



**Memorandum**

**SEP 04 2002**

Date:  
From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820  
Subject: 75-Day Premarket Notification of New Dietary Ingredients  
To: Dockets Management Branch, HFA-305

New Dietary Ingredient: Sutherlandia  
Firm: Power Africa, Inc.  
Date Received by FDA: November 27, 2001  
90-Day Date: February 25, 2002

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 new dietary ingredient should be placed on public display in docket number 95S-0316 as soon as possible since it is past the 90-day date. Thank you for your assistance.

*Felicia B. Satchell*  
Felicia B. Satchell

Attachments

955-0316

RPT108



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**FEB 8 2002**

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Ms. Fedra Sembiante  
Power Africa, Inc.  
P.O. Box 57  
Fairview, NJ 07022

Dear Ms. Sembiante:

This is in response to your correspondence, dated November 21, 2001, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On November 27, 2001, FDA received and filed four separate notifications, each concerning a different botanical that you assert is a new dietary ingredient. The botanicals are listed below as stated in your notifications, with the exception that we italicized the Latin binomial names and capitalized the genus names.

- African Ginger [*Siphonochilus aethiopicus* (Schweinf.) B.L. Burtt]
- African Potato [*Hypoxis hemerocallidea* (Fisch. & C.A.) Mey]
- Sutherlandia [*Sutherlandia frutescens* R. Br. subsp. *microphylla* (Burch. Ex DC.) Moshe & Van Wyk ined.]
- Warburgia [*Warburgia salutaris* (Bertol. f.) Chiov.]

In follow up, we contacted you by phone to request further clarification on the identity of Africa Potato and Sutherlandia. On January 20, 31 and February 7, 2002, you responded by facsimile with information that revises the Latin binomial names (including authors' names) for the two botanicals as indicated below, with the exception that we italicized the Latin binomial names:

- African Potato [*Hypoxis hemerocallidea* Fisch. & C.A. Mey.]
- Sutherlandia [*Sutherlandia frutescens* (L.) R. Br. or *Sutherlandia microphyllia* Burchell ex DC.]

Your notifications describe the plant part, amount and frequency of use for each of the botanicals you intend to market as a dietary supplement as follows:

- African Ginger: roots and rhizomes; no chemical extraction—100% pure plant; 100 mg/capsule or tablet; 1 capsule or tablet 3 times/day with meals

- African Potato: corm, no chemical extraction--100% pure plant; 300 mg/capsule or tablet; 2 capsules or tablets/day
- Sutherlandia: leaves and young stems, no chemical extraction—100% pure plant; 300 mg capsule or tablet; 1 capsule or table twice/day preferably with meals
- Warburgia: leaves, no chemical extraction—100% pure plant; 100 mg/capsule or tablet; 1 capsule or tablet/day preferably with meals

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 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 product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it 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.

You submitted copies of the proposed product labels in your notifications for each of the botanicals you want to market in the U.S. The labels for three of the botanicals include statements about their intended use that represent disease claims. In addition, other information you submitted in support of all four botanicals focuses on recommended uses in the treatment of various diseases. Below are examples of excerpts from your notifications that make disease claims:

- For African Ginger:
  - Proposed label statements:
    - "NATURAL ANTI-INFLAMMATORY"
    - "...may help relieve tension headaches, influenza, sinusitis, sore throats and mild asthma."
  - Other information in the notification:
    - "...for fever or colds and flu...."
    - "...demonstrated to be...anticandidal."
    - "...effectively treat the fever of malaria, as well as the severe headache that accompanies the fever."
    - "...treatment for oral and oesophageal thrush in AIDS patients...."
    - "...oral treatment with African Ginger is effective for vaginal thrush."

- For African Potato:  
Information in the notification:
  - “...it fights AIDS, cancer, TB, yuppie flu, arthritis, psoriasis...”
  - “...Hypoxis plant treatment...seems to slow down the growth of certain types of cancer.”
  
- For Sutherlandia:  
Proposed label statements:
  - “...to help cope with depression and chronic fatigue syndrome.”
  - “...to help treat diabetes, heartburn, gastritis and reflux oesophagitis as well as rheumatism and rheumatoid arthritis.”Other information in the notification:
  - “...contemporary uses of Sutherlandia include use as a tonic for:...wasting from cancer, TB and AIDS...influenza, viral hepatitis, asthma and bronchitis, type 2 diabetes, mild to moderate hypertension, rheumatoid arthritis [and] peptic ulcer, gastritis, and reflux oesophagitis...”
  
- For Warburgia:  
Proposed label statements:
  - “ANTI-MICROBIAL”
  - “...used to help treat yeast, fungal, bacterial and protozoal infections....”
  - “Warburgia may help to treat oral and oesophageal thrush, aphthous ulcers, bronchitis, and is a natural antibiotic particularly for chest infections.”Other information in the notification:
  - “...widely used remedy for coughs, colds and chest complaints.”
  - “The numerous other ailments for which it is used include influenza, rheumatism, malaria, venereal diseases, toothache and gastric ulcers.”
  - “...used to treat yeast, fungal, bacterial and protozoal infections....”

All four product labels include warning statements. These statements advise against the use of these botanicals by children and by pregnant or lactating women. They also advise potential consumers to first consult with a physician if they are using chronic medications or have allergies.

Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Collectively, the information in your notifications represents each of the four botanicals as a product intended to be used to treat one or more diseases. Therefore, each is subject to regulation as a drug under 21 U.S.C. 321(g)(1)(B) and is not a dietary supplement. If you want African Ginger, African Potato, Sutherlandia or Warburgia to be evaluated for its use in the treatment of a disease, you should contact FDA’s Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

As we have stated above, a product containing African Ginger, African Potato, Sutherlandia, or Warburgia is subject to regulation as a drug. Nonetheless, FDA carefully considered the information in your notifications in the event that these botanicals could be marketed as dietary supplements. We have significant concerns about the basis upon which you concluded that a dietary supplement containing African Ginger, African Potato, Warburgia or Sutherlandia is reasonably expected to be safe when used as recommended or suggested in the products' labeling.

The history of use information in your notifications on the four botanicals addressed use in traditional African medicine to treat specific diseases and other health problems. This information does not discuss the chronic, long-term use of these botanicals as a food or dietary supplement by a generally healthy population. In many instances, the source of your information is not identified (i.e., lacks reference citation), and appears to be selected pages printed from a commercial Internet site or promotional literature that is not scientifically objective. Much of the history of use information you submitted addresses the effectiveness and not "safety" of the botanicals, and is based upon anecdotal or testimonial statements that cannot be validated and are not corroborated by scientific data. In some instances, the information you submitted in your notifications pertains to a different preparation of the botanical than you intend to market. For example, most of the history of use information you submitted on African Potato was on an unspecified extract of this botanical versus the corm (whole plant part and not a chemical extraction) that you propose to use in a dietary supplement.

With few exceptions, the history of use information you submitted in your notifications generally lacks details on the amount, frequency and duration of use for each of the botanicals and whether the plant parts and preparation used are the same as what you intend to market in dietary supplements. Without these details, it is not possible for FDA to determine how this information relates to your botanical products and their recommend intakes.

Your notification on Sutherlandia includes information prepared by Phyto Nova, a distributor of Sutherlandia tablets in South Africa, that states there were no adverse effects reported to Phyto Nova in two years of selling this product. However, you did not provide any particulars on: the method used by Phyto Nova to collect this information; whether Phyto Nova's botanical preparation is identical to the one you want to market; the total daily intake of Sutherlandia or its duration of use; or the number, demographics or health status of the people who used Sutherlandia. Without this clarification, FDA cannot interpret this report as providing credible evidence of safety for your product of Sutherlandia and its recommended intake of 600 mg/day.

Your notifications did not include any scientific data (e.g., results from toxicity, animal studies, *invitro*, *invivo* or clinical studies) that addresses the safety of African Ginger, African Potato, Sutherlandia or Warburgia. Your notifications on African Ginger and Sutherlandia

contained some narratives followed by reference lists, but no copies of the articles cited were included. Therefore, it is unknown whether these reference citations provide any support for your safety determination of these botanicals. With the exception of African Potato, none of the other notifications included copies of articles published in peer-reviewed scientific journals, textbooks, or other authoritative references.

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The topics of the two journal articles submitted in your notification on African Potato are on the role or activity of a plant phytosterol called sitosterol and a sitosterol glucoside in human nutrition. Although, African Potato may be a source of these substances, these articles do not provide evidence of safety for African Potato that may contain other bioactive components that affect this botanical's safety profile. The abstract of another published article you submitted in the notification on African Potato assessed the toxicity of a standardized "Hypoxis plant extract." This extract is not the same as the whole plant part of corm that you identified for use in your dietary supplement containing African Potato. In addition, you did not accompany this abstract with a copy of the complete published journal article for FDA's review. Overall, the history of use information you submitted in all four of your notifications has limited usefulness in evaluating the safety of African Ginger, African Potato, Sutherlandia, and Warburgia.

For the reasons discussed above, African Ginger, African Potato, Sutherlandia and Warburgia are subject to regulation as drugs under 21 U.S.C. 321(g)(1)(B), and FDA would consider them to be unapproved new drugs under 21 U.S.C. 355(a). Unapproved new drugs are prohibited under 21 U.S.C. 331(d) from being introduced or delivered for introduction into interstate commerce. Further, if it can be argued that these botanicals may be used as dietary supplements, the information in your notifications does not provide an adequate basis to conclude that African Ginger, African Potato, Sutherlandia or Warburgia will reasonably be expected to be safe when used under the recommended or suggested conditions of use in the products' labeling. Therefore, any product containing African Ginger, African Potato, Sutherlandia or Warburgia may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains one or more new dietary ingredients at levels for which there is inadequate information to provide reasonable assurance that they will not present a significant or unreasonable risk of illness or injury. Adulterated or unsafe dietary supplements are prohibited under 21 U.S.C. 331(a) and (v) from being introduced or delivered for introduction into interstate commerce.

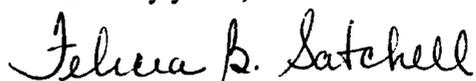
Your notifications will be kept confidential for 90 days after the filing date. After February 25, 2002, the four notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public.

Page 6 – Ms. Fedra Sembiante

For FDA's consideration, you may wish to identify in writing specifically what information in your notifications you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

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Sincerely yours,



Felicia B. Satchell

Director

Division of Standards

and Labeling Regulations

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

# Power Africa™

“Health by Nature”

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February 07, 2002

Division of Standards and Labeling Regulations (HFS-820)  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740-3835

Attention: Ms Rhonda Kane, M S , R D - Consumer Safety Officer

Dear Ms. Kane,

I am pleased to submit the following details regarding the Latin binomial and authors as requested:

#### SUTHERLANDIA:

*Sutherlandia microphylla* Burchell ex DC,  
(*Sutherlandia frutescens* (L.) R. Br., Moshe & Van Wyk ined. - this is recorded in the Missouri Botanical Gardens also but since both *frutescens* and *microphylla* are the same species, both these will be known as *Sutherlandia frutescens*.)

The difficulty in the Latin binomials lies in that the species will be known as *Sutherlandia frutescens*. Currently there is the *Sutherlandia microphylla* also registered which is actually a subspecies of *frutescens*. If necessary, we would prefer to include both Latin binomials to overcome this transition phase in the Latin binomial.

#### AFRICAN POTATO:

*Hypoxis hemerocallidea* Fisch. & C., A., Mey,

I regret the error in typing with the incorrect parenthesis in the notification for African Potato.

The above is correct.

At this point in time, we would not be adding further information to the current notifications.

Thank you for your consideration.

Sincerely



Fedra Sembiante





"Health by Nature"

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January 31, 2002

Division of Standards and Labeling Regulations (HFS-820)  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740-3835

Attention: Ms. Rhonda Kane, M.S., R.D. - Consumer Safety Officer

Dear Ms. Kane

In response to your request for the validation of Latin binomial names for the dietary supplements *Sutherlandia frutescens* and *Hypoxis hemerocallidea*, we regret the delay in receiving response from our botanists and pharmacists.

However, we are pleased to forward the following details for validation purposes:

Upon review, the Kew list was found to be incomplete. *Sutherlandia frutescens* subsp. *microphylla* will not be found because it is not yet published. It is, however, exactly the same plant as *Sutherlandia microphylla* and hence the application should be for *S. microphylla* and *S. frutescens* (these two will become the same species, *S. microphylla* is merely a particular subform of *S. frutescens*)

The list of the Missouri Botanical Garden has been found to be more detailed in this case. To access this, one should go into the Missouri Botanical Gardens website, choose "Library", then choose "Search" then click on "W3Tropicos" (the plant names database) and then enter the plant name. All the plants and their authors will pop out - *Sutherlandia microphylla*, *Hypoxis hemerocallidea*, *Siphonochilus aethiopicus*, *Warburgia salutaris*. All have been checked and confirmed

With reference to the safety requirements, our assumption of safety is based on the widespread and well-documented safe use of the plants as traditional medicine with a long history of use. This is in keeping with WHO guidelines on medicinal plants.

However, we would be delighted to supply any additional information that may be required to suffice FDA standards

Kind regards



Fedra Sembiante





"Health by Nature"

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## facsimile transmittal

To: Ms. Rhonda Kane, M.S., R.D. Fax: 301 436 2639 / 436 2636

From: Fedra Sembiente Date: 1/20/2002

Re: Power Africa Pages: One

Urgent     For Review     Please Comment     Please Reply     Please Recycle

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Dear Ms. Kane,

Further to our recent submittal of four New Dietary Ingredient notifications for Power Africa, please note that although we do have additional information about on-going research, we kindly advise that at this point we do not wish to add to the information already submitted.

We will be sending details of Latin binomial authors in the next few days and are grateful for the opportunity to clarify this aspect of our notifications.

A handwritten signature in cursive script, appearing to read "Fedra Sembiente".

Fedra Sembiente





DEC 21 2001

Mr. Fedra Sembiante  
Power Africa, Inc.  
P.O. Box 57  
Fairview, NJ 07022

Dear Mr. Sembiante:

This is to inform you that the four separate notifications, each dated November 21, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) were all received and filed by the Food and Drug Administration (FDA) on November 27, 2001. Collectively, four botanicals were identified in your notifications that you assert are new dietary ingredients. These botanicals are listed below as stated in your notifications, with the exception that we italicized the Latin binomial names and capitalized the genus names:

- African Ginger [*Siphonochilus aethiopicus* (Schweinf.) B.L. Burt]
- African Potato [*Hypoxis hemerocallidea* (Fisch. & C.A.) Mey]
- Sutherlandia [*Sutherlandia frutescens* R.Br. subsp. *microphylla* (Burch. Ex DC.) Moshe & Var. Wyk ined.]
- Warburgia [*Warburgia salutaris* (Bertol. f.) Chiov.]

In accordance with 21 C.F.R. § 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., February 10, 2002), you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains one or more of the botanicals cited above.

Please note that our acceptance of your notifications for filing is a procedural matter. It does not imply that we have completed our review of the notifications or constitute a finding by FDA that your proposed new dietary ingredients or a supplement that contains them is safe or is not adulterated under 21 U.S.C. 342.

As another procedural matter, your notifications will be kept confidential for 90 days after the filing date. After February 25, 2002, the four notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public.

Page 2 – Mr. Fedra Sembiante

For FDA's consideration, you may wish to identify in writing specifically what information in your notifications you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

We noticed that none of your notifications included either a phone or facsimile (fax) number or an electronic mail address as other ways to contact you. Although you are not required to provide us with this information, we would appreciate your sharing it with us, if it exists, as quicker ways to communicate with you.

Since the receipt of your notification, we have relocated our office. Our new address and other contact information follows:

Division of Standards and Labeling Regulations (HFS-820)  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Faint Branch Parkway  
College Park, Maryland 20740-3835  
Phone: (301) 436-2371  
Fax: (301) 436-2639 or (301) 436-2636

Thank you for your consideration of our request for additional information on how to reach you. Please contact us, if you have any questions concerning this correspondence.

Sincerely yours,



Rhonda R. Kane, M.S., R.D.  
Consumer Safety Officer  
Dietary Supplements Team  
Division of Standards  
and Labeling Regulations  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

RECEIVED

11-27-01

**NEW DIETARY INGREDIENT NOTIFICATION**

Pre-market notification

November 21, 2001

**1) Distributor:**

Power Africa, Inc  
P.O. Box 57  
Fairview, NJ 07022

**2) Name of the new dietary ingredient that is the subject of the pre-market notification, including Latin binomial name and author:**

**Name:** Sutherlandia  
**Latin binomial:** sutherlandia frutescens R. Br. subsp. microphylla  
**Author:** (Burch. Ex DC.) Moshe & Van Wyk ined.

**3) Description of dietary supplement:**

- i **level of new dietary ingredient in dietary supplement:**  
300mg Sutherlandia per one capsule/tablet serving of the same quantity. No chemical extraction - 100% pure plant.
- ii. **conditions of use suggested in labeling of dietary supplement:**  
one capsule/tablet twice daily preferably with meals (please refer to attached copy of label).

**4) History of use, evidence of safety, citations to published articles and additional information that is basis to the distributor's conclusion that the new dietary supplement will be reasonably expected to be safe:**

please refer to copies of material attached.

**5) Signature of person designated by distributor of dietary supplement that contains a new dietary ingredient:**



Fedra Sembiente

# **Sutherlandia Frutescens**

**Presented by Power Africa, Inc.**

Distributed by:  
Power Africa, Inc. PO Box 87  
Fairfax, VA 22032 USA

# Power Africa®

"Health by Nature"

## Sutherlandia

(sutherlandia frutescens)

ALL PURPOSE TONIC\*

300 mg Dietary  
Supplement



60 Capsules

### Supplement Facts:

Serving Size: 1 Capsule

Each capsule contains ..... % Daily Value\*

Sutherlandia frutescens ..... 300 mg

\*Daily value not established

Other Ingredients: Dibasic Potassium Phosphate, Zinc, Magnesium Stearate

**SUGGESTED USE:** As a dietary supplement, take one (1) capsule twice daily, preferably with meals.

Sutherlandia may powerfully assist the body to mobilize its own resources to help cope with diverse physical and mental stress including irritability and hot flashes in menopause, anxiety, depression and chronic fatigue syndrome.

Sutherlandia is widely used by herbalists to help treat diabetes, heartburn, gastritis and reflux esophagitis as well as rheumatism and rheumatoid arthritis.

**WARNING:** As with any dietary supplement, do not use while pregnant or lactating. Consult a physician if on chronic medication or suffer from allergies. Store in a cool dry place. Keep out of reach of children. Do not use if seal under cap is broken or missing.

ITEM # 1101 / EXPIRY DATE / LOT #

Product of South Africa

100% PURE PLANT NO ARTIFICIAL COLORS OR FLAVORS NO PRESERVATIVES OR CHEMICAL SOLVENTS

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any illness or disease. Research is ongoing.

[Help/FAQ's](#)**PRODUCT CODE BUILDER - FINAL RESULTS**[Tutorial](#)**Helpful Tips**

Industry	Product	Code
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Soft Gelatin Capsules / Herbals & Botanicals (not Teas), N.E.C.	54 F B H 99

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Help/FAQ's	<b>PRODUCT CODE BUILDER - FINAL RESULTS</b>		Tutorial
<b>Helpful Tips</b>			
<b>Industry</b>	<b>Product</b>	<b>Code</b>	
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Prompt Release Tablets / Herbals & Botanicals (not Teas), N.E.C.	54 F B A 99	
« Previous	Start Over	Print	

[Help/FAQ's](#)**PRODUCT CODE BUILDER - FINAL RESULTS**[Tutorial](#)**Helpful Tips**

<b>Industry</b>	<b>Product</b>	<b>Code</b>
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Dried - Natural or Artifical / Herbals & Botanicals (not Teas), N.E.C.	54 F B T 99

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# IMPILO

DRUGS (1966) (PTY) LTD

## CERTIFICATE OF ANALYSIS

Batch No. :S3421  
Product :SUTHERLANDIA CAPSULES  
Alternative names :  
Packaging :WHITE PVC JARS (60's)  
Expiry Date :04/2003

	SPECIFICATION	METHOD	RESULT
Description	:Transparent capsule/green powder fill.	Visual	Complies
Average mass	:580 - 620 mg	Balance	601,2 mg
Length	:21,0 - 22 mm	Vernier	21,43 mm
Disintegration	:NMT 60 mins	USP 24 (Discs)	35 mins
Uniformity of mass	Wts. of NMT 2 capsules (of 20) may deviate from ave. by MT 7,5 % and none by more than 15 %	Balance	Complies

**Willem Laas**  
**QA Manager**

Impilo Drugs (1966)(Pty) Ltd - Reg No: 66/00027/07

Directors: A.M. Tully B.Soc. Sci. - M.B. Tully B.Pharm. M.P.S. (Managing)

9 Green St. Isithebe, KwaZulu Natal - PO Box 3322, SUNDRAMBU 4481

Tel: (032) 459 1529 • Fax: (032) 459 1423

E-mail: [impilodrugs@cybertrade.com](mailto:impilodrugs@cybertrade.com)



# IMPILO

DRUGS (1966) (PTY) LTD

## CERTIFICATE OF ANALYSIS

Batch No. :3140  
Product :SUTHERLANDIA TABLETS  
Alternative names :  
Packaging :WHITE PVC JARS (60`s)  
Expiry Date :04/2003

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	SPECIFICATION	METHOD	RESULT
Description	:Pale, olive green speckled tablet.	Visual	Complies
Diameter	:12,0 mm	Vernier	12,08 mm
Average mass	:680 - 720 mg	Balance	700,7 mg
Thickness	:5,7 - 6,3 mm	Vernier	5,66 mm
Hardness	:2 - 14 kg	Hardness tester	10,5 kg
Friability	:NMT 1 %	USP 24	0,0527 %
Disintegration	:NMT 15 mins	USP 24 (Discs)	15 mins
Moisture content	:NMT 10 %	Karl Fischer	5,11 %

Willem Laas  
QA Manager

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Impilo Drugs (1966)(Pty) Ltd - Reg No 1966/000027/07

Directors: A.M. Tully B Soc Sci - M.B. Tully B Pharm M PS (Managing)

9 Green St. Isithebe, KwaZulu Natal - PO Box 3322, SUNDUMBILI 4491

Tel.: (032) 459 1529 - Fax: (032) 459 1423

E-mail: [impilodrugs@cyberta](mailto:impilodrugs@cyberta)



# IMPILO

DRUGS (1966) (PTY) LTD

## CERTIFICATE OF ANALYSIS

Batch No. : I 74 214  
Product : SUTHERLANDIA POWDER  
Alternative names :  
Packaging : 25 KG POLYETHYLENE BAGS  
Expiry Date : 02/2002

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	SPECIFICATION	METHOD	RESULT
Appearance	: Fine olive green fibrous powder	Visual	Complies
Odour	: Characteristic		Complies
Taste	: Bitter with slightly sweet after taste		Complies
Plant material	: Leaves and young stems		Complies
Processing	: Air dried at low temperature in shade		Complies
Identification	: To comply to standard	TLC & UV/Vis	Complies
Loss on drying	: NMT 10 %	Oven @ 100 °C	7,59 %
Preservative	: None		
Foreign matter	: NMT 2 %	Visual (BP 1999)	Complies

**Willem Laas**  
**QA Manager**

is presently evaluating the application of *Sceletium* in the rehabilitation of crack-cocaine and mandrax (Methaqualone) addicts, but there is insufficient information at this stage to be able to comment on efficacy.

**Sutherlandia frutescens case history #1** : Chronic Fatigue Syndrome with recurrent genital herpes.



Sutherlandia flower

Case history submitted

a 43 year old business analyst contracted CFS after a 'flu like illness in 1996. She consulted me initially in 1999, at the time fulfilling the CDC and Oxford criteria for CFS. She was functioning on a Karnofsky scale of 70% at the time, being unable to fulfill a full day's work.

Complicating the syndrome was an almost monthly recurrence of Type II herpes infection for which she was taking Zelitrex (Valaciclovir) constantly. We embarked on a pyramidal treatment program including enterohepatic, mitochondrial, neuroendocrine and immune support. She did well on the program over eight months, but still had significant recurrence of the Herpes lesions. She was able to go back to work but could not exercise without relapsing.

We commenced treatment with *Sutherlandia* in September 2000 after I heard about it at the South African Complementary Medicine Association (SACMA) conference. She had one more outbreak of herpes in October 2000 and since then had no recurrences. Her clinical condition also improved even further, notably improvements in the fatigue and her exercise tolerance. An Exercise test performed in a physiology lab show her to be only mildly exercise intolerant on the 24 October 2000. We have kept her on *Sutherlandia*, and to date the patient remains well-functioning with a Karnofsky scale of 90%.

Comment: In this patient we see the typical obstacle encountered in many CFS patients. She recovered very well on all counts except for the immune system, where we still see evidence of a Th 2 state with viral and fungal reactivation. This is often very difficult to treat except for treatment with expensive and potentially dangerous compounds like the mismatched RNA compound Poly I Poly II CU( Ampligen) or other invasive treatments like Ultra Violet blood irradiation. *Sutherlandia* is a safe alternative which is easy to administer. I have subsequently used it in other CFS patients with promising results.

### **Sutherlandia frutescens - synopsis of clinical applications**

- Multi-purpose adaptogenic tonic
- Wasting syndrome in AIDS, TB and cancer
- Immune modulatory tonic and quality-of-life tonic in AIDS, TB and cancer
- Heartburn, gastritis, reflux oesophagitis, peptic ulceration.
- Hot flushes and irritability in menopause
- Anxiety and depression
- Osteoarthritis and Rheumatoid arthritis

### **Sutherlandia frutescens subsp. microphylla clinical application in AIDS**



Sutherlandia's inflated pods

### **Introduction**

The information presented here is a synthesis of knowledge, research and clinical observations by the "Phyto Nova Team" that includes

A brief outline of each member of the team is included after the references. The members of the "Phyto Nova Team" have collaborated over many years to promote a wider appreciation of indigenous knowledge systems, and particularly the use of indigenous South African medicinal plants on a rational scientific basis. We have all been actively involved in scientific research into the ethnobotany, chemistry, pharmacology,

safety and efficacy of these plants for many years, and we also have clinical experience in the treatment of patients using indigenous natural medicines.

As a contribution to the most pressing public health issue facing South Africa, we decided to take a long and careful look at indigenous medicinal plants that could have novel application in the management of HIV/AIDS and AIDS-related diseases. We decided to focus our efforts on a very promising medicinal plant known as the Cancerbush, *Sutherlandia frutescens* subspecies *microphylla*. We thought that this profound multi-purpose 'tonic' was likely to be acting by more than one significant mechanism of action and would prove very useful, as a minimum, in improving the quality of life in patients with full blown AIDS, and was also likely to be an immunomodulator.

### Chemistry

The chemistry of *Sutherlandia* was studied by

High levels of the known compounds L-canavanine, pinitol and GABA were found in the leaves and green stems of some varieties of the plants. The published biological activities of these compounds certainly seem to validate some of the traditional uses of the plant, and also lend support the use of the plant as a profound quality-of-life tonic in AIDS patients.

- L-Canavanine

L-Canavanine is known to occur in high levels in certain seeds. What is unusual is that very high levels of this compound are found in *Sutherlandia* leaves. This potent non-protein amino acid is an L-arginine antagonist with documented antiviral, anti-bacterial, antifungal and anticancer activities. An average of 30-40 mg of L-canavanine per dry gram of leaf material was found. L-Canavanine has patented antiviral activity, including against influenza virus and retroviruses, including HIV (Green, 1988.) Interestingly *Sutherlandia* was used as a convalescent tonic in South Africa during the 1918 'flu pandemic, and is still traditionally used to treat 'flu. The U.S. patent (Green, 1988) describes how

physiological doses of L-canavanine in certain ratios with arginine result in the selective destruction of 95% of HIV-infected lymphocytes *in-vitro*.

- Pinitol

Pinitol, a known anti-diabetic agent (Narayanan, 1987), has been isolated from *Sutherlandia* leaves, and quantitative work is in progress. A US Patent (Ostlund, 1996) suggests that pinitol may have clinical application in treating the wasting in cancer and AIDS patients. Interestingly *Sutherlandia* has historically been used to treat wasting illnesses, including TB.

- GABA

GABA was isolated from dry *Sutherlandia* leaves in levels up to 14 mg/g dry weight. This inhibitory neurotransmitter could account for the use of the plant for anxiety and stress and depression, and for the rapid improvement in mood and well-being experienced by patients taking *Sutherlandia*.

#### Clinical anecdotes

In June 1999 *Sutherlandia* tablets (300mg) were supplied to \_\_\_\_\_ for supportive treatment of indigent AIDS patients on compassionate grounds as a quality-of-life tonic. \_\_\_\_\_ had asked if we had anything that may be useful for the AIDS patients in the \_\_\_\_\_ began to treat AIDS patients who requested her treatment with Phyto Nova's *Sutherlandia* on compassionate grounds. The tablets were also supplied by \_\_\_\_\_ to local traditional healers, including \_\_\_\_\_ and the \_\_\_\_\_ kindly gave \_\_\_\_\_ permission to see patients from \_\_\_\_\_ the hospital outpatient department, if they requested herbal treatment. I first visited this group in March 2000 to meet the patients first-hand, and will be visiting the clinic again on the first week of March 2001.

Records, including weights, and progress reports have been kept by \_\_\_\_\_ and the outpatient nursing staff and \_\_\_\_\_ on about 80 AIDS patients (many with WHO stage 3 and 4 disease) from the the \_\_\_\_\_ seen at \_\_\_\_\_. Most of these patients are unemployed and impoverished. Some of the patients have been taking *Sutherlandia* at a dose of 300mg twice a day for a year now.

From September 2000 *Sutherlandia* has been made available to \_\_\_\_\_ nursing sister who runs a \_\_\_\_\_ a nursing sister who runs the local municipal clinic in \_\_\_\_\_ has to date treated 60 AIDS patients, who spend seven to ten days at the hospice and then receive a bi-monthly follow-up and \_\_\_\_\_ has treated 60 AIDS patients since October 2000.

Southern Africa's highest traditional healer (*sanusi*), \_\_\_\_\_ has been treating patients with full-blown AIDS with Phyto Nova's *Sutherlandia* for a year now, and has trained other traditional healers in its use in a rural area called \_\_\_\_\_ that has a high incidence of AIDS, including in schoolchildren. On the basis of his own observations of efficacy \_\_\_\_\_ at age eighty, has become an outspoken proponent of the use of *Sutherlandia* as a treatment modality for AIDS, in addition to his promotion of preventive strategies, and indigenous dietary approaches and life-style modification.

\_\_\_\_\_ a respected healer in her own right and is also a qualified nurse, has trained traditional healers to use Phyto Nova's *Sutherlandia* tablets in \_\_\_\_\_ and has established a successful cooperation with the local hospital, where she can refer patients for HIV tests. The hospital doctors refer the HIV/AIDS patients back to the indigenous healers for treatment with *Sutherlandia*.

Strong convergent anecdotes on the efficacy of Phyto Nova's *Sutherlandia* tablets in AIDS have been reported to us by many people, including traditional healers, doctors, nursing sisters, and the lay public, and we have observed first-hand positive results in very ill patients. In patients with full-blown AIDS (WHO stage 3 and 4) the tablets rapidly improve the mood and appetite and energy levels of patients (usually within the first week of treatment). Remarkably we have many reports of bed-ridden AIDS patients able to care for themselves and resume household chores within a month of beginning *Sutherlandia* treatment. Treatment is taken on an ongoing basis.

Many patients wake up at night hungry, and we recommend that the product be taken with food, and we advise the patients' families to ensure that there is enough food in the house. Many cachexic patients gain weight, typically 5-10 kg over a period of 6 to 8 weeks, with up to 15 kg weight gains being reported in

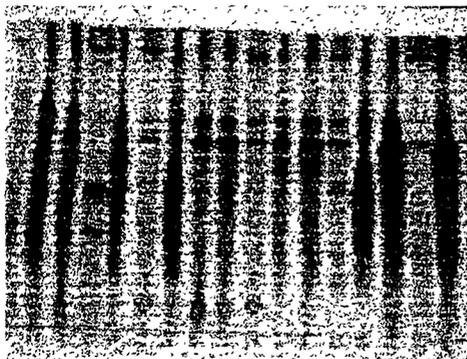
some patients after six months of treatment. The general condition of most patients appears to stabilise, as opposed to the expected deterioration. Other positive effects noted are a decrease in incidence of oral and oesophageal thrush, cessation of the chronic diarrhoea of AIDS, resolution of peripheral neuropathy, and improvement in skin rashes. To date we have recommended that all patients remain on *Sutherlandia* on an ongoing basis, since we have observed relapses in patients who stopped treatment after a few months treatment, since they felt well.

Unfortunately we have not had the financial resources to study the effect of *Sutherlandia* on CD4 counts and viral load, and we have not had official support for the work we are doing. It has recently been reported to us from a neighbouring country that the CD4 count increases significantly in some patients, but we still need to verify this independently. A pilot clinical trial on Phyto Nova's *Sutherlandia* in AIDS will be undertaken in early this year, with sponsorship for the CD4 counts and viral loads by the World Health Organisation (WHO/AFR). The principal investigator of the trial will be

We suspect on the basis of the rapid and sustained clinical improvement that the plant is an immune stimulant, and on the basis of the plant chemistry it is likely to be directly anti-viral as well.

The most serious side-effect that we have noted to date is dizziness if very ill and cachexic patients take *Sutherlandia* without eating. Other side-effects noted on systematic history taking include occasional dry mouth and a mild diuresis.

#### Raw material supply



T.L.C. is used to select the chemotype of *Sutherlandia*

## PHYTO NOVA's SUTHERLANDIA

Prepared by

Updated 10 July 2001

Ref : 00 Sutherlandia Summary 051101

### EXECUTIVE SUMMARY

#### Introduction

*Sutherlandia frutescens* subsp. *microphylla* is generally regarded as the most profound of the medicinal plants in southern Africa, and because of its efficacy as a safe tonic for diverse health conditions it has enjoyed a long history of use by all cultures in southern Africa.

The folk-uses include use of *Sutherlandia* for : wasting from cancer and TB, prevention and treatment of cancers, diabetes, hypertension, hepatitis, anxiety, depression, influenza, rheumatism and arthritis (osteo-arthritis and rheumatoid arthritis), peptic ulcer, gastritis, and reflux oesophagitis.

The innovative South African phytomedicines company Phyto Nova has carefully selected a particular variety or 'chemo-type' of *Sutherlandia* (Phyto Nova's *Sutherlandia*) and has been distributing tablets from this plant for a period of two years. The tablets are made to Phyto Nova's specifications by a registered pharmaceutical manufacturer according to Good Manufacturing Practice (GMP).

#### Chemistry and Pharmacology

Phyto Nova have identified four known compounds that contribute to the efficacy of this medicinal plant : the non-protein amino acid L-canavanine; pinitol; GABA ; and asparagine. In addition a novel triterpenoid glucoside known as SU1 has been isolated and characterized, and this is used in the selection of raw material for tableting.

L-canavanine has well-documented anti-cancer, anti-viral and anti-microbial activities, and is a nitric-oxide synthase inhibitor. Pinitol has anti-diabetic activities, and has been patented in the United States for treating the wasting in cancer and AIDS patients. GABA is a well-known inhibitory neurotransmitter with application in the management of anxiety and depression. Triterpenoids closely related to SU1 have known immune-stimulating activity.

Most importantly, a group of eminent French immunologists assisting Phyto Nova under the auspices of the Paris-based NGO Afrique Initiatives have found that extracts of Phyto Nova's *Sutherlandia* are tumour necrosis factor inhibitors (TNF inhibitors). Excess production of TNF drives the wasting syndrome in cancers,

TB and AIDS. Afrique Initiatives is a prominent development organization, headed by

### **Safety**

In keeping with World Health Organisation guidelines on the assessment of herba medicines, *Sutherlandia* is generally regarded as safe on the basis of its long history of safe use in South Africa. No severe adverse effects have been reported to Phyto Nova in two years of actively selling the product on the South African market. No severe adverse events have been reported by doctors who prescribe *Sutherlandia* for the wasting syndrome in cancer, TB and AIDS patients, and also for improving the quality of life in cancer and AIDS patients. Known side-effects include occasional reports of dry mouth, occasional reports of mild diuretic effect; occasional reports of loose stool, occasional reports of constipation. Slight dizziness has been occasionally noted in very wasted and weak patients (e.g. in an ill adult weighing 35kg) who take *Sutherlandia* without meals this is corrected by instructing wasted patients to take the product after meals.

There were no deaths in mice given 1,500mg/kg by mouth.

### **Clinical application**

Phyto Nova's *Sutherlandia* has shown to have an excellent impact on improving the wasting and quality of life in TB, AIDS and cancer patients. To date approximately 700 AIDS patients (WHO stages 3 and 4) are on treatment. All patients treated show an improvement in appetite, exercise tolerance, and mood. Most wasted patients show an increase in weight within six weeks of starting treatment. Weight gains of 10-15 kg have been documented in wasted cancer and AIDS patients.

Phyto Nova's *Sutherlandia* is effective in the wasting syndrome in AIDS and TB patients, and remarkable improvements are seen in the quality of life of these patients, including improved appetite, mood, sense of well-being and exercise tolerance, and sleep patterns.

Improvements in CD4 counts and decreases in the viral load in AIDS patients taking *Sutherlandia* have been reported to Phyto Nova by clinicians in South Africa and Australia. These promising improvements need to be validated by an independent controlled clinical trial, and a cooperation in this regard is under discussion with the Medical Research Council of South Africa :

### **CD4 and Viral Load changes in patients treated with Phyto Nova *Sutherlandia***

23 May 2001. Before and after actual pathology laboratory reports faxed to Phyto Nova by patient himself who has been under the management of Starting CD4 was 340. After two months of Phyto Nova Sutherlandia a dose of one tablet twice a day : CD4 is 533.

18 June 2001. From a prominent general practitioner in Patient's viral load decreased from 25 000 to 5 000 on two months Phyto Nova Sutherlandia at a dose of two tablets 12 hourly only, apart from vitamins. No change in CD4 (but patient subsequently admitted to using recreational drugs).

18 June 2001 From a licensed herbal practitioner In March 2001 the patient had been off antiretroviral drugs for ~ 2 months, and his viral load was 57,000 and CD4 was 480.

Was started on naturopathic treatment with herbal prescription and antioxidant protocols and continued on these throughout April. In May he also added Sutherlandia. In June, after ~ 6 weeks on the Sutherlandia (one tablet twice a day), his viral load had fallen to 9,200 and his CD4's had risen to 647.

4 July 2001. reported a result in a second patient after 2 months treatment with Phyto Nova's Sutherlandia only : viral load at start 28 000; 2 months later : 13 000.

4 July 2001. A second patient report from The patient's CD4 had increased from 258 on 14 March to 311 on 20 June. Patient had been on Sutherlandia for only 6 weeks and was very happy as this is the highest CD4 count he's had since 1999. His viral load is down to 16,800 but we have not been given the starting level.

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## PHYTO NOVA's SUTHERLANDIA

### 1. INTRODUCTION

*Sutherlandia frutescens* subsp. *microphylla* is generally regarded as the most profound of the medicinal plants in southern Africa, and because of its efficacy as a safe tonic for diverse health conditions it has enjoyed a long history of use by all cultures in southern Africa. Over a period of years the company Phyto Nova has carefully selected a particular variety or 'chemo-type' of *Sutherlandia* (Phyto Nova's *Sutherlandia*) and is farming this valuable type on a commercial scale.

The common names that have been used for *Sutherlandia* in South Africa include : *Sutherlandia* and *Cancerbush* (English); *Kankerbos*, *Wildekeer* [*Wildekeur(tjie)*], *Rooikeurtjie*, *Kalkoenbos*, *Belbos* and *Gansies* (Afrikaans), *Unwele* and *Insiswa* (Zulu); *Musa-Pelo*, *Motlepelo* and *Phethola* (Sotho).

### 2. TRADITIONAL AND FOLK-USES

Since the plant has been used over the centuries as a supplement for diverse health conditions over the centuries it should more correctly be called a 'tonic'. Healthy individuals use *Sutherlandia* to provide energy and an enhanced feeling of well-being. *Sutherlandia* powerfully assists the body to mobilise its own resources to cope with diverse physical and mental stresses, and it should therefore be more correctly known as an adaptogenic tonic. The traditional Tswana name *Phetola* alludes to this : *Phetola* means "it changes", meaning that the plant changes the course of many illness into a favourable outcome. This particular type of tonic used to be called an alterative by the old herbalists of Europe, and is now known by the modern term 'adaptogen'.

#### 2.1 History of use of Sutherlandia

##### 2.1.1 Current use

*Sutherlandia* is still used to this day in South Africa as a popular tonic by doctors, traditional doctors, nurses, farmers, and rural housewives and grandmothers. It is still sold by herbalists on the Parade Market outside the Cape Town City Hall, and is sold as a bitter tea by some health stores in the Western Cape and Eastern Cape provinces of South Africa. The Montagu Museum in Montague, Western Cape sell *Sutherlandia* as a tea, and the Farm Museum in Worcester, Western Cape sell a brandy tincture of *Sutherlandia*.

##### 2.1.2 Literature attesting to historical use

- Anonymous, 1993. *Krueierate van die Montagu Museum*. Publication of the museum and board of trustees. (Translation of title : "Herbal Remedies of the Montagu Museum")

- van Wyk, B.-E., van Oudtshoorn, B. and Gericke, N. 1997. *Medicina! Plants of South Africa*. Briza, Pretoria.
- van Wyk, B.-E. and Gericke, N. 2000. *People's Plants. A Guide to the Useful Plants of Southern Africa*. Briza, Pretoria.
- Rood, B. 1994. *Uit die Veldapteek*. Tafelberg, Cape Town. (Translation of title : "Out of the field-pharmacy").
- Von Koenen, E. 1996. *Heil- Gift und Essbare Pflanzen in Namibia*. Edition Namibia. Klaus Hess Verlag. (Translation of title : Medicinal, Poisonous and edible plants of Namibia).
- Watt, J.M. and Breyer-Brandwijk, M.G. 1962 (2<sup>nd</sup> edition). *The Medicinal and Poisonous Plants of Southern and Eastern Africa* E&S Livingstone Ltd., Edinburgh.
- Pappe, L. 1857. *Florae Capensis Medicae Prodromus*. 2<sup>nd</sup> Edition. Brittain, Cape Town
- Smith, C.A. 1966. *Common Names of South African Plants*. Botanical Survey Memoir No. 35. Government Printer, Pretoria.
- Roberts, M. 1990 *Indigenous Healing Plants*. Southern Book Publishers, Halfway House.

## 2.2 Current and historical traditional and folk-uses of *Sutherlandia*

### • Central Nervous System

*Sutherlandia* has been used to support mental and emotional stress, including irritability, anxiety and depression.

Widows of slain Zulu warriors used *Sutherlandia* as a gentle tranquilliser during the mourning period.

The Sotho name Motlepelo means 'bringing back the heart' meaning that the plant is a traditional treatment for emotional shock and stress.

Agitated warriors returning from battle would drink an infusion of *Sutherlandia* 'to take the war out' – i.e. as a calming herb.

The ancient Zulu name *Insiswa* means 'the one which dispels darkness' alluding to its anti-depressant effect, and to the fact that it is a powerful tonic for diverse health conditions.

The present Zulu name *Unwele* means 'hair' – alluding to the fact that the plant stops people 'pulling out their hair' with distress.

- Respiratory

*Sutherlandia* was traditionally used to good effect to combat the symptoms of 'flu during the 1918 influenza pandemic, and is still used to treat 'flu to this day. *Sutherlandia* is traditionally believed to shorten the duration and severity of the illness and it can also be taken as a convalescent tonic for post-'flu debility.

*Sutherlandia* has traditionally been used in both the prevention and treatment of the symptoms of asthma.

*Sutherlandia* has been traditionally used for centuries to treat the symptoms of TB, including wasting, and bronchitis. It has also been historically used to treat unspecified wasting diseases.

- Gastrointestinal

*Sutherlandia* has been used to treat symptoms of 'heartburn', reflux oesophagitis, gastritis and peptic ulceration. Herbalists at the Parade Market in Cape Town say that *Sutherlandia* is for 'nerves and ulcers'.

*Sutherlandia* was historically used to treat diarrhoea and dysentery, and it was used as a supportive remedy for people with liver conditions. It is slightly purgative at higher doses and has therefore been used as a gentle remedy for constipation.

- Urogenital tract

*Sutherlandia* was used to treat urinary tract infections, including gonorrhoea, and cystitis, particularly what would nowadays be termed 'interstitial cystitis'.

- Diabetes

*Sutherlandia* is widely used to this day by rural herbalists and 'kruie-doktors' to treat diabetes.

- Musculo-skeletal

*Sutherlandia* has been used to treat gout, rheumatoid arthritis and osteoarthritis.

- Cancer

To this day *Sutherlandia* is used as a traditional treatment to improve the quality of life in patients with malignant tumours.

### **2.3 Safety assessment from literature, ethnobotanical and current use.**

*Sutherlandia* is regarded as a very safe, widely used herb. Phyto Nova has had no serious adverse event reported from consumers, in response to about 25 000 units of *Sutherlandia* product sold. No serious adverse events have been reported to Phyto Nova by 15 South African medical doctors prescribing Phyto Nova's *Sutherlandia* in their clinical practices, including the president of the South African Complementary Medicine Association (SACMA), and the Chairperson of the South African HomoToxicology Association .

Side-effects reported to date include occasional reports of : dry mouth, and mild diuresis. Occasional bouts of brief dizziness has been reported by cachexic (wasted) patients who took *Sutherlandia* and missed their meal. The latter can be avoided by instructing patients to take *Sutherlandia* with meals.

Reports have been verified of cancer and other patients who have taken *Sutherlandia* continuously for four years, without any untoward effect, and some cancer patients who have taken far higher doses of *Sutherlandia* than that recommended by Phyto Nova, again without any apparent ill effect.

Although the plant is commonly used traditionally in pregnancy, Phyto Nova do not recommend that *Sutherlandia* should be taken during pregnancy or while breastfeeding.

There were no deaths in mice given 1,500mg/kg by mouth.

## **3. SCIENCE**

### **3.1 Chemistry and Pharmacology**

The chemistry of *Sutherlandia* was studied by [redacted] found high levels of some known compounds. The published biological activities of these compounds appear to validate some of the traditional uses of the plant, and further support the use of the plant as a quality-of-life tonic in AIDS patients.

#### L-Canavanine

L-Canavanine is known to occur in high levels in certain seeds. What is unusual is that significant levels of this compound are found in *Sutherlandia* leaves. This

potent non-protein amino acid is an L-arginine antagonist with documented antiviral, anti-bacterial, antifungal and anticancer activities. has found an average of 2.2 mg of L-canavanine per dry gram of leaf material of *Sutherlandia*. L-Canavanine is a potent L-arginine antagonist that has patented anticancer (Swaffar, 1995; Crooks, 1994.) and antiviral activity, including against influenza virus and retroviruses (Green, 1988.). L-Canavanine is also a selective inhibitor of inducible nitric oxide synthase and therefore has possible application in the treatment of septic shock and chronic inflammation (Anfossi, G. et al. 1999; Levy, B et al. 1999).

### Pinitol

Pinitol, a known anti-diabetic agent (Narayanan, 1987), has been isolated from *Sutherlandia* leaves, and quantitative work is in progress. A US Patent (Ostlund, 1996) suggests that pinitol may have clinical application in treating the wasting in cancer and AIDS patients.

### GABA

GABA was isolated from dry *Sutherlandia* leaves in levels up to 14 mg/g dry weight. This inhibitory neurotransmitter could account for the use of the plant for anxiety and stress, and for the improvement in mood and well-being experienced by many patients

### SU1

A novel terpenoid glucoside known as SU1 has been isolated and characterized, and this is used in the selection of raw material for tableting. The Phyto Nova team believe that this compound has promising biological activities, but this is still the subject of ongoing research.

Most importantly, a group of eminent French immunologists assisting Phyto Nova under the auspices of the Paris-based NGO Afrique Initiatives have found that extracts of *Sutherlandia* are tumour necrosis factor inhibitors (TNF inhibitors). Excess production of TNF drives the wasting syndrome in cancers, TB and AIDS. Afrique Initiatives is a prominent development organization, headed by M. Michel Rocard, a former Prime Minister of France.

#### 3.1.1 References

- Crooks, P.A. and Rosenthal, G.A. (Filed Dec 5, 1994) Use of L-canavanine as a chemotherapeutic agent for the treatment of pancreatic cancer. United States Patent 5,552,440.

- Green, M.H. (Filed Jan 25, 1988) Method of treating viral infections with amino acid analogs. United States Patent 5,110,600.
- Narayanan, et al. (1987) Pinitol – A New Anti-Diabetic compound From the Leaves of *Bougainvillea Spectabilis*. *Current Science* **56**(3), 139-141.
- Ostlund, R.E and Sherman, W.R (Filed March 4, 1996). Pinitol and derivatives thereof for the treatment of metabolic disorders. US Patent 5,882,896.
- Swaffar, D.S. et al. (August 1995) Combination therapy with 5-fluorouracil and L-canavanine: in-vitro and in-vivo studies. *Anticancer Drugs*, **6**(4), 586-93.

### 3.2 Clinical anecdotes

#### CD4 and Viral Load changes on Phyto Nova Sutherlandia

9 May 2001. Before and after actual pathology laboratory reports faxed to Phyto Nova by patient himself who has been under the management of Starting CD4 340. After two months of Phyto Nova Sutherlandia a dose of one tablet twice a day : CD4 is 533.

18 June 2001. From a prominent general practitioner in Patient's viral load decreased from 25 000 to 5 000 on two months Phyto Nova Sutherlandia at a dose of two tablets 12 hourly only, apart from vitamins. No change in CD4 (but patient subsequently admitted to using recreational drugs).

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In addition to these preliminary blood reports, strong convergent anecdotes have been reported to us by many people, including doctors, senior traditional doctors, nurses, homoeopaths, and the lay public. Phyto Nova's *Sutherlandia* has show to have an excellent impact on improving the wasting syndrome and quality of life in

AIDS and cancer patients. To date approximately 500 AIDS patients (WHO stages 3 and 4) are on treatment. All patients treated show an improvement in appetite, exercise tolerance, and mood. Most wasted patients show an increase in weight within six weeks of starting treatment. Weight gains of 10-15 kg have been documented in wasted cancer and AIDS patients.

**3.2.1 Summary of [redacted] latest field trip, that was published in the Australia Journal of Medical Herbalism. Sutherlandia and AIDS patients Update 13 March 2001. Aus J Med Herbalism 13 (1) 2001**

I went up to [redacted] from 5-9 March 2001 at the kind invitation of [redacted]

- To give a seminar to the Integrative Health Initiative group at the Nelson Mandela Medical School, University of Natal
- To give a seminar to interested doctors and nursing staff at Ngwelezane Hospital together with [redacted] and other care-givers administering Sutherlandia to AIDS patients
- To meet with the various people administering Phyto Nova's Sutherlandia, to critically evaluate anecdotal evidence of safety and efficacy.
- To see patients

**A). \_\_\_\_\_**

[redacted] a nursing sister and nun, runs a community-based AIDS hospice at [redacted] which we visited. This was a follow-up visit a year after I was first introduced to [redacted] when we had first made Sutherlandia available to [redacted]

In the last 12 months, in addition to seeing outpatients, [redacted] has admitted 71 AIDS patients for terminal hospice care. In addition to simple wholesome food, the patients get given a dilute cold-water infusion of *Hypoxis* sp. made by [redacted] from locally available plants, and Phyto Nova's *Sutherlandia*. Of the 71 AIDS patients admitted for terminal care in the last 12 months [redacted] was able to ultimately discharge 30 patients back into the community as healthy. Some have been lost to follow-up, but some come back for the Sutherlandia on a regular basis.

[redacted] confirms dramatic improvements in quality of life in patients taking Phyto Nova's *Sutherlandia* : increased appetite, weight gain, improved exercise tolerance, improve sense of well-being and mood, and good sleep. No adverse

effects have been noted by \_\_\_\_\_ on specific questioning for this. I video-  
documented her impressions on my digital video camera.

One of the highlights was an AIDS patient brought to the \_\_\_\_\_ after being found lying in a cane-field with her young daughter. The patient had been found after being abandoned by her family. She spent six months in the hospice, and was discharged healthy with good weight-gain and has since even managed to get a job.

**B).** \_\_\_\_\_

I videoed \_\_\_\_\_ presentation at the hospital seminar, and her approach impressed me because of its holistic nature, with an emphasis on diet, and vitamin and mineral supplementation in addition to Phyto Nova's *Sutherlandia*. \_\_\_\_\_ trained nursing sister, and because of the in-patient situation at the hospice, she has been able to monitor her patients well. The hospice \_\_\_\_\_ is funded by the company ALUSAF.

\_\_\_\_\_ has to date put 60 patients on Phyto Nova's *Sutherlandia*, and to quote her: "Initially we see a much better sense of well-being, then we see a gradual increase in energy, then we see that their appetites begin to return, and longer term we see that they begin to gain weight." All medication is given after meals, crushed into live culture yoghurt, and in addition to *Sutherlandia*, a multivitamin tablet, and folate and iron are also given (also crushed into the yoghurt). No adverse effects of *Sutherlandia* have been noted.

\_\_\_\_\_ confirmed the efficacy of African Ginger (*Siphonochilus*) for oral and oesophageal thrush – it clears completely within two to three days - and also noted that it stops the spiking of temperatures often seen in AIDS in-patients. When they ran out of Phyto Nova's Africa Ginger for two weeks the temperature spiking of the patients reappeared, only to disappear when the African Ginger was restarted.

**C).** \_\_\_\_\_ **outpatients department**

These AIDS patients from \_\_\_\_\_ get seen once a month by \_\_\_\_\_ after being seen by a doctor from the hospital. The patients are also seen on occasion by the hospital superintendent,

There are now a total of just over 170 \_\_\_\_\_ patients being treated with *Sutherlandia*. 25 'old' patients were seen by \_\_\_\_\_ and 8 new patients. Some of the 'old' patients have now been treated for 16 consecutive months with Phyto Nova's *Sutherlandia*.

All the 'old' patients seen felt the *Sutherlandia* was beneficial with improvements in quality of life: increased appetite, weight gain up to 10-15 kg in some patients, improved effort tolerance, improve sense of well-being and mood and good sleep

pattern. In many patients who were not wasted to begin with there appears to generally be a stabilisation of weight, but it is still too early to tell if this will be sustained. In some patients interpretation of weight charts has been complicated because there have been intercurrent infections with cholera and acute viral diarrhoeas, typical of impoverished rural communities without access to sanitation or clean water. One of the patients we saw had survived two episodes of cholera (treated for this as an in-patient in Ngwelezane Hospital ) in the last few months, and intercurrent acute viral diarrhoea. The area is just recovering from a major cholera epidemic.

No adverse effects of *Sutherlandia* ingestion were noted on specific questioning for adverse reactions.

It was clear that the patients were really delighted to see \_\_\_\_\_ and they have greatly benefited from \_\_\_\_\_ personal interest in their plight, and the hope that and encouragement that she gives them. This perception was confirmed by \_\_\_\_\_ at the hospital seminar. \_\_\_\_\_ excellent homemade skin and wound creams from local available plants have helped many patients with itchy rashes, herpes and shingles.

Many from this group of patients are poverty-stricken, with very poor diet at home. We tried to encourage them to eat locally available wild spinaches (*Amaranthus* spp; *Bidens pilosa*; *Portulaca oleracea*, and *Centella asiatica*) in addition to staples, and also to take advantage of the fruit of wild guava trees that are abundant in the area which are high in vitamin C. viral diarrhoeas are common

In some cases the \_\_\_\_\_ patients who are taking *Sutherlandia* are doing so well that they are given a follow-up appointment by the hospital superintendent for two months time, rather than the usual one month.

D): \_\_\_\_\_

\_\_\_\_\_ is a nursing sister who sees HIV positive and AIDS patients who are municipal workers at a municipal clinic \_\_\_\_\_ has treated 60 AIDS patients with *Sutherlandia* since October 2000, including AIDS children who get half the adult dose. No adverse effects were reported on specific questioning and \_\_\_\_\_ is delighted with the results. To quote her : " They all come back with results like : I have energy now, I have good appetite, I feel well".

One of the municipal workers on *Sutherlandia* from \_\_\_\_\_ was also seen by a doctor, who told the patient that his CD4 count had gone up since taking *Sutherlandia*.

was also very happy with the efficacy of the Sutherlandia gel, reporting it rapidly removes the pain of acute Shingles, and facilitates healing of the skin eruption. To quote her: "For shingles, the new one, the gel, they are flocking for it. It makes it numb and takes away the pain".

### Conclusion

- **Phyto Nova's Sutherlandia is clearly having a very significant impact on the weight and quality of life of many patients with WHO stage 3 and 4 AIDS.** The true impact is difficult to communicate in a written report – the actual patients' expressions, and general condition has to be seen to be appreciated. All the care-givers were very positive about the benefits, and want to make more product available to meet the increasing word-of-mouth demand.
- **Many so-called 'terminal' AIDS patients can clearly still be rescued with a holistic approach to healing and good nutrition, and with the addition of Phyto Nova's Sutherlandia.** (This is obviously also the case with modern Highly Active Anti-retroviral Therapy (HAART), should it become available at an affordable price).
- **There is an urgent need for doctors and other health workers caring for HIV/AIDS patients to be educated about the need for appropriate nutrition and vitamin and mineral supplementation.**
- The anecdote of a raised CD4 count supports many other anecdotes that have been reported to Phyto Nova that Sutherlandia raises CD4 counts in AIDS patients. This needs to be verified in a controlled clinical trial as a matter of urgency.
- **No severe adverse reactions have been reported from ingestion in adults or children,** including in very ill patients, and in patients who have been taking Sutherlandia on a daily basis for 16 to 18 months.

### **3.2.2 Email report from leading medical herbalist, and a World Health Organisation expert on traditional herbal medicines).**

Dear

Thank you once again for your very prompt response to our need for more Sutherlandia tablets.  
I received the package on Sunday  
1/3/2001 without any problem.

My comments on the potential  
of the Sutherlandia tablets are as follows:-

We dispensed the whole initial carton of the tablets you sent together with the few that you gave me at to over 150 patients at our clinic, 20 patients at 15 patients at and 5 patients at respectively and 10 patients in our other clinics.

The bulk of the patients were treated for the following conditions:-

50% were HIV and HIV opportunistic infections i.e. TB, generalised chest and skin infections.

The rest of the patients were in the Rheumatism, Arthritis migraine headaches, generalised abdominal conditions, sickle cell anaemia and Epilepsy categories.

The dosage regime amongst the 200 patients varied from ½ tablet twice a day to four tablets a day i.e. one after breakfast, one after lunch and two tablets at bedtime. In all patients except three the tablets were taken together with our appropriate herbal therapy.

Generally all our patients tolerated the Sutherlandia tablets even when mixed with our herbal therapy quite well. There were four patients who complained of diarrhoea, noise in the ear, chest pain etc after taking the tablets.

I can confidentially testify that :-

Sutherlandia tablets have so far proved safe and useful at the dosages and for the conditions we used them for.

(b) The tablets are also effective in prolonging the life of especially the HIV patients; they seem to improve the appetite, weight and general welfare of the patients. They also suppress and in some case cure opportunistic infections. They have also been very effective in tackling joint complains.

We intend to continue with our observations so that, sooner or later we shall give you a more comprehensive report.

You are free to quote our observations in all your communications when and where necessary.

Phyto Nova a pour mission de développer la production de médicaments à base de plantes. Elle ne semble pas avoir les faveurs du MRC (Medical Research Council)

### 3.2.5 A case history on the use of *Sutherlandia* in Chronic Fatigue Syndrome

a 43 year old business analyst contracted CFS after a 'flu like illness in 1996. She consulted me initially in 1999, at the time fulfilling the CDC and Oxford criteria for CFS. She was functioning on a Karnofsky scale of 70% at the time, being unable to fulfill a full day's work.

Complicating the syndrome was an almost monthly recurrence of Type II herpes infection for which she was taking Zelitrex (Valaciclovir) constantly. We embarked on a pyramidal treatment program including enterohepatic, mitochondrial, neuroendocrine and immune support. She did well on the program over eight months, but still had significant recurrence of the Herpes lesions. She was able to go back to work but could not exercise without relapsing.

We commenced treatment with *Sutherlandia* in September 2000 after I heard about it at the South African Complementary Medicine Association (SACMA) conference. She had one more outbreak of herpes in October 2000 and since then had no recurrences. Her clinical condition also improved even further, notably improvements in the fatigue and her exercise tolerance. An Exercise test performed in a physiology lab show her to be only mildly exercise intolerant on the 24 October 2000. We have kept her on *Sutherlandia*, and to date the patient remains well-functioning with a Karnofsky scale of 90%.

Comment: In this patient we see the typical obstacle encountered in many CFS patients. She recovered very well on all counts except for the immune system, where we still see evidence of a Th 2 state with viral and fungal reactivation. This is often very difficult to treat except for treatment with expensive and potentially dangerous compounds like the mismatched RNA compound Poly I Poly II CU (Ampligen) or other invasive treatments like Ultra Violet blood irradiation. *Sutherlandia* is a safe alternative which is easy to administer. I have subsequently used it in other CFS patients with promising results.

### 3.2.6 eTV NEWS 3 April 2001

The South African eTV channel included a news report on Phyto Nova's *Sutherlandia* (eNew Live @ 7 on 3 April 2001), including interviews with

who has been on Phyto Nova's *Sutherlandia* for 12 months now.

was also interviewed. At a follow-up meeting at the invitation of the said

they would fund a pilot clinical trial into *Sutherlandia*, but no definite date has yet been set.

**3.2.7 Quote from  
4 June 2001**

Healing herbs can help in war on Aids Cape Times letter dated 4 June 2001

"There are a number of traditional African herbals, most notably *Hypoxis* (African potato) and *Sutherlandia* which have already demonstrated powerful healing properties with Aids patients. Unfortunately, in the highly politicized Aids environment, it is extremely difficult to get the official medical research establishments to consider these cheap, highly effective and safe substances."

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