Purple Corn Extract: NDI Application
Submitted by Rainforest Botanicals LCC,

August 31, 2005

To:

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835
Telephone Number: (301) 436-2371

SEP 22 2005 FDA

Submitted by:

Juan Ferreira
Rainforest Botanicals LLC
P. O. Box 770065
Miami, FL 33177

Ph: 305-235-9880

E-mail: jferreira@rainforestbotanicals.com

Dear Sir/Madam:

The information provided in the following application shows the basis on which there is reason to conclude that the product "purple corn extract" (herein, the same product known as Purple X®) may be reasonably expected to be safe when used according to label directions.

Apart from web links, attached are copies of all the referenced material including a report on the acute oral toxicity of the product.

2005-6251 Aims

Sincerely,

Juan Ferreira

Product Name:

Purple corn extract (Purple X®)

Product Distributor:

Rainforest Botanicals LLC (formerly Ashaninka Imports, Inc.)
P. O. Box 770065
Miami, FL 33177

Ph: 305-235-9880

jferreira@rainforestbotanicals.com

Product Manufacturer:

Laboratorios Fitofarma E.I.R.L., Av. Nicolas Arriola 2844, San Luis, Lima, Peru. Web site: http://www.laboratoriosfitofarma.com.

Food Use of Purple Corn (*Zea mays* L.)

Purple corn has been traditionally consumed in Peru1 for perhaps centuries, since it was apparently used by the Incan civilization.2 Although purple corn extract (Purple X®) represents a new dietary ingredient in the United States, it is well known that corn chips made from purple corn have been widely consumed in the United States, Canada, and other countries, and evidence suggests that their consumption is increasing. In the past year, exports of purple corn from Peru have increased 36%.NR3 Peruvian purple corn kernels are sold in the U.S. and internationally as a raw food,3 in the form of

flour, as the main ingredient of a dessert, and for preparing "chicha morada",**4,5** a traditional beverage drunk in Peru for many generations.**1**

Product Description

Purple corn extract (Purple X®) is a solvent (water-alcohol) extract of the whole cobs (without the leaves) of a naturally pigmented type of *Zea mays* L. from Peru known by the vernacular, "maiz morado" or purple corn. The form of the extract is a water-soluble powder standardized to contain proanthocyanidins (procyanidonic value of 12),**6** approximately 6% anthocyanins,**7** and approximately 25% total phenolic compounds.**8** The taste of purple corn extract is neutral, the odor is characteristic, and the color is a deep purple. The carrier for the extract is non-GMO maltodextrin.**6**

Laboratory tests**9** show that purple corn extract contains the following general components and characteristics:

Ash
Fat
Protein
Sodium
Carbohydrates

Calcium
Magnesium
Manganese
Zinc
Copper

pH
Moisture

Anthocyanins

Naturally occurring anthocyanins are largely responsible for the intense color of purple corn. On a dry weight basis, their content in Peruvian purple corn is comparable to that of blueberries.**10** Individual anthocyanins detected in purple corn cobs from Peru include C3G (cyanidin-3-glucoside,

also known as 3-*O*-β-D-glucoside or cyanidin-3-*O*-β-glucopyranoside), peonidin-3-glucoside, and pelargonidin-3-glucoside.**2** The most abundant anthocyanin in purple corn is C3G,**2,11** which is also the most abundant anthocyanin in blackberry extract**12** and blood oranges**13** and is also found in appreciable amounts in red wine.**14**

Purple Corn Extract (Purple X®) Manufacturing Process

Suggested Dosage

The dietary supplement containing purple corn extract at a level of 250 mg per capsule or tablet will be suggested to be taken two times per day.

Usage Recommendations

Purple corn extract (Purple X®) is intended for use as a dietary supplement or an ingredient thereof for the purpose of providing a dietary antioxidant. As a precaution, purple corn extract is not intended for use by pregnant or lactating women and a statement to that effect will be made in the product labeling.

Evidence of Safety

A search for evidence of toxicity from "purple corn" and "purple corn extract" was made in PubMed, TOXNET, EMBASE, and BIOSIS on July 9, 2005. No evidence of human or animal toxicity, mutagenicity or cytotoxicity to healthy cells were found.

Heavy Metals, Pesticides, and Caffeine

Arsenic, cadmium, lead and mercury were not found in detectable amounts in purple corn extract (Purple X®) and various pesticides were also not present in detectable amounts.**16** Caffeine content of the extract was found to be less than 0.4 mg/capsule and less than 0.1% (wt/wt, based on capsule content weight).**17**

Acute Toxicity

No acute toxicity was found from purple corn extract (Purple X®) following oral administration in four groups of five male albino rats at doses of 446.43-3571.43 mg/kg. Because no mortalities occurred, the oral LD_{50} of the extract in mice was estimated to be greater than 3571.43 mg/kg.**18**

Conclusion

Evidence of toxicity from purple corn or purple corn extract (Purple X®) was not found. From the long history of use of purple corn as a food, no untoward effects are expected. At the dosage suggested for use of purple corn extract as a dietary supplement or ingredient thereof, evidence from animal tests, tests for heavy metals, pesticides, and caffeine levels indicate that purple corn extract may be reasonably expected to be safe.

Contact for Queries:

Kenneth Jones
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Halfmoon Bay, B.C.
Canada V0N 1Y2

Ph: 604-885-4713

E-mail: armana@dccnet.com

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Kenneth Jones (President)

References

1. Brack-Egg A. *Diccionario Enciclopédico de Plantas Útiles del Perú.* Cuzco, Peru: Imprenta del Centro Bartolomé de Las Casas; 1999:537-538.

2. de Pascual-Teresa S, Santos-Buelga C, Rivas-Gonzalo J C. LC-MS analysis of anthocyanins from purple corn cob. *J Sci Food Agric.* 2002;82(9):1003-1006.

NR3 Ministry of Agriculture, Peru. Crecen exportaciones de maíz morado. http://www.minag.gob.pe/medio.shtml?x=38316. Accessed July, 2005.

3. Nature's First Law Online Superstore: Purple corn kernels: (http://www.rawfood.com/cgi-bin/order/index.cgi?id=242290244354&d=single&item_id=0953&c=Organic_Food&sc=Antioxidants&tc=). Accessed July 13, 2005.

4. El Mercado Grande: Search on "purple corn": http://www.elmercadogrande.com/nsearch.html. Accessed July 13, 2005.

5. Amigo Foods: Search on "purple corn": http://search.store.yahoo.com/cgi-bin/nsearch?catalog=amigofoods&query=morada&.autodone=http%3A%2F%2Fstore.amigofoods.com%2Fnsearch.html. Accessed July 13, 2005.

6. Specifications sheet, purple corn extract (PurpleX®). Rainforest Botanicals, LLC, Miami, FL; 2005.

7. Anthocyanin assay of purple corn extract for Ashaninka Imports. ALPHA Job # 12211. Eurofins Scientific, 1365 Redwood Way, Potaluma, CA 94954. Dec 27, 2001.

8. Total phenolics assay of purple corn extract [PurpleX®] for Ashaninka Imports. ALPHA Job # 12386. Eurofins Scientific, 1365 Redwood Way, Potaluma, CA 94954. Jan 21, 2002.

9. Chemical analysis of purple corn extract [PurpleX®] for Laboratorios Fitofarma E.I.R.L. International Analytical Services S.A.C., Lima, Peru. Informe de Ensayo No. 9605/03. Nov. 17, 2003.

10. Cevallos-Casals BA, Cisneros-Zevallos L. Stoichiometric and kinetic studies of phenolic antioxidants from Andean purple corn and red-fleshed sweetpotato. *J Agric Food Chem*. 2003;51(11):3313-3319.

11. Nakatani N, Fukuda H, Fuwa H. Major anthocyanin of Bolivian purple corn *Zea mays*. *Agric Biol Chem*. 1979;43(2):389-392.

12. Rossi A, Serraino I, Dugo P, et al. Protective effects of anthocyanins from blackberry in a rat model of acute lung inflammation. *Free Radic Res*. 2003;37(8):891-900.

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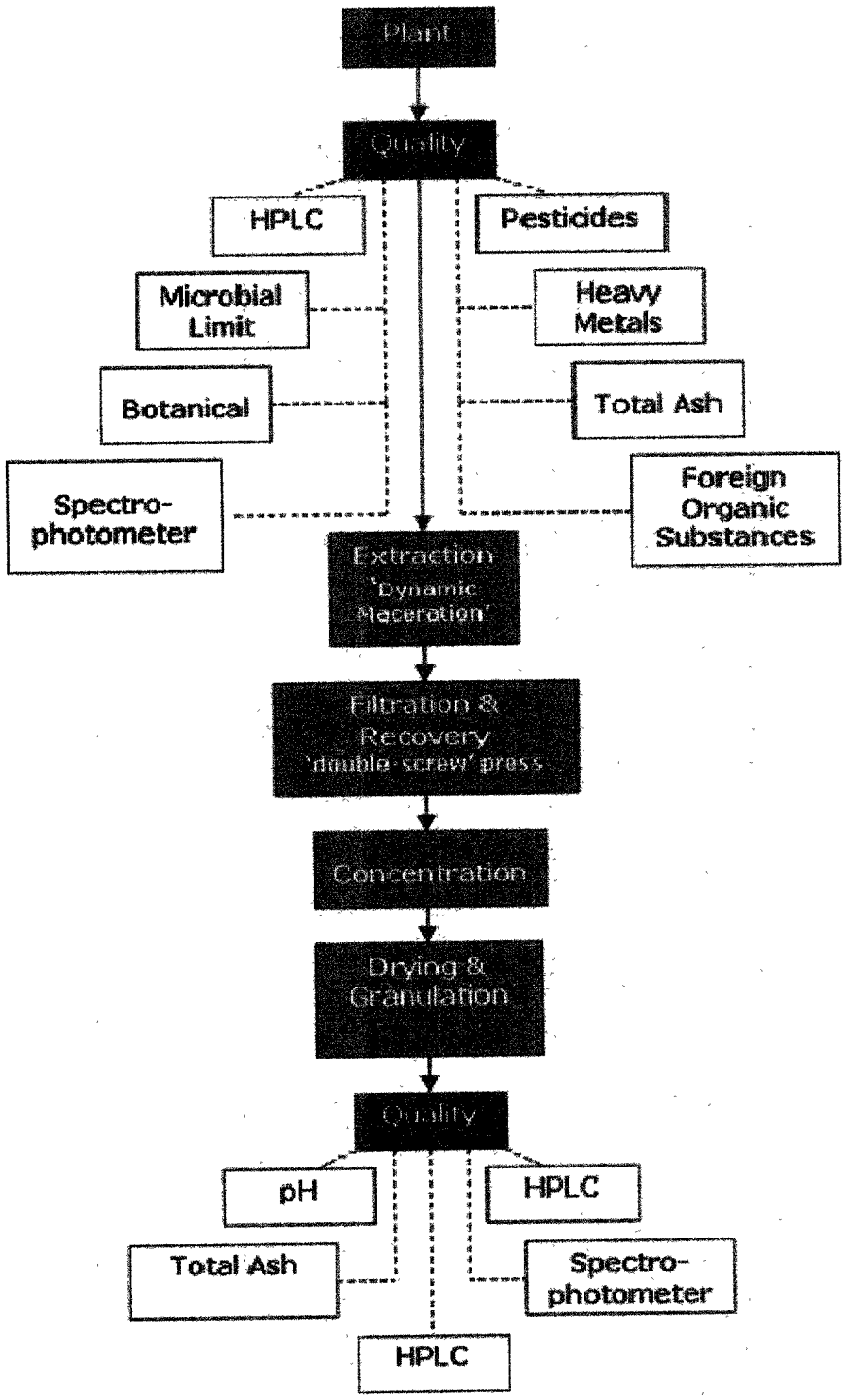
14. García-Beneytez E, Cabello F, and Revilla E. Analysis of grape and wine anthocyanins by HPLC-MS. *J Agric Food Chem*. 2003;51(19):5622-5629.

15. Roberto E. Culotti, Laboratorios Fitofarma. Letter to Kenneth Jones, July 13, 2005. Web address: http://www.laboratoriosfitofarma.com/index.htm.

16. Heavy metals and pesticides assay of purple corn extract [PurpleX®] for Laboratorios Fitofarma E.I.R.L. International Analytical Services S.A.C., Lima, Peru. Informe de Ensayo No. 7567/03. Sept. 8, 2003.

17. Caffeine content assay [of PurpleX®] for Ashaninka Imports. ALPHA Job # 15723. Eurofins Scientific, 1365 Redwood Way, Potaluma, CA 94954. March 14, 2003.

18. Oral LD50 test of purple corn extract [PurpleX®] in rats for Laboratorios Fitofarma E.I.R.L. Universidad Peruana Cayetano Heredia, Av. Honorio Delgado 430, Urb. Ingenieria, San Martin de Porres, Peru. Informe de Ensayo No. P015799/02. Oct. 18, 2002.


Plant
Quality
HPLC
Pesticides
Microbial Limit
Heavy Metals
Botanical
Total Ash
Spectro-photometer
Foreign Organic Substances
Extraction
'Dynamic Maceration'
Filtration & Recovery
'double-screw' press
Concentration
Drying & Granulation
Quality
pH
HPLC
Total Ash
Spectro-photometer
HPLC

PURPLE X
PURPLE CORN EXTRACT
The Color of Life!

Specification Sheet PURPLE-X Powder Extract

Country of Origin:	Peru
Botanical name:	Zea Mays
Family:	Graminea
Variety:	Purple
Common name:	Purple corn, maiz morado.
Inca name:	Moro sara, Kulli sara
Part used:	Cob
Form:	Standardized Powder Extract
Activity: **Method:**	25% Total Phenols Folin Ciocalteau by UV-Vis
Activity: **Method:**	6% Anthocyanins UV-Vis
Activity: **Method:**	Proacyanidonic Value 12 UV-Vis
Characteristics:	Fine powder
Mesh:	200 mesh
Bulk Density:	0.384gm/cc
Color:	Deep purple
Odor:	Characteristic
Taste:	Neutral
Solubility:	Soluble in water
Moisture:	Not more than 8%
pH:	3-4
Solvent:	Water-alcohol
Carrier:	**Non GMO** Maltodextrine

PURPLE-X is a registered trademark. US Patent Disclosure # 531255
Distributed by Rainforest Botanicals LLC
Phone: 305 235 9880 Efax 702 973 7978 email: info@rainforestbotanicals.com

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Committed to Uncompromising Science and Customer Support

December 27, 2001

Juan Ferreira
Ashaninka Imports
PO 770065
Miami FL 33177-0065

ALPHA Job # 12211

Sample Identification:
Alpha Sample #: 01-6176 Zea Mays Dry Extract, Powder, Lot #ENS2
Date Received: 12-21-01, Time Received: 11:45 AM

ALPHA Method:
UV128: Anthocyanins as Anthocyanidins by Ultraviolet-Visible Spectrophotometry (UV-Vis)

Results:

ALPHA Sample #	Anthocyanins as Anthocyanidins (% wt/wt)
01-6176	6.75
01-6176 (D)	6.93

(D) = Duplicate

Christina Stuart
Christina Stuart
Chemist

Tom C. Miller for
Jules Skamarack
Director, Client Services

Alpha Laboratories Division
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January 21, 2002

Juan Ferreira
Ashaninka Imports
PO 770065
Miami FL 33177-0065

ALPHA Job # 12386

Sample Identification:
Alpha Sample #: 01-6176 Zea Mays Dry Extract, Powder, Lot #ENS2
Date Received: 12-21-01, Time Received: 11:45 AM

ALPHA Method:
AL126: Total Phenols as Gallic Acid (Folin-Ciocalteu Method)
by Ultraviolet - Visible Spectrophotometry (UV-Vis)

Results:

ALPHA Sample #	Total Phenols (Folin-Ciocalteu) (% wt/wt)
01-6176	26.5

Note: Test was run on water extract of sample.

Jules Skamarack
Director, Client Services

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Informe De Ensayo N° 9605/03

SOLICITANTE	:	LABORATORIOS FITOFARMA E.I.R.L.
DOMICILIO LEGAL	:	Av. Nicolás Arriola N° 2844 San Luis
PRODUCTO	:	EXTRACTO DE MAIZ MORADO
CANTIDAD RECIBIDA	:	01 muestra x 500g. aprox.
PRESENTACION	:	Bolsa de plástico sellada
IDENTIFICACION	:	Sin Identificación
FECHA DE RECEPCION	:	2003-11-12
FECHA DE ANALISIS	:	2003-11-12,15
ENSAYO REALIZADO EN	:	Av. La Marina N° 3035 - San Miguel
SOLICITUD DE ANALISIS	:	AN-03-7476, 7498
REFERENCIA	:	MUESTRA PROPORCIONADA POR EL CLIENTE

ANALISIS QUÍMICOS	RESULTADOS
PROTEINA (N x 6.25)(%)	2,52
GRASA(%)	0.20
HUMEDAD (%)	6,48
CENIZAS(%)	6,48
FIBRA (%)	0,12
CARBOHIDRATOS (%)	84,4
CALORÍAS (Kcal/100g)	349
MANGANESO (mg/Kg)	14
MAGNESIO (mg/Kg)	1906
CALCIO (mg/Kg)	620
ZINC (mg/Kg)	40
COBRE (mg/Kg)	12
CLORUROS (Exp. como Cloruro de Sodio)(%)	1,86

Métodos.-
- PROTEINA : ISO 1953. Second Edition 1997.
- GRASA: AOAC 920.39 C. Vol. 2 17 th Ed. 2000
HUMEDAD : FCC p.197. apartado B. P. 749 Tercera Edición 1996
CENIZAS : FCC p.748. Apendice II - C. Fourth Edition 1996
FIBRA : AOCS Ba 6-84 Fifth Edition 1998.
CARBOHIDRATOS, CALORIAS: Determinación: Por cálculo.
- MANGANESO: AOAC 935.18.Vol 1, c.4,p45 17 th Ed. 2000
- MAGNESIO: AOAC 968.08 Vol 1, c.4,p40.17 th Ed. 2000
- CALCIO: AOAC 968.08 Vol.1, c.4,p40 17 th Ed. 2000
- ZINC: AOAC 968.08. Vol.1, c.4,p40 17 th Ed. 2000
- COBRE: AOAC 968.08.Vol.1, c.4,p40 .17 th Ed. 2000
CLORUROS: Handbook of U.S. colorants for Foods, Drugs and cosmetics, c.6 1979.

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Mónica Núñez Caballero
Jefe División De Laboratorios
C.B.P. N° 2210

Lima, 17 de Noviembre del 2003
sa/rc

FOSFA INTERNATIONAL ANALYST MEMBER SUPERINTENDENT MEMBER

Gafta ANALYST MEMBER SUPERINTENDENT MEMBER

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