



Memorandum

Date: DEC 22 2003 5 13 9 '04 JAN 16 21:50

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Bactris Balanoidea

Firm: Co-Creations

Date Received by FDA: April 7, 2003

90-Day Date: July 11, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutzel for
Tanya Jackson

95S-0316

RPT187



JUN 25 2003

Ms. Kimberly Hudson
Co-Creations
P.O. Box 91896
Long Beach, California 90809

Dear Ms. Hudson:

This is to inform you that the notification, dated April 7, 2003, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) was filed by the Food and Drug Administration (FDA) on April 10, 2003. Your notification identified the substance "Bactris balanoidea" as the product that you intend to market as a new dietary ingredient in a powdered herbal tea form and in the "Bactris balanoidea herbal dietary supplement" form (pill).

The description of the dietary supplement in the notification states that the "Bactris balanoidea herbal tea" should be prepared by boiling 1 to 3 tsp of powdered herbal tea in 24 oz of water. This volume should be reduced by half, filtered and consumed throughout the day. The notification further states that the "Bactris balanoidea herbal tea" can be stored in a glass container and refrigerated for up to 45 hours. The notification states that 1-4 pills of the "Bactris balanoidea herbal dietary supplement" should be taken throughout the day. "For best results, chew and allow it to dissolve in the mouth. Take last dose at least two hours before bed."

Your notification fails to correctly identify the plant that is the subject of the notification. The notification apparently uses the name "Bactris balanoidea" to describe the spiny palm tree *Bactris major* Jacq. var. *major* which is the subject of the new dietary ingredient notification.

Your submission does not include reprints or photostatic copies of references to published literature that you cite as a basis for your conclusion that a dietary supplement containing "Bactris balanoidea" will reasonably be expected to be safe, and does not include complete English translations of submitted information. These items should be included in a complete submission.

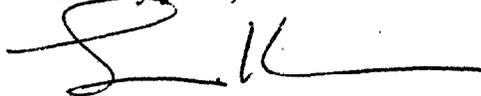
The safety information submitted consists of three acute studies in which the test materials administered to small groups of mice or rats are not clearly identified. The relationship of these tested materials to the botanical preparations that are the subject of the notification is not stated; it is unclear how the information submitted relates qualitatively and quantitatively to the proposed dietary supplement. In addition, the notification includes several testimonials from physicians. The materials consumed by the patients are described variously as a "decoction of the roots" or "a solution made of the root" or "500 mg of the extract." In none of these testimonials is the material consumed by the patients clearly described nor is its relationship to the proposed new dietary ingredient stated."

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your new dietary ingredient, 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. 342(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 an 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).

Your notification will be kept confidential for 90 days after the filing date of April 10, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Pre-Market Notification

For

“Bactris Balanoidea”

A New Dietary Ingredient

Submitted by
Co-Creations
PO Box 91896, Long Beach, CA 90809
(562) 438-9630 Phone (562) 438-1273 Fax
cocreations@charter.net

April 7, 2003

New Dietary Ingredient Notification

- (1) Co-Creations, PO Box 91896, Long Beach, CA 90809, Contact Kimberly Hudson (562) 438-9630 Phone (562) 438-1273 Fax or E-mail cocreations@charter.net

- (2) The Latin name for this new dietary ingredient is *Bactris Balanoidea* from Standely and Steyermark, Flora of Guatemala, (see Appendix 1, 6 pages). *Bactris Balanoidea*'s common name is "Biscoyol" in Spanish. Gluconat, Xaya-X, and Xaya-Y, are brand names not planned to be used in the US.

- (3) "Bactris Balanoidea Herbal Tea" contains 100% *Bactris Balanoidea* dried and ground into powder. The "Bactris Balanoidea Herbal Dietary Supplement" in pill form contains 500 mg of *Bactris Balanoidea* (see Attachment A) Spanish and English translation.
 - (i) The powder is planned to be packaged, in raw bulk form, as an herbal tea. The root of the single ingredient, *Bactris Balanoidea* is dried and ground into a powder. "Bactris Balanoidea Herbal Dietary Supplement" in pill form contains 500 mg of *Bactris Balanoidea*.

 - (ii) Conditions of use recommended on the labeling:
"Bactris Balanoidea Herbal Tea" Directions for Brewing: Boil 1 to 3 TSP of powder herbal tea in 24oz of water. Reduce by half and filter than drink throughout the day. Can be stored in a glass container and refrigerated for up to 45 hours.

"Bactris Balanoidea Herbal Dietary Supplement" in pill form Directions: Take 1 to 4 pills orally throughout the day. For best results, chew and allow it to dissolve in the mouth. Take last dose at least two hours before bed.

Co-Creations make no claims of medicinal use. Currently there are no commonly known medicinal values.

Our product directions suggest a maximum dose of 2 grams, which is 40% of 5 grams found to be safe and non-toxic by doctors administering tea and pills to more than 300 volunteer since 1991 (see attachments).

- (4) History of use and studies. There have been many studies in the USA, Latin America and clinically observed history of use, in Latin America the Netherlands. Summary statements of the **most relevant** studies and observation are attached. In addition, there have been animal studies, in the USA, Guatemala, and Ghana. In all these studies the animals exhibited no signs of acute toxicity.

More than 400 people have been drinking “Bactris Balanoidea Herbal Tea, from 1991 to 1999, and most have switched to taking 500 mg “Bactris Balanoidea Herbal Dietary Supplement” in pill form (up to 5 grams), from 1999 to present. No studies or letters, reporting clinically observed history of use of *Bactris Balanoidea*, observed or reported adverse side effects or toxic conditions. The attached studies and statements conclude that *Bactris Balanoidea* is safe and non-toxic for humans in the oral dosages observed (up to 5 grams). **Therefore, it is reasonable to expect that use of the herb, *Bactris Balanoidea*, under conditions suggested by our products’ labeling (up to 2grams), is safe and non-toxic.**

Attachments and Appendix Summary and Table of Content

- Appendix 1 Latin description of *Bactris Balanoidea* from Standley and Steyermark, Flora of Guatemala, 6 pages.
- Attachment A Description of Supplement (in Spanish with English translations).
- Attachment B Summary statement from Dr Louis Zetima Baldizon's study, from 1991 to 1997, with more than 20 patients without reports of secondary effects or adverse reactions. (Spanish and English translation)., 2 pages
- Attachment C Summary statement from Dr. Mynor R Villeda E's clinically observed history of use, from 1991 to 1999, with more than 300 patients, finding *Bactris Balanoidea* to be non-toxic
- Attachment D Summary statement from Peter J. VanDerSchaar MD PhD Director International Biomedical Center, Leende Netherlands. He clinically observed history of use and encountered no adverse effects, from 1999 to present, with dosages of 500mg to 5 grams,
- Appendix 2 (Spanish) Acute Toxicity Study on Mice by San Carlos University, Guatemala, 4 pages.
- Attachments E (English translation) Acute Toxicity Study on Mice by San Carlos University, Guatemala, 4 pages. Discussion: "The aqueous extract of the roots of this plant could be safely used in humans without risk of toxicity."(page 3 of 4)
- Attachment F Toxicity Report by NAMSA of the USA, 6 pages
Conclusion: "Under the conditions of the study, there was no mortality or significant evidence of toxicity observed in the rats..."
(page 3 of 6)
- Attachment G Summary statement from Dr. Mynor R Villeda E finding *Bactris Balanoidea* to be non-toxic in clinically observed history of use, from 1999 to 2002, with more than 300 patients, with dosages of 500 mg to 5 grams.

BACTRIS Jacquin

Reference: Burret, *Repert. Sp. Nov.* 34: 167, 237, 241. 1934 (including *Guilielma* Martius and *Pyrenoglyphis* Karsten).

Low or tall palms, abundantly armed with short or long spines, the stems solitary or forming dense clumps or colonies, the stems or trunk annulate; leaves terminal or scattered along the upper part of the stem, equally or unequally pinnatisect, the sheath elongate, spiny; spathes 2, longer than the spadix, cymbiform or fusiform; spadix simple or simply branched, inserted among the leaves; flowers monoecious in the same spadix, sessile, the lower ones ternate with the middle flower pistillate, or the sexes irregularly scattered; staminate calyx annular, urceolate, or 3-parted; stamens 6, 9, or 12, included, the filaments subulate, the anthers linear, affixed by the bifid base, erect; pistillate calyx various, the corolla longer than the calyx or of the same length, tridenticulate at the apex, the staminodia free and dentiform, or united in a ring; ovary 3-celled, the 3 stigmas short, sessile, finally recurved; fruit ovoid, subglobose, or oblong, 1-celled and 1-seeded, the stigma terminal, the pericarp hard and almost ligneous or fleshy and juicy, the endocarp osseous, 3-pored near the apex or above the middle; seed pendulous below the apex of the cell, the raphe reticulate, the endosperm uniform, corneous, the embryo opposite one of the pores.

Nearly 200 species are known, distributed almost throughout tropical America but mostly in South America. A few species are found in Mexico, and more occur farther south in Central America. It is probable that others may be found in Guatemala, but they have not been collected.

Many of the species are more offensively armed, perhaps, than any other Central American plants, and that is saying a great deal.

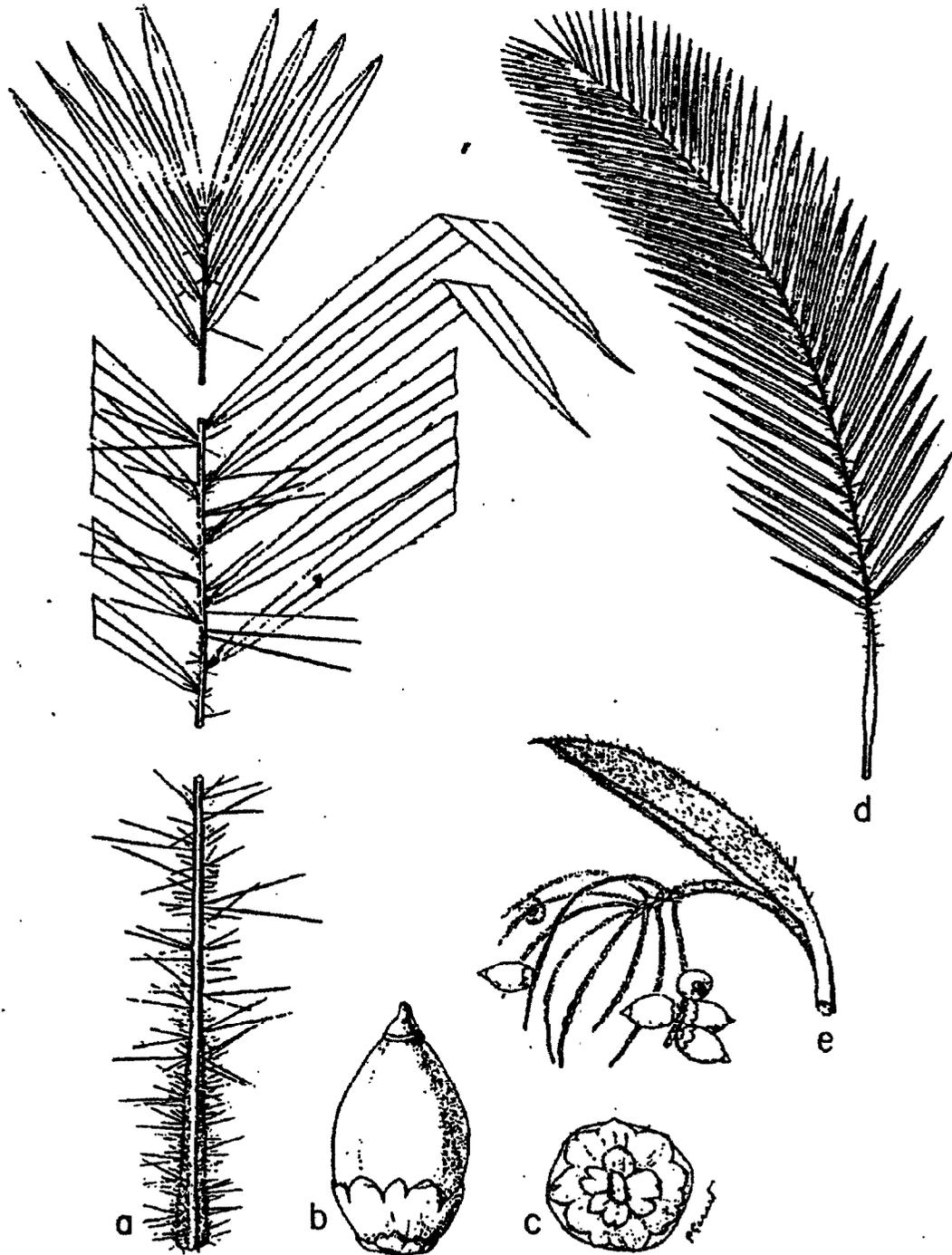


FIG. 38. *Bactris balanoidea*. a, Apical, median, and lower portions of leaf ($\times \frac{1}{2}$). b, Fruit, side view ($\times \frac{3}{4}$). c, Fruit, ventral view ($\times \frac{3}{4}$). d, Entire leaf ($\times \frac{1}{10}$). e, Fruiting branch with spathe ($\times \frac{1}{2}$).

From STANDLEY AND STEYERMARK:
FLORA OF GUATEMALA

STANDLEY AND STEYERMARK: FLORA OF GUATEMALA 211

Bactris Gasipaes HBK. Nov. Gen. & Sp. 1: 302, pl. 700. 1816.
Guilielma Gasipaes L. H. Bailey, Gentes Herb. 2: 187. 1930. *G. utilis*
Oerst. Vid. Medd. Kjoebenhavn 1858: 46. 1859. *Pejibaye*.

Native from Costa Rica to Colombia, and perhaps southward to Peru; planted occasionally in Guatemala at low and middle elevations, particularly in the North Coast, also in Escuintla and at Antigua.

Trunk sometimes 8 meters high or more; fruits either red or yellow at maturity.

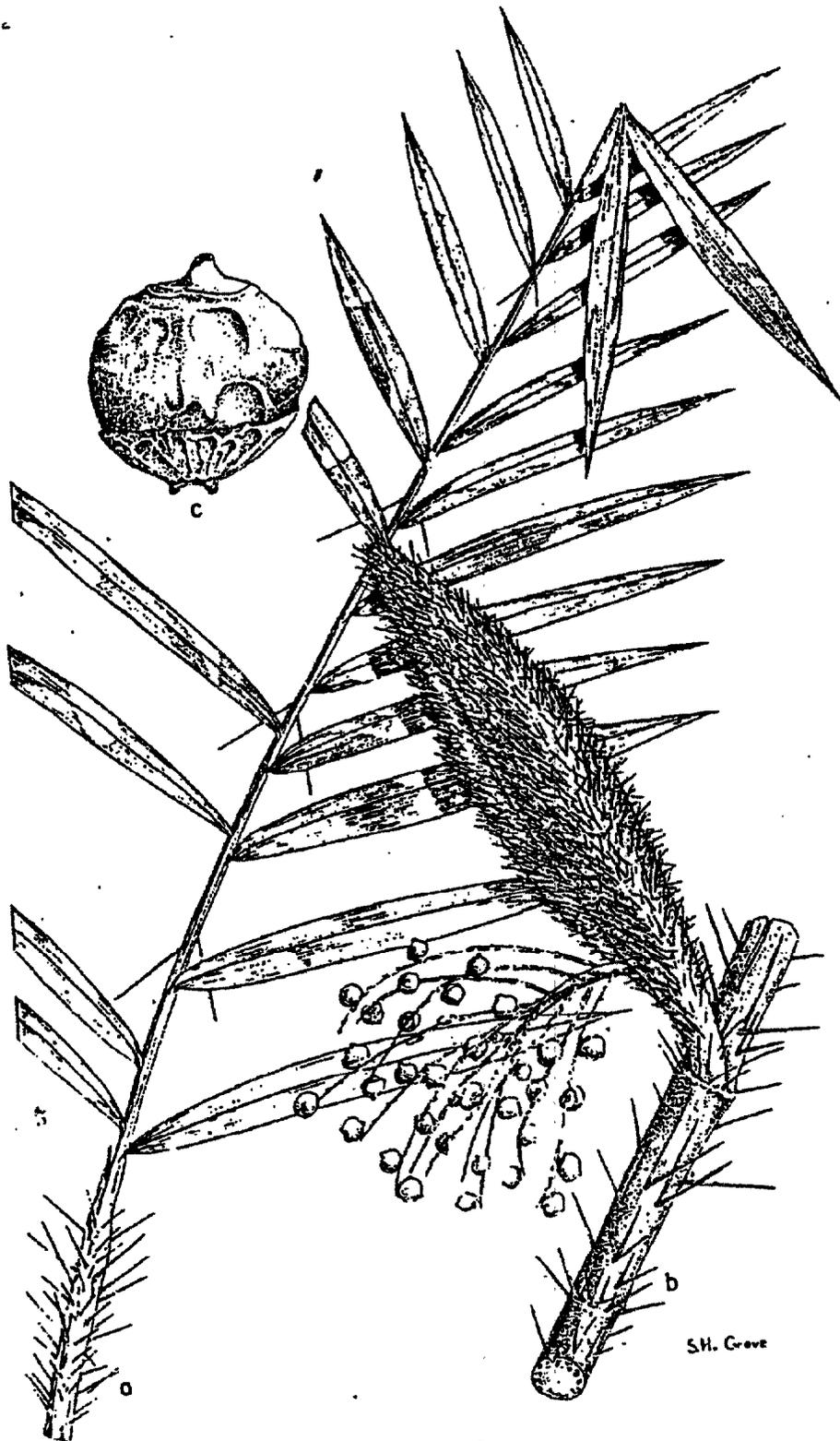
Apparently only a few plants of the pejibaye are in cultivation in Guatemala but in Costa Rica in certain regions they are abundant, both wild and cultivated. It is, however, unknown whether the apparently wild plants really are so, or only remnants of former plantations. In Costa Rica the palm is sometimes called "chonta," a word of South American (Quechua?) origin. In that country the pejibaye is one of the most highly valued plants because of its abundant fruits, which are much sought in the markets during their brief season. When boiled, the flesh of the fruit is mealy and sweet, in flavor and consistency somewhat suggesting boiled chestnuts (*Castanea*) or sweet potato. The very hard wood was used formerly by the Indians of Costa Rica for fashioning bows, arrow points, and other articles. Like other palms, this is an ornamental one for cultivation, the chief objection to it being the too great abundance of offensive spines on the trunk, which makes it unsuitable for planting too close to dwellings.

Bactris trichophylla Burret, Repert. Sp. Nov. 32: 113. 1933; 34: 214. 1934. *Güiscoyol*; *Huscoyol*. Figure 39.

Moist or wet thickets, often in wooded swamps, 900 meters or lower; Petén; Alta Verapaz; Izabal. British Honduras, the type from Stann Creek Valley, at 300 meters, *W. A. Schipp* S368.

Plants rather large and as much as 8 meters high, caespitose and often forming dense clumps or thickets, the stems 3-6 cm. in diameter; petioles 60 cm. long or more, furluraceous-tomentose or glabrate, armed below with slender but stiff, blackish spines 4-7 cm. long; leaf blades 1.5-2 meters long, the rachis densely spiny below; leaf segments about 25 on each side, grouped, linear, mostly 30-60 cm. long and 2-4 cm. wide, acuminate, 2-3-nerved, deep green above, somewhat paler beneath and pubescent; upper spathe 24 cm. long, narrow-acuminate, fuscous-leprose, not at all tomentose, armed with slender spines 5-10 mm. long; peduncles about 11 cm. long, pale-tomentose, densely spiny, the branched portion 16 cm. long, the branches about 40 and 8-12 cm. long, fuscous-furfuraceous; pistillate calyx 3.5 mm. broad, with 3 very short, acute teeth, the corolla obscurely 3-dentate; ripe fruit depressed-globose, mammillate, 1.5 cm. high and broad, glabrous; fruiting perianth 1 cm. broad.

From STANDLEY AND STEYERMARK:
FLORA OF GUATEMALA



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From STANDLEY AND STEYERMARK:
FLORA OF GUATEMALA

STANDLEY AND STEYERMARK: FLORA OF GUATEMALA

This plant and *Bactris balanoidea* are much alike in the characters which have in common their most outstanding and offensive characters, which commonly attract more attention than the differences by which botanists distinguish them. Both plants are known among the native people, who naturally do not distinguish the plants, by the name "huiscoyol" or "guiscoyol," a Nahuatl term signifying "spiny palm." They are abundant in the lowlands of Guatemala.

FIG. 39. *Bactris trichophylla*. a, Leaf ($\times \frac{1}{10}$). b, Portion of trunk with fruiting branch and spathe ($\times \frac{1}{6}$). c, Fruit ($\times 3\frac{1}{2}$).

This page is confidential commercial information--request omissions form internet

Description of Supplement in Spanish

Formula Cualitativa-cuantitativa:

Cada tableta contiene:

Bactris Balanoidea	500 mg
Lactosa	290 mg
Pvp k-30	180 mg
Estearato de magnesio	20 mg
Goma Laca (the coating)	10 mg

Especificaciones del producto:

Forma farmacéutica	Tableta
Forma	Redonda
Color	Café moteado
Olor	Hierba
Diámetro	13 mm
Dureza	7-9 Kg Fuerza
Friabilidad	menor del 0.5%
Peso	0.9 – 1.1 gr/tab
Contenido	Bactris Balanoidea; 450-500 mg/tab
Presentación	Frasco plastico con 50 tabletas etiquetado (this form the local market)

English translation from Spanish above

Each tablets contains:

Bactris Balanoidea.....	500mg
Lactose.....	290mg
Pvp k-30.....	180mg
Magnesium estearato	20mg
Gum lac (the coating).....	10mg

Specification of products

Pharmaceutical forms.....	tablets
Shape.....	round
Color.....	coffee speckled
Smell.....	herbal
Diameter.....	13mm
Brittleness.....	7-9 Kg force
Bitterness.....	less than 0.5%
Weight.....	0.9 – 1.1 gr/tab
Presentation.....	labeled plastic and foil container with 10 tablets (from the local market)

Testimony by Dr. Luis Humberto Zetino Baldizon
Regarding the toxicity of the product
(see English translation on back page)

GUATEMALA, JULIO 1999

A QUIEN INTERESE

DR. LUIS ZETINA BALDIZON

CONFIRMO QUE HEMOS ADMINISTRADO LA SOLUCION HECHA DE LAS RAICES DEL ARBOL DE LAS ESPECIES *BALANOIDEA BACTRIS* EN PACIENTES VOLUNTARIOS, TOMANDO CANTIDADES QUE VAN DE MEDIO LITRO, UN LITRO A LITRO Y MEDIO POR DIA. MAS DE VEINTE PACIENTES HAN TOMANDO LA SOLUCION POR UN PERIODO DE SEIS AÑOS O MAS DESDE 1991.

EL PRODUCTO HA SIDO USADO CON EFECTIVIDAD CLINICA, NO HEMOS TENIDO REPORTES DE EFECTOS SECUNDARIOS O REACCIONES ADVERSAS DURANTE SU UTILIZACION PROLONGADA, TODOS ESTOS AÑOS.

POR ESTA RAZON PUEDO VERIFICAR QUE LA SOLUCION DE *BALANOIDEA BACTRIS*, HA DEMOSTRADO NO SER TOXICA ADMINISTRADA ORALMENTE POR LARGOS PERIODOS DE TIEMPO, Y EN NUESTRA EXPERIENCIA NO POSEE TOXICIDAD CRONICA DE NINGUN TIPO.


Dr. Luis Humberto Zetino Baldizon
MEDICO Y CIRUJANO
C.O.L. 3824

DR. LUIS HUMBERTO ZETINA BALDIZON
MEDICO Y CIRUJANO
COLEGIADO 3824

GUATEMALA, JULY 1999
TO WHOM IT MAY CONCERN

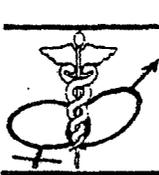
DR. LUIS ZETIMA BALDIZON

I CONFIRM THAT I HAVE ADMINISTERED A DECOCTION MADE OF ROOTS OF THE PLANT *Balanoidea bactris* ON VOLUNTARY PATIENTS TAKING QUANTITIES VARYING FROM HALF A LITER PER DAY TO ONE AND A HALF LITERS PER DAY. MORE THAN 20 PATIENTS HAVE BEEN DRINKING THE SOLUTION FOR A PERIOD OF 6 YEARS OR MORE, SINCE 1991.

THE PRODUCT HAS BEEN USED WITH CLINICAL EFFECTIVENESS WITHOUT REPORTS OF SECONDARY EFFECTS OR ADVERSE REACTIONS DURING THIS PROLONGED USE ALL THESE YEARS.

FOR THIS REASON I CAN VERIFY THAT THE SOLUTION OF *Balanoidea bactris* HAS DEMONSTRATED THAT IT HAS NO TOXICITY WHILE BEING TAKEN ORALLY FOR LONG PERIODS OF TIME, AND IN OUR EXPERIENCE IT DOES NOT POSSESS ANY CHRONIC TOXICITY OF ANY KIND.

*Testimony regarding the toxicity of the product
By Dr. Mynor R. Villeda E.*



Dr. Mynor R. Villeda E.

1 A. AVENIDA 6-12. ZONA 3, RESID. ALTOS BÁRCENAS III. VILLA NUEVA.

Telemensaje (tels. 232-2109 y 238-3911) en unidad 45218

Teléfono: (502) 636-5448

E-Mail: myvilleda@yahoo.com

July 15 of 1999

To Whom it May Concern:

I, hereby confirm that we have been administering a solution made of the root of the tree, species *Balanoidea bactris*, by having volunteer patients drinking quantities varying from half a liter a day to one and a half liters per day on a continuing basis. More than 120 patients have taken the solution on a daily basis for a period of five years or more since 1991. The product has been used by more than 300 patients with clinical effectiveness. There have been no reports of side effects or adverse reactions with long term utilization on a daily basis during that period of time. For this reason I can verify that the solution of *Balanoidea bactris* has been shown to be non-toxic when orally administered over long periods of time and therefore, in our experience does not possess chronic toxicity of any sort.

Dr. Mynor Roberto Villeda Escobar
MÉDICO Y CIRUJANO
Colegiado No. 7564


Mynor Roberto Villeda Escobar
MÉDICO Y CIRUJANO
Colegiado No. 7,564

Date: Fri, 28 Mar 2003 19:35:14 +0100 (West-Europa (standaarttijd))
X-Mailer: IncrediMail 2001 (1850931)
From: "Peter J. VanDerSchaar"
X-FID: BA285063-5BCE-11D4-AF8D-0050DAC67E11
X-FVER:
X-FIT:
X-FCOL:
X-FCAT:
X-FDIS:
X-BG: <B9A0174B-8AB0-449E-A646-3AB95E5501B0>
X-BGT: repeat
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X-ASNF: 0
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X-APF: 1
X-AD: C3C52140-4147-11D4-BA3D-0050DAC68030
X-ADF: 0
X-AUTO: X-ASN,X-ASH,X-AN,X-AP,X-AD
X-CNT: ;

Subject: Re: Fwd: Testimonial
STATEMENT

Dear Mr. Kosowsky,

I hereby testify that I have been using capsules of 500 mg of the Balanoides Bactris extract, for more than 4 years mainly for the purpose of stabilizing serum glucose levels in diabetic patients, type 1 as well as type 2. However, I noticed that this product was also active in combating respiratory viral infections, if administered in higher doses, at the onset of symptoms.

I never encountered any adverse effect, even with the higher doses.

You are free to use this statement for any purpose you wish

Sincerely

Peter J. VanDerSchaar MD, PhD. Director International Biomedical Center, Leende,
Netherlands

Analysis of the roots prepared by the
University of San Carlos in Guatemala

UNIVERSIDAD DE SAN CARLOS
DE GUATEMALA



FACULTAD DE OC. QQ. Y FARMACIA

Edificio "T-12"
Ciudad Universitaria, Zona 12
Guatemala, Centroamérica

INFORME DEL TAMIZAJE FITOQUIMICO DE LA
RAIZ DE *Bactris major*, variedad
major, MEDIANTE CROMATOGRAFIA EN CAPA
FINA

INFORMACION BOTANICA SOBRE LA PLANTA

SINONIMOS: *Bactris balanoidea* Oerst., *Augustinea balanoidea* Oerst.,
Pyrenoglyphis balanoidea Karsten.

NOMBRES COMUNES EN GUATEMALA: güiscoyol, viscoyol, huiscoyol,
pahuac.

NOMBRES COMUNES EN OTROS PAISES: hones (Belice), marayáu (Bolivia),
marajá (Brasil), lata (Colombia), huiscoyol (Honduras, Nicaragua),
Jahuacté (México), caña brava (Panamá), cubarro (Venezuela).

FAMILIA: Arecaceae.

CARACTERISTICAS BOTANICAS:

Tallos en racimo, con frecuencia largos y densos, espinosos, de 1 a 10 metros de alto y 2 a 6 cm. de diámetro. Las hojas 3-10, son pinadas, espinosas; la vaina, peciolo y raquis con muchas espinas cortas entremezcladas con espinas más largas, negras, de 11 cm de largo; hojuelas 24-48 por lado, lineares, ordenadas regularmente, y esparcidas en el mismo plano (rara vez en forma de racimo). Las inflorescencias tienen ramas con flores (1-)5-17, y 2-4 mm. de ancho; bráctea peduncular cubierta en forma difusa a moderada con espinas negras, cafés o amarillas de 2 cm. de largo; frutos irregularmente elipsoides a ampliamente obovoides, de 2.5 a 4.5 cm. de largo y 1.3 a 3.5 cm. de diámetro, de color púrpura-negro, mesocarpo jugoso; el periantio del fruto posee un anillo estaminal.

RANGO Y HABITAT:

Parte sur de Méjico (Chiapas, Oaxaca, Tabasco, Veracruz), costa atlántica y pacífica de Centro América, y a lo largo de la parte

*Analysis of the roots prepared by the
University of San Carlos in Guatemala*

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norte de Sur América, este y norte de Los Andes, hasta el sur de Bolivia, pero no en Ecuador y Perú; siempre cerca de aguas subterráneas. En Guatemala crece en matorrales secos a húmedos, o en bosques, frecuentemente en terreno pantanoso, principalmente a 250 metros o menos, en El Petén, Izabal, Santa Rosa, Escuintla y Retalhuleu, probablemente en la costa pacífica de los departamentos.

USOS:

Los frutos, que tienen pulpa jugosa, son utilizados comúnmente como alimento o como saborizante de bebidas.

OTROS DATOS:

Se divide en cuatro variedades (Henderson, 1994), aunque en algunos casos los límites entre cada una de ellas no siempre son claros: variedad *major*, con inflorescencias que tienen (3-)5-10(-17) ramas con flores, y frutos de 3.3-4.5 cm de largo y 2.3-3.5 cm de diámetro, desde México, Centro América, norte de Colombia, Venezuela, Trinidad, y las Guayanas. Variedad *megalocarpa*, con inflorescencias con 11-17 ramas de flores y frutos de 1.5-2 cm de longitud y 2 cm de diámetro, desde el noreste de Venezuela, Trinidad, las Guayanas, y el noreste de Brasil. Variedad *infesta*, con inflorescencias con (1-)2-5 ramas de flores y frutos de 2.5 a 3 cm. de longitud y 1.3-2 cm de diámetro, desde Venezuela, las Guayanas, Brasil y Bolivia. Variedad *socialis*, con inflorescencias con 8-12 ramas de flores y frutos de 3.5-4 cm de largo y 2-3 cm de diámetro, de Bolivia.

**RESULTADOS DEL TAMIZAJE FITOQUIMICO DE
LA RAIZ DE *Bactris major*, var. *major*.****INTRODUCCION**

En el presente informe se describen los resultados del tamizaje fitoquímico efectuado en la raíz de viscoyol, (*Bactris major*), mediante el método de cromatografía en capa fina, utilizando como fase estacionaria cromatoplacas de sílica gel 60F-254 (Merck, Darmstadt). Se decidió utilizar este método, tomando en cuenta que de todos los muchos métodos cromatográficos disponibles en la actualidad, éste es el más ampliamente utilizado para el análisis de plantas y productos fitoterapéuticos. Posee las ventajas de que el tiempo necesario para demostrar los constituyentes de la planta es relativamente corto, permite hacer análisis semi-cuantitativos, proporciona la huella cromatográfica de la planta, lo cual es útil para evaluar la identidad y pureza, así como para detectar adulteraciones y sustituciones, y además puede ser debidamente documentada.

RESULTADOS:

Compuesto evaluado	Resultado
Alcaloides	Negativo
Saponinas	Negativo
Principios amargos	Negativo
Antraquinonas	Negativo
Aceites volátiles	Negativo
Arbutina	Negativo
Flavonoides	Positivo
Cumarinas	Positivo
Taninos	Trazas
Compuestos fenólicos	Positivo
Terpenos	Positivo

DISCUSION Y CONCLUSIONES

En base a los resultados obtenidos, puede afirmarse que la raíz de *Bactris major*, variedad *major*, contiene los siguientes metabolitos secundarios: por lo menos 11 glicósidos flavonoides, cantidades traza de taninos, cinco cumarinas (una de las cuales es no sustituida) y compuestos fenólicos.

Los flavonoides constituyen uno de los grupos más numerosos y ampliamente distribuidos en las plantas, por lo que no es raro que se encuentren en la muestra evaluada. Estos compuestos son en su mayoría responsables de los colores amarillo y blanco de flores, hojas y frutos. Se caracterizan por su estructura constituida por dos anillos aromáticos, llamados A y B, enlazados a una unidad de tres carbonos que pueden o no formar un tercer anillo, que en caso de existir, es llamado C. Dichos anillos generalmente están sustituidos por varios grupos hidroxilo, con lo cual se convierten en fenoles.

Los flavonoides se emplearon durante mucho tiempo como colorantes de lana, y actualmente se usan en la conservación de grasas o jugos de frutas, debido a sus propiedades antioxidantes. Algunos se emplean como edulcorantes, la rotenona como insecticida, etc. Su acción farmacológica es también extensa y variada. Así, por ejemplo, la rutina y sus derivados actúan contra la fragilidad capilar, los glicósidos de apigenina se utilizan como espasmolíticos, mientras que otros poseen acción antihepatotóxica, antimicrobiana y fungitóxica.

Los taninos son polímeros fenólicos que forman soluciones coloidales con el agua. Están ampliamente distribuidos en plantas vasculares, sobre todo en las angiospermas, principalmente a nivel de corteza y raíz. Se caracterizan por reaccionar con proteínas, formando polímeros estables e insolubles con el agua. Desde el punto de vista industrial los taninos se utilizan para transformar la piel de animales en cuero. También se ha encontrado evidencia de su valor potencial como agentes antineoplásicos.

Las cumarinas son compuestos comúnmente presentes en las plantas, principalmente en las familias Umbeliferaceae y Rutaceae, pudiendo encontrarse en todas las partes de la planta, desde la raíz a las flores y frutos, en donde se pueden hallar ya sea en forma libre o como glicósidos. Su estructura química deriva del sistema benzo-alfa-pirona, el cual contiene un anillo lactónico hexagonal. Generalmente se encuentran formando fenoles. Hasta hoy se conoce un gran número de cumarinas, con múltiples actividades, tales como la acción anticoagulante y antibacterial del dicumarol, la acción antibiótica de la novobiocina, la aguda hepatotoxicidad y

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carcinogenicidad de las aflatoxinas derivadas de ciertos hongos, la actividad estrogénica del cumestrol, la acción fotosensibilizadora de furanocumarinas como el bergapteno y la xantotoxina. Cabe destacar también las aplicaciones de las cumarinas como saborizantes y en perfumería.

Tomando en cuenta que tanto los flavonoides, taninos y cumarinas se caracterizan por contener en su estructura anillos fenólicos, es lógico que se haya detectado la presencia de éstos.

Finalmente los terpenos constituyen un enorme rango de sustancias derivadas de plantas. Todos se basan en la molécula del isopreno, y sus esqueletos carbonados se forman a través de la unión de dos o más de estas unidades. Varían desde los constituyentes de aceites volátiles -los mono- y sesquiterpenos volátiles- (C_{10} y C_{15}) hasta los triterpenos no volátiles y esteroides (C_{30}) y pigmentos carotenoides (C_{40}). Cada una de las distintas clases de terpenos son importantes en el crecimiento y metabolismo de la planta, y en la industria farmacéutica y de alimentos poseen múltiples aplicaciones.



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*Report on toxicity
By The San Carlos University in Guatemala*

UNIVERSIDAD DE SAN CARLOS
DE GUATEMALA



FACULTAD DE CC. QQ. Y FARMACIA

Edificio "T-12"
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**ACUTE TOXICITY STUDY OF THE AQUEOUS EXTRACT OF THE
ROOT OF *Bactris Balanoidea***

INTRODUCTION

Acute toxicity is defined as a harmful effect that is produced in a short period of time and that results from the exposure of experimental animals (mice and rats)¹ to a single or repetitive dose of a substance².

An LD50 is defined as the calculated dose of a substance which is expected to cause the death of 50% of an entire defined experimental animal population. It is determined from the exposure to the substance by any route (other than inhalation) of a significant number from that population^{1,2}.

MATERIALS

Plant Material:

An aqueous extract was prepared from the coarse powder already grounded of the roots *B. balanoidea* in the following way: 2.5, 5.0 and 7.5 grams of the powder were separately boiled in 50 mL of distilled water to obtain concentrations of (5, 10 and 15% of dried plant material per 100 mL of water = 5, 10 and 15% w/v).

Animals:

Adult Swiss male albino mice (25 to 30 g) were used in this study. The weight difference among animals did not exceed 20%³.

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(continued)

EXPERIMENTAL PROCEDURE

Acute toxicity studies and the determination of LD₅₀ were evaluated by oral and intraperitoneal administration of the aqueous extract of *B. balanoides*.

Oral Administration:

4 groups (3 treated and one control) consisting of 10 animals each, were studied. Treated groups received a single dose (1000, 2000 y 3000 mg/Kg*, p.o., respectively) of the aqueous extract of the roots of *B. balanoides*. Control group was orally treated with distilled water.

*milligrams of plant material per animal weight in kilograms.

Intraperitoneal administration:

4 groups (3 treated and one control) consisting of 10 animales each were studied. Treated groups received a single dose (1000, 1500, 2000 mg/Kg, i.p., respectively) of the aqueous extract of the roots of *B. balanoides*. Control group was intraperitoneally administered with physiological solution.

Evaluation of acute toxicity of the aqueous extract

This study followed the rules established by OMS, OCDE y NIOSH for determination of LD₅₀. Animals were housed under controlled temperature (22 ± 3 ° C) and humidity. Light-dark cycles were of 12 hours. This animals were supplied with food and water, ad-libitum.

Animal observation for the determination of toxicity signs was done after 60, 120 minutes, 4, 6, 10, 24 hours of administration (p.o and i.p.) of the aqueous extract. Animals will be kept in observation until 14 days after treatment.

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(continued)

RESULTS

Oral administration of the aqueous extract of *Bactris balanoidea* (1000, 2000, 3000 mg/Kg) to adult mice did not cause any death. No toxicity signs were registered in comparison with controls.

Intraperitoneal administration of the aqueous extract of the plant (1000, 1500 y 2000 mg/Kg) did not cause the death of any of the experimental animals.

Doses of 1500 y 2000 mg/Kg, i.p. produced a central depression in the experimental animals one hour after treatment, as compared with controls. This depression decreased after two hours. The dose of 1500 mg/Kg produced tremors and piloerection in treated animals, six hours after administration of the extract..

All animals treated with doses of 1500 and 2000 mg/Kg, i.p. formed groups during the evaluation period, in contrast to controls.

None of the animals showed any toxic sign 14 days after treatment either orally or intraperitoneally.

DISCUSSION

These results show that the aqueous extract of the roots of *B. balanoidea* is no toxic when orally or intraperitoneally administered in mice.

The aqueous extract of the roots of this plant could be safely used in humans without any risk of toxicity.

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(continued)*

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**Toxicity Report by NAMSA
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Lab No. 98T 14398 00
P.O. No. 000198

ACUTE ORAL TOXICITY STUDY IN THE RAT

TEST ARTICLE:

Herbal Supplement

IDENTIFICATION NO.:

MM041916

TEST FACILITY:

NAMSA
2261 Tracy Road
Northwood, OH 43619-1397

SPONSOR:

DR. H.G. HAINES
MAYAMEDIC
11511 S.W. 127TH STREET
MIAMI, FL 33176

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SUMMARY

The test article, Herbal Supplement, MM041916, was extracted in physiological saline. This extract was evaluated for oral toxicity potential. A single dose of 10 ml/kg of body weight was gavaged to 10 rats. The animals were then observed for up to 14 days for any signs of toxicity.

Under the conditions of this study, there was no mortality or significant evidence of toxicity observed in the rats. The test article extract would not be considered toxic at a dose of 10 ml/kg by the oral route in the rat.

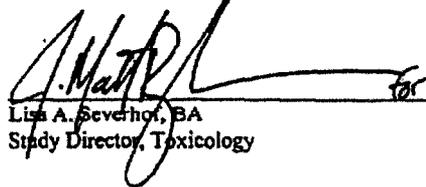
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INTRODUCTION

The test article identified below was evaluated for oral toxicity based on the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. The purpose of the study was to determine the potential for systemic toxicity of the material following a single gavage in the rat. The test article was received on November 6, 1998. Animals were dosed on November 16, 1998, and the observations were concluded on November 30, 1998.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	Herbal Supplement
Identification No:	MM041916
Storage Conditions:	Room temperature
Preparation:	Based on a ratio of 4 g:20 ml, 8 g of test article was covered with 40 ml of 0.9% saline. The test article was extracted at 121°C for 1 hour.
Sample Disposition:	Any remaining sample was discarded.
Condition of Test Extract:	Clear with dark brown tint.

METHODS

Test System:

Species:	Rat (<i>Rattus norvegicus</i>)
Strain:	Crl:CD (SD) BR
Source:	Charles River Laboratories
Sex:	Five male, five female
Body Weight Range:	209 grams to 223 grams prior to fasting
Age:	No particular age was prescribed for this test
Acclimation Period:	Minimum 5 days
Number of Animals:	Ten
Identification Method:	Ear punch

Justification of Test System:

The rat has historically been used to establish hazardous substance labeling data. The oral route of dosing is selected as the strongest challenge for materials that could be accidentally ingested.

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Animal Management:

- Husbandry: Conditions conformed to Standard Operating Procedures which are based on the "Guide for the Care and Use of Laboratory Animals."
- Food: PROLAB® R-M-H 1000 Rodent Diet was provided daily. Food was withheld 16-20 hours prior to dosing.
- Water: Freely available, municipal (Toledo, OH) water was delivered through an automatic watering system.
- Contaminants: Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.
- Housing: Animals were housed in groups of up to five per sex in stainless steel suspended cages identified by a card indicating the lab number, animal numbers, test code, sex, animal code and date dosed.
- Environmental: The room temperature was monitored daily. The temperature range for the rat was 64-79°F.
The room humidity was monitored daily. The humidity range for the rat was 30-70%.
The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
- Facility: NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Protection from Research Risk.
- Personnel: Associates involved were appropriately qualified and trained.
- Selection: Only healthy, previously unused animals were selected.

Experimental Procedure:

Each rat was weighed and the food was removed from each cage 16-20 hours prior to dosing. Each rat was weighed and gavaged with the test article extract (via stainless steel blunt-tipped cannula) at a dose of 10 ml/kg of body weight. The animals were then returned to their cages and food was returned after treatment.

Animals were observed immediately after dosing, at 4 hours, and daily for up to 14 days for signs of illness or mortality. Body weights were recorded at dosing and at 14 days for survivors. Animals found dead during the study or those euthanized (carbon dioxide inhalation) at termination of the study were subjected to a macroscopic examination of the viscera.



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RESULTS

Individual observations appear in Table I.

Body Weight: Body weight data were acceptable.

Mortality: No animals died during the 14 day study.

Clinical Observations: All animals appeared clinically normal throughout the study.

Necropsy: There were no macroscopic changes in the viscera at necropsy that could be attributed to the single oral dose.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSAs. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and EN45001 Quality Standards (TUV Product Services 1/96).

CONCLUSION

Under the conditions of this study, the test article extract would not be considered toxic at a dose of 10 ml/kg by the oral route in the rat.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSAs archive files.

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TESTIMONIAL

Guatemala, 1st April, 2003

I hereby confirm that I have been administrating an extract of the plant *Balanoidea bactris*, to treat various ailments ever since 1991.

The extract had been provided by Mr. Oved Kosovsky, who discovered the qualities of this plant, in the form of 500-mg capsules.

It was used by volunteers, more than 300 in number.

There have been no reports of side effects or adverse reactions with long term utilization on a daily basis for doses of 500 mg per day up to 5 grams per day.

(Please note: Retyped for clarity and easy of reading see original sign document attached).

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TESTIMONIAL

Guatemala, 1st April, 2003.

I hereby confirm that I have been administering an extract of the plant *Bakamoides hachis*, to treat various ailments ever since 1991.

The extract had been provided by Mr. Oved Kosovsky, who discovered the qualities of this plant, in the form of 500-mg capsules.

It was used by volunteers, more than 100 in number.

There have been no reports of side effects or adverse reactions with long term utilization on a daily basis for doses of 500 mg per day up to 5 grams per day.

