciclopedia de Plantas Medicinales Mexicanas (1982)*, Espinosilla, pp.265
- Linares Mazari, *Selección de Plantas Medicinales de México (1993)*, Espinosilla, pp.40
- P. C. Standley, *Trees and shrubs of México (1961)*, Loeselia mexicana, pp.1211

Chancarro (scientific name *Cecropia obtusifolia* Bert., Mexican name Guarumbo)

- M. Martinez, *Las Plantas Medicinales de México (1959)*, Guarumbo, pp.151-153
- Sociedad Farmacéutica Mexicana, *La Nueva Farmacopea Mexicana (1952)*, Coilotapalo, pp.146
- H. García Rivas, *Enciclopedia de Plantas Medicinales Mexicanas (1982)*, Guarumbo, pp.301
- S.del Amo, *Plantas Medicinales del Edo.de Veracruz (1979)*, Cecropia obtusifolia, pp.52
- P. C. Standley, *Trees and shrubs of México (1961)*, Cecropia, pp.216-217
- J.F. Morton, *Atlas of Medicinal Plants of Middle América, Bahamas to Yucatán (1981)*, Chancarro, pp.142-144

Copies of the twenty-four articles are enclosed, along with English translations (made by a legal expert translator) of the eighteen articles originally in Spanish. These new dietary ingredients will not be marketed in the US for interstate commerce for 75 days after your expected receipt of this notice.

Very truly yours,


Natalia Garza
Export Manager


Lourdes Quintero

Project Development Chemistry Manager

NEW DIETARY INGREDIENTS

Tronadora *Tecoma mollis*, H.B.K. or *T.stans* Juss.

Zoapatle *Montanoa tormentosa* Cerv.

Pericón *Tagetes lucida* Cav. or *Tagetes florida* Sw.

Espinosilla *Loeselia mexicana* (Lam.) Brand.

Chancarro *Cecropia obtusifolia* Bert.

PHOTOSTATICS OF ORIGINAL PUBLISHED ARTICLES
AND THEIR ENGLISH TRANSLATION

DÁVILA'S TRANSLATIONS

ENGLISH-SPANISH-ENGLISH

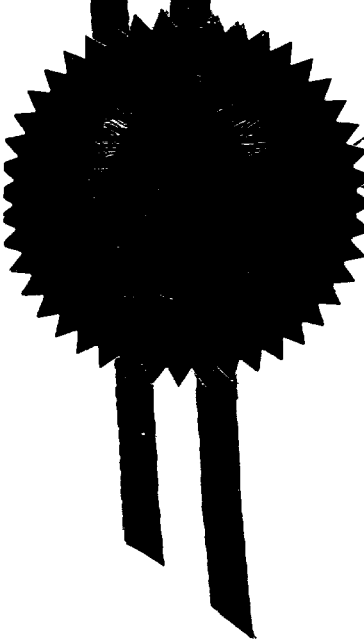
FTRN: DABH-281103T8A - CERTIFIED OFFICIAL TRANSLATOR, GOVERNMENT OF THE STATE OF N.L.
BRAVO SUR 544, COLONIA MARÍA LUISA
64040 MONTERREY, N.L., MÉXICO
PHONES: 3-43-49-25 & 3-42-72-56 FAX: 3-43-49-25

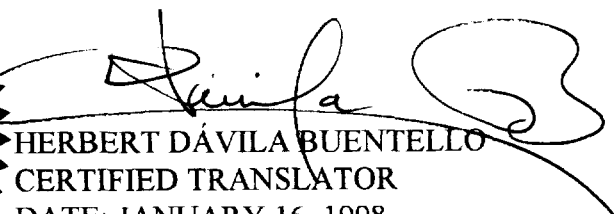
UNITED MEXICAN STATES)
STATE OF NUEVO LEON) SS
CITY OF MONTERREY)

I, the undersigned, HERBERT DÁVILA BUENTELLO, certified translator appointed by the GOVERNMENT OF THE STATE, THE HONORABLE HIGH COURT OF JUSTICE AND THE JUDICIAL POWER OF THE STATE OF NUEVO LEON, under official letter No. 661, issued in Monterrey, Nuevo Leon, on March 14, 1995, hereby CERTIFY under oath that the attached translation(s) from Spanish into English of:

8 HERBS

which appear(s) with my official seal and signature is (are) true and correct to the best of my knowledge, with nothing added and nothing deleted, and pertain(s) to the attached document(s) sealed and signed by me.




HERBERT DÁVILA BUENTELLO
CERTIFIED TRANSLATOR
DATE: JANUARY 16, 1998

ESPINOSILLA

Common names: Herb of the Virgin, Wild myrtle, Hummingbird, Huitzilzitzin, Huitzitzilxochitl, Cuauchichil and Cuachile.

Scientific name: *Loeselia mexicana* (Lamb.) Brand. Family of the Polemoneáceas.

Growing region: The valley of Mexico, Querétaro, Chihuahua, San Luis Potosí, Hidalgo, Oaxaca, and etc.

Characteristics: Multi-limbed, hardy, pubescent, one meter-tall plant; its stalks are glandular in type, as is all the plant; alternate leaves that have a very short petiole and are ovate and lanceolate in shape, with serrated spiny edges, rough to the touch; single flowers with tubular calyx; five-sided red tubular corolla, with five unequal lobes and having 5 protruding stamens with long stylus divided into three parts; very small oval-shaped seeds.

Parts used: the leaves and their stalks.

Chemical composition: Solid fat, neutral resin, chlorophyll, rubber, residues of essential oil, a yellow coloring matter, two acid resins, tannin, alkaloid (leseline), gum, albumin matter, saponine glucose, cellulose, ligneous material, starch and mineral salts.

The alkaloid can be prepared as per the following procedure: "Prepare an alcoholic tincture of the plant by acidulating it with hydrochloric acid; reduce to an extract, and treat with hot water that will dissolve the chlor-hydrate of the alkaloid and the tannin acid; alkalinize with ammonium and evaporate in a steam bath until dry. Treat the resulting extract with benzene, ether or chloroform, which take up the alkaloid, and purify by successive reactions in alcohol" (Medical Substance).

Uses: People use this plant as a purge, for increasing bodily secretions, and for combatting baldness.

Of the experiments that were made with rabbits at the National Medical Institute, it is deduced that the ingestion of this plant does, in fact, provoke biliar and saliva secretions; however, it does not produce perspiration nor does it act as a diuretic.

With relation to its vomiting and purging properties, it was found that these properties are indeed effective, since both the boiling of its parts in water as well as a 10% infusion produced bilious vomit, accompanied by abundant mucous salivation in dogs. The number of provoked vomitings was 2 to 3 times, and this number was the same for bowel movements in a period of 2 to 3 hours, with the status of the animal being normal. The preparation was ingested orally; its aqueous extract was also used. In spite of all of the above, the Medical Substances Treaty does not recommend the

Espinosilla as a purge or vomit inducer. The powder obtained from its stalks, as well as that of its roots in the amount of 1 gram produces 2 or 3 vomits after 2 or 3 minutes of its ingestion without having an additional purging effect.

With respect to combatting baldness, common wisdom is not so wrong, since the liquid resulting from the maceration of the plants parts or the boiling of its leaves in water, due to the saponine it contains, can be of help for conservation, but this does not mean that it will cure baldness.

With respect to its being a fever suppressant, the results have been negative, in keeping with the observations which have been carried out. The doses employed have been ingestion of 80 grams per day of tincture, distributed from 2 to 4 grams of the hydro-alcoholic extract. People use the plant in its fresh state, i.e., dry or washed in water, and then drink water it as water and firmly believe that it is efficacious against fever. Could it not be that the alcoholic extract varies its properties?

Professor Oropeza considers the Espinosilla as having diaphoretic properties.

The Medical Substances record states that the existence of saponine in the plant leads to the supposition that it does have expectorant properties, thus replacing the Virginia milkwort.

Doses: To lower fever: 30 grams of alcoholic tincture; a water or hydro-alcoholic extract as a fever suppressant and emetic, 2 to 4 grams, respectively; the boiled leaves at 10 percent, 150 grams per day.

References: Mexican Medical Substances. Tome II, Page 67, Mexico, 1898.

Dr. Leopoldo Flores, The Therapeutic Manual of Mexican Plants. Mexico, 1907.

Prof. Marcial Oropeza. Thesis, Mexico, 1873. Reprinted in "La Naturaleza" and in "El Estudio," both works published in Mexico.

ESPINOSILLA.

Common names: Herb of the Virgin, wild myrtle, hummingbird, hummingbird flower and cuauchile; in Mexico huitzitziloxochitl and quahuchichil.

Scientific name: *Loeselia coccinea*, G. Don, Polemoniáceas.

Natural Growing Region: The Valley of Mexico, Querétaro, San Luis Potosí, Puebla, Oaxaca, Chiapas, etc.

Parts Used: The plant with its flower.

Characteristics: Sub-ligneous, cylindrical, hairy gray colored stalks, with single, petiolated, alternate leaves, from 0.04 to 0.05 millimeters long by 0.015 to 0.02 millimeters wide, rhomboidal-elliptical in shape, with a spiny serrated border. Its branches are yellowish green in color and rough to the touch. The flowers are axillary and are provided with 5 lineal-lanceolated brachia. They have a tubular calyx with 5 partitions that are found all over the plant; their corolla is and infundibular-bullet formed shape with 5 partitions and red in color, with 5 stamens, which are excluded and almost equal; an tri-ocular ovary with a three fold style. Its fruit is a small capsule which is _____ by its apex, with a few egg shaped seeds.

This drug is odorless and has a bitter taste. When macerated and shaken in water, it forms an abundant and persistent white foam.

Harvest time:- From July to October.

Chemical Composition: It contains an alkaloid (lesiline), saponine, three resins, a yellowish coloring matter, essential oil, tannin, fat and other unimportant small residues.

Therapeutic use.- It is commonly used as a fever repressive in typhus fever, in pneumonia and other fever producing diseases. It also has a reputation as a diuretic and having a diaphoreses property, as a vomiting and purging agent, and it is considered to be beneficial as a hair conservant and to prevent hair ends from splitting.

In reality it appears to produce salivation, acts as an expectorant and acts as an emetic-cathartic.

Common use. It is cooked and its distillate is used as a 10% washing fluid; its tincture is used to rub in for combating seborrhea. Up to 15.00 grains of the plant can be ingested from its cooked distillate per day, and 30 cc of tincture for rubbing in.

ESPINOSILLA

Loselia mexicana (Lam.) Brand Polemoniáceas

Common name: Espinosilla (Federal District, State of Mexico, Hidalgo, Michoacan, Morelos, Puebla, Tlaxcala), guachichile (Durango), huitzizilic (Jalisco), hitzitzilxochitl (Federal District).

Natural growing region: It is common in the Republic of Mexico, from Sonora to San Luis Potosí, Puebla and Chiapas.

Characteristics: It is a 40 to 80 - centimeter high shrub, with stiff leaves that are wider at the base than at the apex, or they are lance-shaped, with edges serrated with spines. Single or various flowers at the axillary positions of the leaves with red colored petals. The shrub is found around bushes and grass in forests; it is abundantly cultivated in especial areas..

Uses: A boiled distillate from the plant is used as a rinse for treating dandruff. For preventing the fall of hair, the plant's infusion or lotion is applied to the head. Another manner of using the Espinosilla in order to prevent hair loss, is to wash hair with a distillate prepared from boiling its leaves, stalks and flowers, to be applied every 15 days.

Observations: During the preHispanic era, and at present, the name of *huitzitzilxochitl* is given the plant because it is a plant that is frequently visited by humming birds and the stated name means "humming bird flower."

ESPINOSILLA (*Loeselia mexicana*)

A Mexican shrub of the polmoniácea family, commonly known by the name of *huizoche*. It reaches one and a half meters in height, with subsessile lance shaped obtuse or acute leaves with a crib shape at their base; it has single flowers, that have a 2 and-a-half centimeter corolla and are 2 and one half centimeters in length, with whole lobules that are much shorter than their stalk. This plant is very beautiful when it is in full bloom. The flowers are yellow in color and from them an infusion prepared has diuretic properties (which excretes a diaphoretic agent (which causes perspiration), it is also emetic cathartic (a purge and provokes vomit at the same time), it is also a fever repressive (against fever) and promotes salivation (it increases saliva secretion).

APPLICATION AND MANNER OF USE

For hair care, the head is washed with a distillate prepared from boiled leaves and flowers.

Losaelia mexicana (Lam.) Brand
Common name: *espinosilla*, *The Virgin's Herb*

DESCRIPTION:

A perennial herb with a sub-shrub base and a glandular pubescent organ, from 40 to 100 centimeters in height; having simple rigid green leaves, that are from 2 to 3 centimeters long, and have serrated (spiny) edges; flowers with a brachia, and bell shaped, with five acute divisions; a red corolla, from 25 to 30 millimeters in length, bell shaped, having its stem divided into 5 oblique lobules which are shorter than the stalk; 5 stamens, inserted in the corolla tube, "exertos": upper ovary, "tricarpetal" tri-ocular, in filiform style, "exerto", with a three-way stigma: capsular fruit, divided into 3 valves, surrounded by the calyx.

It is a Mexican plant, which is found throughout temperate-warm zones.

OTHER NAMES:

Hernández (1959) did not report this plant. De la Cruz and Badiano (1964) mention it with the name of cuahuitzilxochitl, and Sagáhun (1979) and Martínez (1959) also mention it with the name of hitzitzilxochitl. According to Martínez (1969) it is also known by the names of wild myrtle, humming bird, cuahuil and cuachile.

USES: De la Cruz and Badiano (1964) and Sahágun (1979) mention it, but they do not report its use. According to Martínez (1969) this plant is used against fevers, as a vomiting agent, as a purge, and in order to increase biliary and saliva secretions.

In the Sonora market, it is recommended for the following uses: as a fever repressive, taken as a tea; to prevent hair loss, it is macerated and rubbed into hair to be rinsed and hair is thus left shining.

This plant is considered to have a fresh nature.

GUARUMBO

Scientific name: *Cecropia obtusifolia*.

Family name: *Moraceas*.

Common names: Guarumo, Chancarro.

Natural growing region: The State of Veracruz to Oaxaca, and Chiapas and in the Pacific Zone of the southern part of Sinaloa.

Human use: Heart and Kidneys.

Description: This is a tropical tree which reaches a height of from 10 to 20 meters. Its leaves are largely petiolate, palm-lobulate like, and have a diameter of from 20 to 50 centimeters, with its underside having a whitish color. The flowers are grouped in long, hanging tassels, with a length of from 15 to 30 centimeters. The flower stalks produce a milky liquid which is caustic and which is commonly used for eradicating warts; the stalk is hollow and inhabited by ants who attack whoever touches the tree.

This tree is found from Veracruz to Oaxaca and Chiapas and in the Pacific zone of the southern part of Sinaloa. There is another species (*Cecropia peltata* L.), in Veracruz, San Luis Potosí, Chiapas and Yucatán, which is distinguished by its 3 to 5-centimeter-long tassels. In addition, Standley mentions a *Cecropia Schiedeana* Klotzsch in Papantala and other places in the State of Veracruz.

Its leaves are said to have medicinal properties against hydropsy and obesity, and also against asthma and some hepatic infections as well as diabetes. Generally, a leaf is boiled in one liter of water. The cooked distillate contains a substance named "ambaína" which belongs to the saponine group. "It is soluble in absolute alcohol and insoluble in ether and chloroform. In spite of the plant's saponine, it lacks the most common toxic effect of these substances, which provokes a cytolysis of the red blood cells". Dr. Muricio Langpón, a Uruguayan citizen, has carried out pharmaceutical tests and has come to the conclusion that the "ambaína" is a heroic cardiac tonic as well as a diuretic whose action is similar to that of digitoxin, over which it has the advantage of being bearly toxic and almost innocuous," (Alfredo Paredes, Boletín de Ciencias Naturales, L. p. 89. 1952).

The bark of the flower stalks and the tree's roots contain "eccropine" which is a cardiac tonic and a diuretic.

"Experimenting with the alcohol extraction of the guarumbo tree, a weak toxic substance has been found which can be clinically administered in regular quantities. Its main action is on the heart. This action, in non-toxic doses, determines a considerable increase in the amplitude of cardiac contractions; while in larger doses, a progressive slowing cardiac contractions which last for up to forty five minutes is observed following heart attacks, without a complete paralysis of the stated organ. Therefore, in the first case, the active principle of the Guarumbo tree notably increases the energy of ventricular contraction, which results in an excellent condition for therapeutic applications. It has also been noted that the guarumbo extract acts very well on kidneys, since it has appreciable diuretic properties, increasing urinary secretion by three times its normal volume and can reach up to 3,500 gr. and more per day, thus making the anxious type of respiration of the several types of hydropsy normal, moderating and regulating cardiac pulsations."

"The use which can result from this alcoholic extract from the Guarumbo tree (30 drops of potion) per day for a-systolic cardiopathy patients as well as for hydropsy patients is quite notable. This action is so remarkable that our forgotten Garumbo tree could be used as one of the best heart tonics and a notable diuretic. The boiling of leaves operates very well in Korea, for asthma and other nervous afflictions." (David J. Guzmán. Salvadoran Flora).

The above medical transcribed observations refer to the **Cecropia peltata L.** It is presumed that all of the Cecropias have analogous properties.

References: Paul C. Standley and J.A. Steyermark. Guatemalan Flora. XXIV (IV). 1946.

David J. Guzmán. Salvadoran Flora.

William Fawcett. Jamaican Flora. III. 1914.

Maximino Martínez. Plantas de la Flora Mexicana. Mexico, 1959.

GUARUMO (*Cecropia Obtusa*)

Tree that belongs to the *moracea* family, having a trunk and limbs that are knotty, with alternate leaves that are lobbed as with the palm genus, diecious flowers (masculine and feminine). Several species of ants house themselves within its hollow trunk and live symbiotically with it. This tree produces nutritious corpuscles, called Müller, on which ants feed. The hollow trunk is employed by natives as a tube for water conduction; from its bark, fibers are obtained for the manufacture of ropes and cords. Its leaves, with salt, are a good cattle food.

COILOTAPALO

Scientific name: *Cecropia Mexicana*

Family name: *Urticáceas*

Common names: Hemsley, Saruma or Guaruma.

Natural growing region: In the State of Michoacán and the Valley of Mexico.

Human use: Its juice is used as a caustic for painless ulcers, and for eradicating calluses and warts.

SCIENTIFIC NAME: FAMILY: CECROPIA SPECIES: FAMILY: MORAC
 OBTUSE, TRECUL
 COMMON NAME: GUARAMO (Yucatan) KOOCHLE (Yucatan) X-KO (Yucatan)
 BIOLOGICAL FORM: TREE
 VEGETATION TYPE: ACAHUAL

<u>KNOWN USES</u>	<u>EVALUATION</u>	<u>PART USED</u>	<u>HOW TAKEN</u>	<u>REFERENCE</u>
ANTIPYRETIC	100			1182
DIAFORETIC	100			1182
EMENAGOGUE	100			1182
STIMULANT	100			1182
URINE,	100			1181
RETENTION OF CHILD BIRTH	100			1182

SCIENTIFIC NAME: FAMILY: CECROPIA SPECIES: FAMILY: MORAC
 OBTUSIFOLIA BERT.
 COMMON NAME: GUARUMBO XKOOCHLE (Yucatan)
 BIOLOGICAL FORM: TREE
 VEGETATION TYPE: ACAHUAL ACAHUAL DERIVATIVE BORDER OF THE
 RIPARIA OF HIGH JUNGLE 4 JUNGLE OF
 HIGH JUNGLE YEAR ACAHUAL BROSIMUM
 PERENNIFOLIA

<u>KNOWN USES</u>	<u>EVALUATION</u>	<u>PART USED</u>	<u>HOW TAKEN</u>	<u>REFERENCE</u>
DIABETES	100			1183
DIABETES	200	1	3	E.P.
PULMONARY DISEASES	200	1	3	E.P.

BAJO PROMESA DE DECIR VERDAD, EL SUSCRITO ARTURO MAY MIJARES, PERITO TRADUCTOR AUTORIZADO POR EL TRIBUNAL SUPERIOR DE JUSTICIA DEL ESTADO DE NUEVO LEÓN MEDIANTE OFICIO No. 42799 DE FECHA 26 DE MAYO DE 1989. CERTIFICA Y DA FE QUE LA ANTERIOR TRADUCCION DEL ESPAÑOL AL INGLES QUE CONSTA DE.....3.....FOJAS, ES FIEL Y CORRECTA, SIN OMISIONES NI AGREGADOS, LA CUAL CORRESPONDE AL DOCUMENTO TAMBIEN ANEXO REDACTADO EN IDIOMA ESPAÑOL INTEGRADO POR.....3.....FOJAS EXPEDIDA EN MONTERREY, N. L., A 21 DE Enero DE 1998.-CONSTA EL C. ARTURO MAY MIJARES PERITO TRADUCTOR R. E. C. MAMA-441224.

Arturo May

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